BETALIDO KIT- betamethasone sodium phosphate, betamethasone acetate, lidocaine, povidine iodine
Asclemed USA, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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Rx Only

DESCRIPTION

Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP is a sterile aqueous suspension containing betamethasone 3 mg per milliliter as betamethasone sodium phosphate, and betamethasone acetate 3 mg per milliliter. Inactive ingredients per mL: dibasic sodium phosphate 7.1 mg; monobasic sodium phosphate 3.4 mg; edetate disodium 0.1 mg; and benzalkonium chloride 0.2 mg as a preservative. The pH is adjusted to between 6.8 and 7.2.

The formula for betamethasone sodium phosphate is C_{22}H_{28}FNa_{2}O_{8}P and it has a molecular weight of 516.41. Chemically, it is 9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 21-(disodium phosphate).

The formula for betamethasone acetate is C_{24}H_{31}FO_{6} and it has a molecular weight of 434.50. Chemically, it is 9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 21-acetate.

The chemical structures for betamethasone sodium phosphate and betamethasone acetate are as follows:

![Betamethasone Sodium Phosphate](image1)

![Betamethasone Acetate](image2)

Betamethasone sodium phosphate is a white to practically white, odorless powder, and is hygroscopic. It is freely soluble in water and in methanol, but is practically insoluble in acetone and in chloroform.

Betamethasone acetate is a white to creamy white, odorless powder that sinters and resolidifies at about 165°C, and remelts at about 200°C-220°C with decomposition. It is practically insoluble in water, but freely soluble in acetone, and is soluble in alcohol and in chloroform.
GLUCOCORTICOSTEROIDS

Glucocorticoids, naturally occurring and synthetic, are adrenocortical steroids that are readily absorbed from the gastrointestinal tract. Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency states. Their synthetic analogs are primarily used for their anti-inflammatory effects in disorders of many organ systems. A derivative of prednisolone, betamethasone has a 16β-methyl group that enhances the anti-inflammatory action of the molecule and reduces the sodium- and water-retaining properties of the fluorine atom bound at carbon 9.

Betamethasone sodium phosphate, a soluble ester, provides prompt activity, while betamethasone acetate is only slightly soluble and affords sustained activity.

INDICATIONS AND USAGE

When oral therapy is not feasible, the intramuscular use of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension is indicated as follows:

**Allergic States** Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in asthma, atopic dermatitis, contact dermatitis, drug hypersensitivity reactions, perennial or seasonal allergic rhinitis, serum sickness, transfusion reactions.

**Dermatologic Diseases** Bullous dermatitis herpetiformis, exfoliative erythroderma, mycosis fungoides, pemphigus, severe erythema multiforme (Stevens-Johnson syndrome).

**Endocrine Disorders** Congenital adrenal hyperplasia, hypercalcemia associated with cancer, nonsuppurative thyroiditis.

Hydrocortisone or cortisone is the drug of choice in primary or secondary adrenocortical insufficiency. Synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy mineralocorticoid supplementation is of particular importance.

**Gastrointestinal Diseases** To tide the patient over a critical period of the disease in regional enteritis and ulcerative colitis.

**Hematologic Disorders** Acquired (autoimmune) hemolytic anemia, Diamond-Blackfan anemia, pure red cell aplasia, selected cases of secondary thrombocytopenia.

**Miscellaneous** Trichinosis with neurologic or myocardial involvement, tuberculous meningitis with subarachnoid block or impending block when used with appropriate antituberculous chemotherapy.

**Neoplastic Diseases** For palliative management of leukemias and lymphomas.

**Nervous System** Acute exacerbations of multiple sclerosis; cerebral edema associated with primary or metastatic brain tumor or craniotomy.

**Ophthalmic Diseases** Sympathetic ophthalmia, temporal arteritis, uveitis and ocular inflammatory conditions unresponsive to topical corticosteroids.

**Renal Diseases** To induce diuresis or remission of proteinuria in idiopathic nephrotic syndrome or that due to lupus erythematosus.

**Respiratory Diseases** Berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, idiopathic eosinophilic pneumonias, symptomatic sarcoidosis.

**Rheumatic Disorders** As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis; acute rheumatic carditis; ankylosing spondylitis; psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy). For the treatment of dermatomyositis, polymyositis, and systemic lupus erythematosus.
The **intra-articular or soft tissue administration** of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension is indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis, acute and subacute bursitis, acute nonspecific tenosynovitis, epicondylitis, rheumatoid arthritis, synovitis of osteoarthritis.

The **intralesional administration** of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension is indicated for alopecia areata; discoid lupus erythematosus; keloids; localized hypertrophic, infiltrated, inflammatory lesions of granuloma annulare, lichen planus, lichen simplex chronicus (neurodermatitis), and psoriatic plaques; necrobiosis lipoidica diabeticorum.

Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension may also be useful in cystic tumors of an aponeurosis or tendon (ganglia).

**CONTRAINDICATIONS**

Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension is contraindicated in patients who are hypersensitive to any components of this product. Intramuscular corticosteroid preparations are contraindicated for idiopathic thrombocytopenic purpura.

**WARNINGS**

**General**

Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension should not be administered intravenously.

Rare instances of anaphylactoid reactions have occurred in patients receiving corticosteroid therapy (see ADVERSE REACTIONS).

In patients on corticosteroid therapy subjected to any unusual stress, hydrocortisone or cortisone is the drug of choice as a supplement during and after the event.

**Cardio-Renal**

Average and large doses of corticosteroids can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. These effects are less likely to occur with the synthetic derivatives except when used in large doses. Dietary salt restriction and potassium supplementation may be necessary. All corticosteroids increase calcium excretion.

Literature reports suggest an apparent association between use of corticosteroids and left ventricular free wall rupture after a recent myocardial infarction; therefore, therapy with corticosteroids should be used with great caution in these patients.

**Endocrine**

Corticosteroids can produce reversible hypothalamic-pituitary adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment.

Metabolic clearance of corticosteroids is decreased in hypothyroid patients and increased in hyperthyroid patients. Changes in thyroid status of the patient may necessitate adjustment in dosage.

**Infections**

**General**

Patients who are on corticosteroids are more susceptible to infections than are healthy individuals. There may be decreased resistance and inability to localize infection when corticosteroids are used. Infection with any pathogen (viral, bacterial, fungal, protozoan, or helminthic) in any location of the
body may be associated with the use of corticosteroids alone or in combination with other immunosuppressive agents. These infections may be mild to severe. With increasing doses of corticosteroids, the rate of occurrence of infectious complications increases. Corticosteroids may also mask some signs of current infection.

Fungal Infections
Corticosteroids may exacerbate systemic fungal infections and therefore should not be used in the presence of such infections unless they are needed to control drug reactions. There have been cases reported in which concomitant use of amphotericin B and hydrocortisone was followed by cardiac enlargement and congestive heart failure (see PRECAUTIONS, Drug Interactions, Amphotericin B Injection and Potassium-Depleting Agents section).

Special Pathogens
Latent disease may be activated or there may be an exacerbation of intercurrent infections due to pathogens, including those caused by Amoeba, Candida, Cryptococcus, Mycobacterium, Nocardia, Pneumocystis, and Toxoplasma. It is recommended that latent amebiasis or active amebiasis be ruled out before initiating corticosteroid therapy in any patient who has spent time in the tropics or in any patient with unexplained diarrhea.

Similarly, corticosteroids should be used with great care in patients with known or suspected Strongyloides (threadworm) infestation. In such patients, corticosteroid-induced immunosuppression may lead to Strongyloides hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicemia.

Corticosteroids should not be used in cerebral malaria.

Tuberculosis
The use of corticosteroids in active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for the management of the disease in conjunction with an appropriate antituberculous regimen.

If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary as reactivation of the disease may occur. During prolonged corticosteroid therapy, these patients should receive chemoprophylaxis.

Vaccination
Administration of live or live, attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of corticosteroids. Killed or inactivated vaccines may be administered. However, the response to such vaccines cannot be predicted. Immunization procedures may be undertaken in patients who are receiving corticosteroids as replacement therapy, eg, for Addison’s disease.

Viral Infections
Chicken pox and measles can have a more serious or even fatal course in pediatric and adult patients on corticosteroids. In pediatric and adult patients who have not had these diseases, particular care should be taken to avoid exposure. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If exposed to measles, prophylaxis with immunoglobulin (IG) may be indicated. (See the respective package inserts for complete VZIG and IG prescribing information.) If chickenpox develops, treatment with antiviral agents should be considered.

Neurologic
Reports of severe medical events have been associated with the intrathecal route of administration (see
ADVERSE REACTIONS, Gastrointestinal and Neurologic/Psychiatric sections).

Results from one multicenter, randomized, placebo controlled study with methylprednisolone hemisuccinate, an IV corticosteroid, showed an increase in early mortality (at 2 weeks) and late mortality (at 6 months) in patients with cranial trauma who were determined not to have other clear indications for corticosteroid treatment. High doses of corticosteroids, including Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, should not be used for the treatment of traumatic brain injury.

Ophthalmic

Use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. The use of oral corticosteroids is not recommended in the treatment of optic neuritis and may lead to an increase in the risk of new episodes. Corticosteroids should not be used in active ocular herpes simplex.

PRECAUTIONS

General

This product, like many other steroid formulations, is sensitive to heat. Therefore, it should not be autoclaved when it is desirable to sterilize the exterior of the vial.

The lowest possible dose of corticosteroid should be used to control the condition under treatment. When reduction in dosage is possible, the reduction should be gradual.

Since complications of treatment with glucocorticoids are dependent on the size of the dose and the duration of treatment, a risk/benefit decision must be made in each individual case as to dose and duration of treatment and as to whether daily or intermittent therapy should be used.

Kaposi’s sarcoma has been reported to occur in patients receiving corticosteroid therapy, most often for chronic conditions. Discontinuation of corticosteroids may result in clinical improvement.

Cardio-Renal

As sodium retention with resultant edema and potassium loss may occur in patients receiving corticosteroids, these agents should be used with caution in patients with congestive heart failure, hypertension, or renal insufficiency.

Endocrine

Drug-induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy. Therefore, in any situation of stress occurring during that period, naturally occurring glucocorticoids (hydrocortisone, cortisone), which also have salt-retaining properties, rather than betamethasone, are the appropriate choices as replacement therapy in adrenocortical deficiency states.

Gastrointestinal

Steroids should be used with caution in active or latent peptic ulcers, diverticulitis, fresh intestinal anastomoses, and nonspecific ulcerative colitis, since they may increase the risk of a perforation.

Signs of peritoneal irritation following gastrointestinal perforation in patients receiving corticosteroids may be minimal or absent.

There is an enhanced effect of corticosteroids in patients with cirrhosis.

Intra-Articular and Soft Tissue Administration
Intra-articular injected corticosteroids may be systematically absorbed. Appropriate examination of any joint fluid present is necessary to exclude a septic process.

A marked increase in pain accompanied by local swelling, further restriction of joint motion, fever, and malaise are suggestive of septic arthritis. If this complication occurs and the diagnosis of sepsis is confirmed, appropriate antimicrobial therapy should be instituted.

Injection of a steroid into an infected site is to be avoided. Local injection of a steroid into a previously injected joint is not usually recommended.

Corticosteroid injection into unstable joints is generally not recommended.

Intra-articular injection may result in damage to joint tissues (see ADVERSE REACTIONS, Musculoskeletal section).

**Musculoskeletal**

Corticosteroids decrease bone formation and increase bone resorption both through their effect on calcium regulation (ie, decreasing absorption and increasing excretion) and inhibition of osteoblast function. This, together with a decrease in the protein matrix of the bone secondary to an increase in protein catabolism, and reduced sex hormone production, may lead to inhibition of bone growth in pediatric patients and the development of osteoporosis at any age. Special consideration should be given to patients at increased risk of osteoporosis (ie, postmenopausal women) before initiating corticosteroid therapy.

**Neuro-Psychiatric**

Although controlled clinical trials have shown corticosteroids to be effective in speeding the resolution of acute exacerbations of multiple sclerosis, they do not show that they affect the ultimate outcome or natural history of the disease. The studies do show that relatively high doses of corticosteroids are necessary to demonstrate a significant effect (see DOSAGE AND ADMINISTRATION). An acute myopathy has been observed with the use of high doses of corticosteroids, most often occurring in patients with disorders with neuromuscular transmission (eg, myasthenia gravis), or in patients receiving concomitant therapy of neuromuscular blocking drugs (eg, pancuronium). This acute myopathy is generalized, may involve ocular and respiratory muscles, and may result in quadriplegia. Elevation of creatinine kinase may occur. Clinical improvement or recovery after stopping corticosteroids may require weeks to years.

Psychic derangements may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.

**Ophthalmic**

Intraocular pressure may become elevated in some individuals. If steroid therapy is continued for more than 6 weeks, intraocular pressure should be monitored.

**Information for Patients**

Patients should be warned not to discontinue the use of corticosteroids abruptly or without medical supervision, to advise any medical attendants that they are taking corticosteroids and to seek medical advice at once should they develop fever or other signs of infection.

Persons who are on corticosteroids should be warned to avoid exposure to chickenpox or measles. Patients should also be advised that if they are exposed, medical advice should be sought without delay.

**Drug Interactions**

Aminoglutethimide
Aminoglutethimide may lead to a loss of corticosteroid-induced adrenal suppression.

Amphotericin B Injection and Potassium-Depleting Agents
When corticosteroids are administered concomitantly with potassium-depleting agents (ie, amphotericin-B, diuretics), patients should be observed closely for development of hypokalemia. There have been cases reported in which concomitant use of amphotericin B and hydrocortisone was followed by cardiac enlargement and congestive heart failure.

Antibiotics
Macrolide antibiotics have been reported to cause a significant decrease in corticosteroid clearance.

Anticholinesterases
Concomitant use of anticholinesterase agents and corticosteroids may produce severe weakness in patients with myasthenia gravis. If possible, anticholinesterase agents should be withdrawn at least 24 hours before initiating corticosteroid therapy.

Anticoagulants, Oral
Coadministration of corticosteroids and warfarin usually results in inhibition of response to warfarin, although there have been some conflicting reports. Therefore, coagulation indices should be monitored frequently to maintain the desired anticoagulant effect.

Antidiabetics
Because corticosteroids may increase blood glucose concentrations, dosage adjustments of antidiabetic agents may be required.

Antitubercular Drugs
Serum concentrations of isoniazid may be decreased.

Cholestyramine
Cholestyramine may increase the clearance of corticosteroids.

Cyclosporine
Increased activity of both cyclosporine and corticosteroids may occur when the two are used concurrently. Convulsions have been reported with this concurrent use.

Digitalis Glycosides
Patients on digitalis glycosides may be at increased risk of arrhythmias due to hypokalemia.

Estrogens, Including Oral Contraceptives
Estrogens may decrease the hepatic metabolism of certain corticosteroids, thereby increasing their effect.

Hepatic Enzyme Inducers (eg, barbiturates, phenytoin, carbamazepine, rifampin)
Drugs which induce hepatic microsomal drug-metabolizing enzyme activity may enhance the metabolism of corticosteroids and require that the dosage of the corticosteroid be increased.

Ketoconazole
Ketoconazole has been reported to decrease the metabolism of certain corticosteroids by up to 60%, leading to an increased risk of corticosteroid side effects.
Nonsteroidal Anti-inflammatory Agents (NSAIDS)

Concomitant use of aspirin (or other nonsteroidal anti-inflammatory agents) and corticosteroids increases the risk of gastrointestinal side effects. Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia. The clearance of salicylates may be increased with concurrent use of corticosteroids.

Skin Tests
Corticosteroids may suppress reactions to skin tests.

Vaccines
Patients on prolonged corticosteroid therapy may exhibit a diminished response to toxoids and live or inactivated vaccines due to inhibition of antibody response. Corticosteroids may also potentiate the replication of some organisms contained in live attenuated vaccines. Route administration of vaccines or toxoids should be deferred until corticosteroid therapy is discontinued if possible (see WARNINGS, Infections, Vaccination section).

Carcinogenesis, Mutagenesis, Impairment of Fertility
No adequate studies have been conducted in animals to determine whether corticosteroids have a potential for carcinogenesis or mutagenesis.
Steroids may increase or decrease motility and number of spermatozoa in some patients.

Pregnancy
Teratogenic Effects

Pregnancy Category C
Corticosteroids have been shown to be teratogenic in many species when given in doses equivalent to the human dose. Animal studies in which corticosteroids have been given to pregnant mice, rats, and rabbits have yielded an increased incidence of cleft palate in the offspring. There are no adequate and well-controlled studies in pregnant women. Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have received corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

Nursing Mothers
Systematically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when corticosteroids are administered to a nursing woman.

Pediatric Use
The efficacy and safety of corticosteroids in the pediatric population are based on the well-established course of effect of corticosteroids, which is similar in pediatric and adult populations. Published studies provide evidence of efficacy and safety in pediatric patients for the treatment of nephrotic syndrome (>2 years of age), and aggressive lymphomas and leukemias (>1 month of age). Other indications for pediatric use of corticosteroids, eg, severe asthma and wheezing, are based on adequate and well-controlled trials conducted in adults, on the premises that the course of the diseases and their pathophysiology are considered to be substantially similar in both populations.

The adverse effects of corticosteroids in pediatric patients are similar to those in adults (see ADVERSE REACTIONS). Like adults, pediatric patients should be carefully observed with frequent measurements of blood pressure, weight, height, intraocular pressure, and clinical evaluation for the presence of infection, psychosocial disturbances, thromboembolism, peptic ulcers, cataracts, and
osteoporosis. Pediatric patients who are treated with corticosteroids by any route, including systematically administered corticosteroids, may experience a decrease in their growth velocity. This negative impact of corticosteroids on growth has been observed at low systemic doses and in the absence of laboratory evidence of HPA axis suppression (ie, cosyntropin stimulation and basal cortisol plasma levels). Growth velocity may therefore be a more sensitive indicator of systemic corticosteroid exposure in pediatric patients than some commonly used tests of HPA axis function. The linear growth of pediatric patients treated with corticosteroids should be monitored, and the potential growth effects of prolonged treatment should be weighed against clinical benefits obtained and the availability of treatment alternatives. In order to minimize the potential growth effects of corticosteroids, pediatric patients should be titrated to the lowest effective dose.

Geriatric Use
No overall differences in safety or effectiveness were observed between elderly subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and young patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS
(listed alphabetically, under each subsection)

Allergic Reactions
Anaphylactoid reaction, anaphylaxis, angioedema.

Cardiovascular
Bradyarrhythmias, cardiac arrest, cardiac arrhythmias, cardiac enlargement, circulatory collapse, congestive heart failure, fat embolism, hypertension, hypertrophic cardiomyopathy in premature infants, myocardial rupture following recent myocardial infarction (see WARNINGS), pulmonary edema, syncope, tachycardia, thromboembolism, thrombophlebitis, vasculitis.

Dermatologic
Acne, allergic dermatitis, cutaneous and subcutaneous atrophy, dry scaly skin, ecchymoses and petechiae, edema, erythema, hyperpigmentation, hypopigmentation, impaired wound healing, increased sweating, rash, sterile abscess, striae, suppressed reactions to skin tests, thin fragile skin, thinning scalp hair, urticaria.

Endocrine
Decreased carbohydrate and glucose tolerance, development of cushingoid state, glucosuria, hirsutism, hypertrichosis, increased requirements for insulin or oral hypoglycemic adrenocortical and pituitary unresponsiveness (particularly in times of stress, as in trauma, surgery, or illness), suppression of growth in pediatric patients.

Fluid and Electrolyte Disturbances
Congestive heart failure in susceptible patients, fluid retention, hypokalemic alkalosis, potassium loss, sodium retention.

Gastrointestinal
Abdominal distention, bowel/bladder dysfunction (after intrathecal administration), elevation in serum liver enzyme levels (usually reversible upon discontinuation), hepatomegaly, increased appetite, nausea, pancreatitis, peptic ulcer with possible perforation and hemorrhage, perforation of the small and large intestine (particularly in patients with inflammatory bowel disease), ulcerative esophagitis.

Metabolic
Negative nitrogen balance due to protein catabolism.
**Musculoskeletal**

Aseptic necrosis of femoral and humeral heads, calcinosis (following intra-articular or intralesional use), Charcot-like arthropathy, loss of muscle mass, muscle weakness, osteoporosis, pathologic fracture of long bones, postinjection flare (following intra-articular use), steroid myopathy, tendon rupture, vertebral compression fractures.

**Neurologic/Psychiatric**

Convulsions, depression, emotional instability, euphoria, headache, increased intracranial pressure with papilledema (pseudotumor cerebri) usually following discontinuation of treatment, insomnia, mood swings, neuritis, neuropathy, paresthesia, personality changes, psychotic disorders, vertigo.

Arachnoiditis, meningitis, paraparesis/paraplegia, and sensory disturbances have occurred after intrathecal administration (see **WARNINGS, Neurologic** section).

**Ophthalmic**

Exophthalmos, glaucoma, increased intraocular pressure, posterior subcapsular cataracts, rare instances of blindness associated with periocular injections.

**Other**

Abnormal fat deposits, decreased resistance to infection, hiccups, increased or decreased motility and number of spermatozoa, malaise, moon face, weight gain.

**OVERDOSAGE**

Treatment of acute overdose is by supportive and symptomatic therapy. For chronic overdosage in the face of severe disease requiring continuous steroid therapy, the dosage of the corticosteroid may be reduced only temporarily, or alternate day treatment may be introduced.

**DOSAGE AND ADMINISTRATION**

Benzyl alcohol as a preservative has been associated with a fatal “Gasping Syndrome” in premature infants and infants of low birth weight. Solutions used for further dilution of this product should be preservative-free when used in the neonate, especially the premature infant. The initial dosage of parenterally administered Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension may vary from 0.25 to 9.0 mg per day depending on the specific disease entity being treated. However, in certain overwhelming, acute, life-threatening situations, administrations in dosages exceeding the usual dosages may be justified and may be in multiples of the oral dosages.

*It Should Be Emphasized That Dosage Requirements Are Variable and Must Be Individualized on the Basis of the Disease Under Treatment and the Response of the Patient.* After a favorable response is noted, the proper maintenance dosage should be determined by decreasing the initial drug dosage in small decrements at appropriate time intervals until the lowest dosage which will maintain an adequate clinical response is reached. Situations which may make dosage adjustments necessary are changes in clinical status secondary to remissions or exacerbations in the disease process, the patient’s individual drug responsiveness, and the effect of patient exposure to stressful situations not directly related to the disease entity under treatment. In this latter situation it may be necessary to increase the dosage of the corticosteroid for a period of time consistent with the patient’s condition. If after long-term therapy the drug is to be stopped, it is recommended that it be withdrawn gradually rather than abruptly.

In the treatment of acute exacerbations of multiple sclerosis, daily doses of 30 mg of betamethasone for a week followed by 12 mg every other day for 1 month are recommended (see **PRECAUTIONS, Neuro-psychiatric** section).

In pediatric patients, the initial dose of betamethasone may vary depending on the specific disease entity being treated. The range of initial doses is 0.02 to 0.3 mg/kg/day in three or four divided doses (0.6 to
For the purpose of comparison, the following is the equivalent milligram dosage of the various glucocorticoids:

| Cortisone, 25 | Triamcinolone, 4 |
| Hydrocortisone, 20 | Paramethasone, 2 |
| Prednisolone, 5 | Betamethasone, 0.75 |
| Prednisone, 5 | Dexamethasone, 0.75 |
| Methylprednisolone, 4 |

These dose relationships apply only to oral or intravenous administration of these compounds. When these substances or their derivatives are injected intramuscularly or into joint spaces, their relative properties may be greatly altered.

If coadministration of a local anesthetic is desired, Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension may be mixed with 1% or 2% lidocaine hydrochloride, using the formulations which do not contain parabens. Similar local anesthetics may also be used. Diluents containing methylparaben, propylparaben, phenol, etc., should be avoided, since these compounds may cause flocculation of the steroid. The required dose of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension is first withdrawn from the vial into the syringe. The local anesthetic is then drawn in, and the syringe shaken briefly. Do not inject local anesthetics into the vial of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension.

**Bursitis, Tenosynovitis, Peritendinitis**

In acute subdeltoid, subacromial, olecranon, and prepatellar bursitis, one intrabursal injection of 1.0mL Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension can relieve pain and restore full range of movement. Several intrabursal injections of corticosteroids are usually required in recurrent acute bursitis and in acute exacerbations of chronic bursitis. Partial relief of pain and some increase in mobility can be expected in both conditions after one or two injections. Chronic bursitis may be treated with reduced dosage once the acute condition is controlled. In tenosynovitis and tendinitis, three or four local injections at intervals of 1 to 2 weeks between injections are given in most cases. Injections should be made into the affected tendon sheaths rather than into the tendons themselves. In ganglions of joint capsules and tendon sheaths, injection of 0.5 mL directly into the ganglion cysts has produced marked reduction in the size of the lesions.

**Rheumatoid Arthritis and Osteoarthritis**

Following intra-articular administration of 0.5 to 2.0 mL of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, relief of pain, soreness, and stiffness may be experienced. Duration of relief varies widely in both diseases. Intra-articular Injection of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension is well tolerated in joints and periarticular tissues. There is virtually no pain on injection, and the “secondary flare” that sometimes occurs a few hours after intra-articular injection of corticosteroids has not been reported with Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension. Using sterile technique, a 20- to 24-gauge needle on an empty syringe is inserted into the synovial cavity and a few drops of synovial fluid are withdrawn to confirm that the needle is in the joint. The aspirating syringe is replaced by a syringe containing Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension and injection is then made into the joint.

**Recommended Doses for Intra-articular Injection**

<table>
<thead>
<tr>
<th>Size of Joint</th>
<th>Location</th>
<th>Dose (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
<td></td>
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</table>
A portion of the administered dose of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension is absorbed systemically following intra-articular injection. In patients being treated concomitantly with oral or parenteral corticosteroids, especially those receiving large doses, the systemic absorption of the drug should be considered in determining intra-articular dosage.

**Dermatologic Conditions**

In intralesional treatment, 0.2 mL/cm² of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension is injected intradermally (not subcutaneously) using a tuberculin syringe with a 25-gauge, 1/2-inch needle. Care should be taken to deposit a uniform depot of medication intradermally. A total of no more than 1.0 mL at weekly intervals is recommended.

**Disorders of the Foot**

A tuberculin syringe with a 25-gauge, 3/4-inch needle is suitable for most injections into the foot. The following doses are recommended at intervals of 3 days to a week.

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension Dose (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bursitis under heloma durum or heloma molle under calcaneal spur over hallux rigidus or digiti quinti varus Tenosynovitis, periostitis of cuboid Acute gouty arthritis</td>
<td>0.25 - 0.5 0.5 0.5 0.5 0.5 - 1.0</td>
</tr>
</tbody>
</table>

**HOW SUPPLIED**

Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP, 5 mL multiple dose vial; box of one: NDC 0517-0720-01

**SHAKE WELL BEFORE USING.**

Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Protect from light.

Rx Only

AMERICAN REGENT, INC.
SHIRLEY, NY 11967

Revised December 2009
AQUEOUS SOLUTIONS FOR INFILTRATION
AND NERVE BLOCK

Ampul

Plastic Multiple-dose Fliptop Vial

Glass Teartop Vial

Rx only

DESCRIPTION

Lidocaine Hydrochloride Injection, USP is a sterile, nonpyrogenic solution of lidocaine hydrochloride in water for injection for parenteral administration in various concentrations with characteristics as follows:

<table>
<thead>
<tr>
<th>Concentration</th>
<th>0.5%</th>
<th>1%</th>
<th>1.5%</th>
<th>2%</th>
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</thead>
<tbody>
<tr>
<td>mg/mL lidocaine HCl (anhyd.)</td>
<td>5</td>
<td>10</td>
<td>15</td>
<td>20</td>
</tr>
<tr>
<td>mg/mL sodium chloride</td>
<td>8</td>
<td>7</td>
<td>6.5</td>
<td>6</td>
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</tbody>
</table>

Multiple-dose vials contain 0.1% of methylparaben added as preservative. May contain sodium hydroxide and/or hydrochloric acid for pH adjustment. The pH is 6.5 (5.0 to 7.0). See HOW SUPPLIED section for various sizes and strengths.

Lidocaine is a local anesthetic of the amide type.

Lidocaine Hydrochloride, USP is chemically designated 2-(diethylamino)-N-(2,6-dimethylphenyl)-acetamide monohydrochloride monohydrate, a white powder freely soluble in water. The molecular weight is 288.82. It has the following structural formula:

![Structural formula of Lidocaine](image)

The semi-rigid vial used for the plastic vials is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper drug concentration.

CLINICAL PHARMACOLOGY

**Mechanism of action:** Lidocaine stabilizes the neuronal membrane by inhibiting the ionic fluxes required for the initiation and conduction of impulses, thereby effecting local anesthetic action.

**Hemodynamics:** Excessive blood levels may cause changes in cardiac output, total peripheral resistance, and mean arterial pressure. With central neural blockade these changes may be attributable to block of autonomic fibers, a direct depressant effect of the local anesthetic agent on various components of the cardiovascular system and/or the beta-adrenergic receptor stimulating action of epinephrine when present. The net effect is normally a modest hypotension when the recommended dosages are not exceeded.
Pharmacokinetics and metabolism: Information derived from diverse formulations, concentrations and usages reveals that lidocaine is completely absorbed following parenteral administration, its rate of absorption depending, for example, upon various factors such as the site of administration and the presence or absence of a vasoconstrictor agent. Except for intravascular administration, the highest blood levels are obtained following intercostal nerve block and the lowest after subcutaneous administration.

The plasma binding of lidocaine is dependent on drug concentration, and the fraction bound decreases with increasing concentration. At concentrations of 1 to 4 mcg of free base per mL, 60 to 80 percent of lidocaine is protein bound. Binding is also dependent on the plasma concentration of the alpha-1-acid glycoprotein.

Lidocaine crosses the blood-brain and placental barriers, presumably by passive diffusion.

Lidocaine is metabolized rapidly by the liver, and metabolites and unchanged drug are excreted by the kidneys. Biotransformation includes oxidative N-dealkylation, ring hydroxylation, cleavage of the amide linkage, and conjugation. N-dealkylation, a major pathway of biotransformation, yields the metabolites monoethylglycinexylidide and glycinexylidide. The pharmacological/toxicological actions of these metabolites are similar to, but less potent than, those of lidocaine. Approximately 90% of lidocaine administered is excreted in the form of various metabolites, and less than 10% is excreted unchanged. The primary metabolite in urine is a conjugate of 4-hydroxy-2, 6-dimethylaniline.

The elimination half-life of lidocaine following an intravenous bolus injection is typically 1.5 to 2.0 hours. Because of the rapid rate at which lidocaine is metabolized, any condition that affects liver function may alter lidocaine kinetics. The half-life may be prolonged two-fold or more in patients with liver dysfunction. Renal dysfunction does not affect lidocaine kinetics but may increase the accumulation of metabolites.

Factors such as acidosis and the use of CNS stimulants and depressants affect the CNS levels of lidocaine required to produce overt systemic effects. Objective adverse manifestations become increasingly apparent with increasing venous plasma levels above 6.0 mcg free base per mL. In the rhesus monkey arterial blood levels of 18-21 mcg/mL have been shown to be threshold for convulsive activity.

INDICATIONS AND USAGE

Lidocaine Hydrochloride Injection, USP is indicated for production of local or regional anesthesia by infiltration techniques such as percutaneous injection and intravenous regional anesthesia by peripheral nerve block techniques such as brachial plexus and intercostal and by central neural techniques such as lumbar and caudal epidural blocks, when the accepted procedures for these techniques as described in standard textbooks are observed.

CONTRAINDICATIONS

Lidocaine is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type.

WARNINGS

LIDOCAINE HYDROCHLORIDE INJECTION, FOR INFILTRATION AND NERVE BLOCK, SHOULD BE EMPLOYED ONLY BY CLINICIANS WHO ARE WELL VERSED IN DIAGNOSIS AND MANAGEMENT OF DOSE-RELATED TOXICITY AND OTHER ACUTE EMERGENCIES THAT MIGHT ARISE FROM THE BLOCK TO BE EMPLOYED AND THEN ONLY AFTER ENSURING THE IMMEDIATE AVAILABILITY OF OXYGEN, OTHER RESUSCITATIVE DRUGS, CARDIOPULMONARY EQUIPMENT, AND THE PERSONNEL NEEDED FOR PROPER
MANAGEMENT OF TOXIC REACTIONS AND RELATED EMERGENCIES (See also ADVERSE REACTIONS and PRECAUTIONS). DELAY IN PROPER MANAGEMENT OF DOSE-RELATED TOXICITY, UNDERVENTILATION FROM ANY CAUSE AND/OR ALTERED SENSITIVITY MAY LEAD TO THE DEVELOPMENT OF ACIDOSIS, CARDIAC ARREST AND, POSSIBLY, DEATH.

Intra-articular infusions of local anesthetics following arthroscopic and other surgical procedures is an unapproved use, and there have been post-marketing reports of chondrolysis in patients receiving such infusions. The majority of reported cases of chondrolysis have involved the shoulder joint; cases of gleno-humeral chondrolysis have been described in pediatric and adult patients following intra-articular infusions of local anesthetics with and without epinephrine for periods of 48 to 72 hours. There is insufficient information to determine whether shorter infusion periods are not associated with these findings. The time of onset of symptoms, such as joint pain, stiffness and loss of motion can be variable, but may begin as early as the 2nd month after surgery. Currently, there is no effective treatment for chondrolysis; patients who experienced chondrolysis have required additional diagnostic and therapeutic procedures and some required arthroplasty or shoulder replacement.

To avoid intravascular injection, aspiration should be performed before the local anesthetic solution is injected. The needle must be repositioned until no return of blood can be elicited by aspiration. Note, however, that the absence of blood in the syringe does not guarantee that intravascular injection has been avoided.

Local anesthetic solutions containing antimicrobial preservatives (e.g., methylparaben) should not be used for epidural or spinal anesthesia because the safety of these agents has not been established with regard to intrathecal injection, either intentional or accidental.

PRECAUTIONS

General:

The safety and effectiveness of lidocaine depend on proper dosage, correct technique, adequate precautions, and readiness for emergencies. Standard textbooks should be consulted for specific techniques and precautions for various regional anesthetic procedures.

Resuscitative equipment, oxygen, and other resuscitative drugs should be available for immediate use. (See WARNINGS and ADVERSE REACTIONS). The lowest dosage that results in effective anesthesia should be used to avoid high plasma levels and serious adverse effects. Syringe aspirations should also be performed before and during each supplemental injection when using indwelling catheter techniques. During the administration of epidural anesthesia, it is recommended that a test dose be administered initially and that the patient be monitored for central nervous system toxicity and cardiovascular toxicity, as well as for signs of unintended intrathecal administration before proceeding. When clinical conditions permit, consideration should be given to employing local anesthetic solutions that contain epinephrine for the test dose because circulatory changes compatible with epinephrine may also serve as a warning sign of unintended intravascular injection. An intravascular injection is still possible even if aspirations for blood are negative. Repeated doses of lidocaine may cause significant increases in blood levels with each repeated dose because of slow accumulation of the drug or its metabolites. Tolerance to elevated blood levels varies with the status of the patient. Debilitated, elderly patients, acutely ill patients and children should be given reduced doses commensurate with their age and physical condition. Lidocaine should also be used with caution in patients with severe shock or heart block. Lumbar and caudal epidural anesthesia should be used with extreme caution in persons with the following conditions: existing neurological disease, spinal deformities, septicemia and severe hypertension.

Local anesthetic solutions containing a vasoconstrictor should be used cautiously and in carefully circumscribed quantities in areas of the body supplied by end arteries or having otherwise compromised blood supply. Patients with peripheral vascular disease and those with hypertensive
vascular disease may exhibit exaggerated vasoconstrictor response. Ischemic injury or necrosis may result. Preparations containing a vasoconstrictor should be used with caution in patients during or following the administration of potent general anesthetic agents, since cardiac arrhythmias may occur under such conditions.

Careful and constant monitoring of cardiovascular and respiratory (adequacy of ventilation) vital signs and the patient’s state of consciousness should be accomplished after each local anesthetic injection. It should be kept in mind at such times that restlessness, anxiety, tinnitus, dizziness, blurred vision, tremors, depression or drowsiness may be early warning signs of central nervous system toxicity.

Since amide-type local anesthetics are metabolized by the liver, lidocaine should be used with caution in patients with hepatic disease. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at greater risk of developing toxic plasma concentrations. Lidocaine should also be used with caution in patients with impaired cardiovascular function since they may be less able to compensate for functional changes associated with the prolongation of A-V conduction produced by these drugs. Many drugs used during the conduct of anesthesia are considered potential triggering agents for familial malignant hyperthermia. Since it is not known whether amide-type local anesthetics may trigger this reaction and since the need for supplemental general anesthesia cannot be predicted in advance, it is suggested that a standard protocol for the management of malignant hyperthermia should be available. Early unexplained signs of tachycardia, tachypnea, labile blood pressure and metabolic acidosis may precede temperature elevation. Successful outcome is dependent on early diagnosis, prompt discontinuance of the suspect triggering agent(s) and institution of treatment, including oxygen therapy, indicated supportive measures and dantrolene (consult dantrolene sodium intravenous package insert before using).

Proper tourniquet technique, as described in publications and standard textbooks, is essential in the performance of intravenous regional anesthesia. Solutions containing epinephrine or other vasoconstrictors should not be used for this technique.

Lidocaine should be used with caution in persons with known drug sensitivities. Patients allergic to para-aminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown cross sensitivity to lidocaine.

**Use in the Head and Neck Area:** Small doses of local anesthetics injected into the head and neck area, including retrobulbar, dental and stellate ganglion blocks, may produce adverse reactions similar to systemic toxicity seen with unintentional intravascular injections of larger doses. Confusion, convulsions, respiratory depression and/or respiratory arrest and cardiovascular stimulation or depression have been reported. These reactions may be due to intra-arterial injections of the local anesthetic with retrograde flow to the cerebral circulation. Patients receiving these blocks should have their circulation and respiration monitored and be constantly observed. Resuscitative equipment and personnel for treating adverse reactions should be immediately available. Dosage recommendations should not be exceeded. (See **DOSAGE AND ADMINISTRATION**).

**Information for Patients:**

When appropriate, patients should be informed in advance that they may experience temporary loss of sensation and motor activity, usually in the lower half of the body following proper administration of epidural anesthesia.

**Clinically Significant Drug Interactions:**

The administration of local anesthetic solutions containing epinephrine or norepinephrine to patients receiving monoamine oxidase inhibitors or tricyclic antidepressants may produce severe prolonged hypertension.

Phenothiazines and butyrophenones may reduce or reverse the pressor effect of epinephrine. Concurrent use of these agents should generally be avoided. In situations when concurrent therapy is
necessary, careful patient monitoring is essential. Concurrent administration of vasopressor drugs (for the treatment of hypotension related to obstetric blocks) and ergot-type oxytocic drugs may cause severe persistent hypertension or cerebrovascular accidents.

**Drug Laboratory Test Interactions:**

The intramuscular injection of lidocaine may result in an increase in creatine phosphokinase levels. Thus, the use of this enzyme determination without isoenzyme separation as a diagnostic test for the presence of acute myocardial infarction may be compromised by the intramuscular injection of lidocaine.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:**

Studies of lidocaine in animals to evaluate the carcinogenic and mutagenic potential or the effect on fertility have not been conducted.

**Pregnancy:**

*Teratogenic Effects. Pregnancy Category B.* Reproduction studies have been performed in rats at doses up to 6.6 times the human dose and have revealed no evidence of harm to the fetus caused by lidocaine. There are, however, no adequate and well-controlled studies in pregnant women. Animal reproduction studies are not always predictive of human response. General consideration should be given to this fact before administering lidocaine to women of childbearing potential, especially during early pregnancy when maximum organogenesis takes place.

**Labor and Delivery:**

Local anesthetics rapidly cross the placenta and when used for epidural, paracervical, pudendal or caudal block anesthesia, can cause varying degrees of maternal, fetal and neonatal toxicity (See **CLINICAL PHARMACOLOGY—Pharmacokinetics**). The potential for toxicity depends upon the procedure performed, the type and amount of drug used, and the technique of drug administration. Adverse reactions in the parturient, fetus and neonate involve alterations of the central nervous system peripheral vascular tone and cardiac function.

Maternal hypotension has resulted from regional anesthesia. Local anesthetics produce vasodilation by blocking sympathetic nerves. Elevating the patient’s legs and positioning her on her left side will help prevent decreases in blood pressure. The fetal heart rate also should be monitored continuously, and electronic fetal monitoring is highly advisable.

Epidural, spinal, paracervical, or pudendal anesthesia may alter the forces of parturition through changes in uterine contractility or maternal expulsive efforts. In one study, paracervical block anesthesia was associated with a decrease in the mean duration of first stage labor and facilitation of cervical dilation. However, spinal and epidural anesthesia have also been reported to prolong the second stage of labor by removing the parturient’s reflex urge to bear down or by interfering with motor function. The use of obstetrical anesthesia may increase the need for forceps assistance.

The use of some local anesthetic drug products during labor and delivery may be followed by diminished muscle strength and tone for the first day or two of life. The long-term significance of these observations is unknown. Fetal bradycardia may occur in 20 to 30 percent of patients receiving paracervical nerve block anesthesia with the amide-type local anesthetics and may be associated with fetal acidosis. Fetal heart rate should always be monitored during paracervical anesthesia. The physician should weigh the possible advantages against risks when considering paracervical block in prematurity, toxemia of pregnancy and fetal distress. Careful adherence to recommended dosage is of the utmost importance in obstetrical paracervical block. Failure to achieve adequate analgesia with recommended doses should arouse suspicion of intravascular or fetal intracranial injection. Cases compatible with unintended fetal intracranial injection of local anesthetic solution have been reported.
following intended paracervical or pudendal block or both. Babies so affected present with unexplained neonatal depression at birth, which correlates with high local anesthetic serum levels, and often manifest seizures within six hours. Prompt use of supportive measures combined with forced urinary excretion of the local anesthetic has been used successfully to manage this complication.

Case reports of maternal convulsions and cardiovascular collapse following use of some local anesthetics for paracervical block in early pregnancy (as anesthesia for elective abortion) suggest that systemic absorption under these circumstances may be rapid. The recommended maximum dose of each drug should not be exceeded. Injection should be made slowly and with frequent aspiration. Allow a 5-minute interval between sides.

**Nursing Mothers:**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when lidocaine is administered to a nursing woman.

**Pediatric Use:**

Dosages in pediatric patients should be reduced, commensurate with age, body weight and physical condition. See **DOSAGE AND ADMINISTRATION**.

**ADVERSE REACTIONS**

**Systemic:** Adverse experiences following the administration of lidocaine are similar in nature to those observed with other amide local anesthetic agents. These adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage, rapid absorption or inadvertent intravascular injection, or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature. The following types are those most commonly reported:

**Central Nervous System:** CNS manifestations are excitatory and/or depressant and may be characterized by lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. The excitatory manifestations may be very brief or may not occur at all, in which case the first manifestation of toxicity may be drowsiness merging into unconsciousness and respiratory arrest. Drowsiness following the administration of lidocaine is usually an early sign of a high blood level of the drug and may occur as a consequence of rapid absorption.

**Cardiovascular System:** Cardiovascular manifestations are usually depressant and are characterized by bradycardia, hypotension, and cardiovascular collapse, which may lead to cardiac arrest.

**Allergic:** Allergic reactions are characterized by cutaneous lesions, urticaria, edema or anaphylactoid reactions. Allergic reactions may occur as a result of sensitivity either to local anesthetic agents or to the methylparaben used as a preservative in multiple dose vials. Allergic reactions as a result of sensitivity to lidocaine are extremely rare and, if they occur, should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

**Neurologic:** The incidences of adverse reactions associated with the use of local anesthetics may be related to the total dose of local anesthetic administered and are also dependent upon the particular drug used, the route of administration and the physical status of the patient. In a prospective review of 10,440 patients who received lidocaine for spinal anesthesia, the incidences of adverse reactions were reported to be about 3 percent each for positional headaches, hypotension and backache; 2 percent for shivering; and less than 1 percent each for peripheral nerve symptoms, nausea, respiratory inadequacy and double vision. Many of these observations may be related to local anesthetic techniques, with or without a contribution from the local anesthetic.
In the practice of caudal or lumbar epidural block, occasional unintentional penetration of the subarachnoid space by the catheter may occur. Subsequent adverse effects may depend partially on the amount of drug administered subdurally.

These may include spinal block of varying magnitude (including total spinal block), hypotension secondary to spinal block, loss of bladder and bowel control, and loss of perineal sensation and sexual function. Persistent motor, sensory and/or autonomic (sphincter control) deficit of some lower spinal segments with slow recovery (several months) or incomplete recovery have been reported in rare instances when caudal or lumbar epidural block has been attempted. Backache and headache have also been noted following use of these anesthetic procedures.

There have been reported cases of permanent injury to extraocular muscles requiring surgical repair following retrobulbar administration.

**OVERDOSAGE**

Acute emergencies from local anesthetics are generally related to high plasma levels encountered during therapeutic use of local anesthetics or to unintended subarachnoid injection of local anesthetic solution (see **ADVERSE REACTIONS**, **WARNINGS** and **PRECAUTIONS**).

**Management of Local Anesthetic Emergencies**: The first consideration is prevention, best accomplished by careful monitoring of cardiovascular and respiratory vital signs and the patient’s state of consciousness after each local anesthetic injection. At the first sign of change, oxygen should be administered.

The first step in the management of convulsions, as well as underventilation or apnea due to unintended subarachnoid injection of drug solution, consists of immediate attention to the maintenance of a patent airway and assisted or controlled ventilation with oxygen and a delivery system capable of permitting immediate positive airway pressure by mask. Immediately after the institution of these ventilatory measures, the adequacy of the circulation should be evaluated, keeping in mind that drugs used to treat convulsions sometimes depress the circulation when administered intravenously. Should convulsions persist despite adequate respiratory support, and if the status of the circulation permits, small increments of an ultra-short acting barbiturate (such as thiopental or thiamylal) or a benzodiazepine (such as diazepam) may be administered intravenously. The clinician should be familiar, prior to use of local anesthetics, with these anticonvulsant drugs. Supportive treatment of circulatory depression may require administration of intravenous fluids and, when appropriate, a vasopressor as directed by the clinical situation (e.g., ephedrine).

If not treated immediately, both convulsions and cardiovascular depression can result in hypoxia, acidosis, bradycardia, arrhythmias and cardiac arrest. Underventilation or apnea due to unintentional subarachnoid injection of local anesthetic solution may produce these same signs and also lead to cardiac arrest if ventilatory support is not instituted. If cardiac arrest should occur standard cardiopulmonary resuscitative measures should be instituted.

Endotracheal intubation, employing drugs and techniques familiar to the clinician, may be indicated, after initial administration of oxygen by mask, if difficulty is encountered in the maintenance of a patent airway or if prolonged ventilatory support (assisted or controlled) is indicated.

Dialysis is of negligible value in the treatment of acute overdosage with lidocaine.

The oral LD$_{50}$ of lidocaine HCl in non-fasted female rats is 459 (346–773) mg/kg (as the salt) and 214 (159–324) mg/kg (as the salt) in fasted female rats.

**DOSAGE AND ADMINISTRATION**

Table 1 (Recommended Dosages) summarizes the recommended volumes and concentrations of Lidocaine Hydrochloride Injection, USP for various types of anesthetic procedures. The dosages
suggested in this table are for normal healthy adults and refer to the use of epinephrine-free solutions. When larger volumes are required only solutions containing epinephrine should be used, except in those cases where vasopressor drugs may be contraindicated.

There have been adverse event reports of chondrolysis in patients receiving intra-articular infusions of local anesthetics following arthroscopic and other surgical procedures. Lidocaine is not approved for this use (see **WARNINGS** and **DOSEAGE AND ADMINISTRATION**).

These recommended doses serve only as a guide to the amount of anesthetic required for most routine procedures. The actual volumes and concentrations to be used depend on a number of factors such as type and extent of surgical procedure, depth of anesthesia and degree of muscular relaxation required, duration of anesthesia required, and the physical condition of the patient. In all cases the lowest concentration and smallest dose that will produce the desired result should be given. Dosages should be reduced for children and for elderly and debilitated patients and patients with cardiac and/or liver disease.

The onset of anesthesia, the duration of anesthesia and the degree of muscular relaxation are proportional to the volume and concentration (i.e., total dose) of local anesthetic used. Thus, an increase in volume and concentration of Lidocaine Hydrochloride Injection will decrease the onset of anesthesia, prolong the duration of anesthesia, provide a greater degree of muscular relaxation and increase the segmental spread of anesthesia. However, increasing the volume and concentration of Lidocaine Hydrochloride Injection may result in a more profound fall in blood pressure when used in epidural anesthesia. Although the incidence of side effects with lidocaine is quite low, caution should be exercised when employing large volumes and concentrations, since the incidence of side effects is directly proportional to the total dose of local anesthetic agent injected.

For intravenous regional anesthesia, only the 50 mL single-dose vial containing 0.5% Lidocaine Hydrochloride Injection, USP should be used.

**Epidural Anesthesia**

For epidural anesthesia, only the following available specific products of Lidocaine Hydrochloride Injection by Hospira are recommended:

1% .......................... 30 mL single-dose teardrop vials
1.5% .......................... 20 mL single-dose ampuls
2% .............................. 10 mL single-dose ampuls

Although these solutions are intended specifically for epidural anesthesia, they may also be used for infiltration and peripheral nerve block provided they are employed as single dose units. These solutions contain no bacteriostatic agent. In epidural anesthesia, the dosage varies with the number of dermatomes to be anesthetized (generally 2−3 mL of the indicated concentration per dermatome).

**Caudal and Lumbar Epidural Block:** As a precaution against the adverse experiences sometimes observed following unintentional penetration of the subarachnoid space, a test dose such as 2−3 mL of 1.5% lidocaine hydrochloride should be administered at least 5 minutes prior to injecting the total volume required for a lumbar or caudal epidural block. The test dose should be repeated if the patient is moved in a manner that may have displaced the catheter. Epinephrine, if contained in the test dose (10−15 mcg have been suggested), may serve as a warning of unintentional intravascular injection. If injected into a blood vessel, this amount of epinephrine is likely to produce a transient "epinephrine response" within 45 seconds, consisting of an increase in heart rate and systolic blood pressure, circumoral pallor, palpitations and nervousness in the unsedated patient. The sedated patient may exhibit only a pulse rate increase of 20 or more beats per minute for 15 or more seconds. Patients on beta-blockers may not manifest changes in heart rate, but blood pressure monitoring can detect an evanescent rise in systolic blood pressure. Adequate time should be allowed for onset of anesthesia after administration of each test dose. The rapid injection of a large volume of Lidocaine Hydrochloride Injection through the catheter should be avoided, and, when feasible, fractional doses should be administered.
In the event of the known injection of a large volume of local anesthetic solutions into the subarachnoid space, after suitable resuscitation and if the catheter is in place, consider attempting the recovery of drug by draining a moderate amount of cerebrospinal fluid (such as 10 mL) through the epidural catheter.

**Maximum Recommended Dosages**

*NOTE:* The products accompanying this insert do not contain epinephrine.

**Adults:** For normal healthy adults, the individual maximum recommended dose of lidocaine HCl with epinephrine should not exceed 7 mg/kg (3.5 mg/lb) of body weight and in general it is recommended that the maximum total dose not exceed 500 mg. When used without epinephrine, the maximum individual dose should not exceed 4.5 mg/kg (2 mg/lb) of body weight and in general it is recommended that the maximum total dose does not exceed 300 mg. For continuous epidural or caudal anesthesia, the maximum recommended dosage should not be administered at intervals of less than 90 minutes. When continuous lumbar or caudal epidural anesthesia is used for non-obstetrical procedures, more drug may be administered if required to produce adequate anesthesia.

The maximum recommended dose per 90 minute period of lidocaine hydrochloride for paracervical block in obstetrical patients and non-obstetrical patients is 200 mg total. One-half of the total dose is usually administered to each side. Inject slowly five minutes between sides. (See also discussion of paracervical block in **PRECAUTIONS**).

For intravenous regional anesthesia, the dose administered should not exceed 4 mg/kg in adults.

**Children:** It is difficult to recommend a maximum dose of any drug for children, since this varies as a function of age and weight. For children over 3 years of age who have a normal lean body mass and normal body development, the maximum dose is determined by the child’s age and weight. For example, in a child of 5 years weighing 50 lbs., the dose of lidocaine HCl should not exceed 75 — 100 mg (1.5 — 2 mg/lb). The use of even more dilute solutions (i.e., 0.25 — 0.5%) and total dosages not to exceed 3 mg/kg (1.4 mg/lb) are recommended for induction of intravenous regional anesthesia in children.

In order to guard against systemic toxicity, the lowest effective concentration and lowest effective dose should be used at all times. In some cases it will be necessary to dilute available concentrations with 0.9% sodium chloride injection in order to obtain the required final concentration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever the solution and container permit. Solutions that are discolored and/or contain particulate matter should not be used.

| Table 1 |
|---|---|---|
| Recommended Dosages of Lidocaine Hydrochloride Injection, USP for Various Anesthetic Procedures in Normal Healthy Adults | Lidocaine Hydrochloride Injection, USP (without Epinephrine) |  |
| Procedure | Conc. (%) | Vol. (mL) | Total Dose (mg) |
| Infiltration | | | |
| Percutaneous | 0.5 or 1.0 | 1—60 | 5–300 |
| Intravenous Regional | 0.5 | 10–60 | 50–300 |
| Peripheral Nerve Blocks, e.g. | | | |
| Brachial | 1.5 | 15–20 | 225–300 |
| Dental | 2.0 | 1–5 | 20–100 |
| Intercostal | 1.0 | 3 | 30 |
| Paravertebral | 1.0 | 3–5 | 30–50 |
| Pudendal (each side) | 1.0 | 10 | 100 |
| Paracervical | | | |
### Obstetrical Analgesia

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<tr>
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### Sympathetic Nerve Blocks, e.g.

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<th></th>
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<tbody>
<tr>
<td>Cervical (stellate ganglion)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Lumbar</td>
<td>1.0</td>
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<td>50–100</td>
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### Central Neural Blocks

#### Epidural*

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</thead>
<tbody>
<tr>
<td>Thoracic</td>
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<tr>
<td>Lumbar</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Analgesia</td>
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</tr>
<tr>
<td>Anesthesia</td>
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</tr>
<tr>
<td></td>
<td>2.0</td>
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<td>200–300</td>
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#### Caudal

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</tr>
</thead>
<tbody>
<tr>
<td>Obstetrical Analgesia</td>
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<td></td>
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<tr>
<td>Surgical Anesthesia</td>
<td>1.5</td>
<td>15–20</td>
<td>225–300</td>
</tr>
</tbody>
</table>

*Dose determined by number of dermatomes to be anesthetized (2 to 3 mL/dermatome).

THE ABOVE SUGGESTED CONCENTRATIONS AND VOLUMES SERVE ONLY AS A GUIDE. OTHER VOLUMES AND CONCENTRATIONS MAY BE USED PROVIDED THE TOTAL MAXIMUM RECOMMENDED DOSE IS NOT EXCEEDED.

**Sterilization, Storage and Technical Procedures:** Disinfecting agents containing heavy metals, which cause release of respective ions (mercury, zinc, copper, etc.) should not be used for skin or mucous membrane disinfection as they have been related to incidence of swelling and edema. When chemical disinfection of multi-dose vials is desired, either isopropyl alcohol (91%) or 70% ethyl alcohol is recommended. Many commercially available brands of rubbing alcohol, as well as solutions of ethyl alcohol not of USP grade, contain denaturants which are injurious to rubber and, therefore, are not to be used. It is recommended that chemical disinfection be accomplished by wiping the vial stopper thoroughly with cotton or gauze that has been moistened with the recommended alcohol just prior to use.

**HOW SUPPLIED**

Lidocaine Hydrochloride Injection, USP is supplied as follows:

<table>
<thead>
<tr>
<th>NDC</th>
<th>Container</th>
<th>Concentration</th>
<th>Size</th>
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<tbody>
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<td>0409-4278-01</td>
<td>Glass Teartop Vial</td>
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<td>50 mL</td>
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<tr>
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<td>Glass Ampul</td>
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<tr>
<td>0409-4713-02</td>
<td>Glass Ampul</td>
<td>1% (10 mg/mL)</td>
<td>5 mL</td>
<td>50</td>
</tr>
<tr>
<td>0409-4713-05</td>
<td>Glass Ampul</td>
<td>1% (10 mg/mL)</td>
<td>5 mL (bulk – 400 units)</td>
<td>50</td>
</tr>
<tr>
<td>0409-4713-20</td>
<td>Glass Ampul</td>
<td>1% (10 mg/mL)</td>
<td>20 mL</td>
<td>200</td>
</tr>
<tr>
<td>0409-4713-32</td>
<td>Glass Ampul</td>
<td>1% (10 mg/mL)</td>
<td>2 mL</td>
<td>20</td>
</tr>
<tr>
<td>0409-4713-62</td>
<td>Glass Ampul</td>
<td>1% (10 mg/mL)</td>
<td>2 mL (bulk – 800 units)</td>
<td>20</td>
</tr>
<tr>
<td>0409-4713-65</td>
<td>Glass Ampul</td>
<td>1% (10 mg/mL)</td>
<td>5 mL (bulk – 800 units)</td>
<td>50</td>
</tr>
<tr>
<td>0409-4279-02</td>
<td>Glass Teartop Vial</td>
<td>1% (10 mg/mL)</td>
<td>30 mL</td>
<td>300</td>
</tr>
<tr>
<td>0409-4270-01</td>
<td>Sterile Glass Teartop Vial</td>
<td>1% (10 mg/mL)</td>
<td>30 mL</td>
<td>300</td>
</tr>
<tr>
<td>0409-4776-01</td>
<td>Glass Ampul</td>
<td>1.5% (15 mg/mL)</td>
<td>20 mL</td>
<td>300</td>
</tr>
<tr>
<td>0409-4056-01</td>
<td>Sterile Glass Ampul</td>
<td>1.5% (15 mg/mL)</td>
<td>20 mL</td>
<td>300</td>
</tr>
<tr>
<td></td>
<td>Active Ingredient</td>
<td>Purpose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>-------------------</td>
<td>-------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Povidone Iodine 10% v/v</td>
<td>Antiseptic</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Purpose:**

- First aid antiseptic to help prevent skin infection in minor cuts, scrapes and burns.
- For preparation of the skin prior to surgery.
- Helps reduce bacteria that can potentially cause skin infections.

**Warnings:**

**FOR EXTERNAL USE ONLY**

**Do not use:**

- As a first aid antiseptic for more than 1 week.
- In the eyes.
- Over large areas of the body.

**Ask a doctor before use if you have:**

- Deep puncture wounds
- Animal bites
- Serious burns
Stop Use:

- If irritation and redness develop
- If condition persists for more than 72 hours, consult a physician.

Keep Out Of Reach Of Children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center.

Directions Povidone iodine:

Tear at notch, remove applicator, use only once.

As a first aid antiseptic
- clean affected area
- apply 1 to 3 times daily
- may be covered with a sterile bandage, if bandaged let dry.

For preoperative patient skin preparation

- clean area
- apply to operative site prior to surgery using the applicator

Other information:

Store at room temperature.
Avoid excessive heat
For use as an
- first aid antiseptic
- pre-operative skin preparation

Inactive Ingredients

Inactive ingredients: nonoxynol-9, water

Active ingredient

Isopropyl Alcohol 70% v/v

Purpose

Antiseptic

Uses

For first aid to decrease germs in
- minor cuts
• scrapes
• burns

For preparation of the skin prior to injection

**Warnings**

**For external use only**

**Flammable - keep away from fire or flame**

**Do not use**

with electrocautery procedures

**When using this product do not**

- get into eyes
- apply over large areas of the body
- in case of deep or puncture wounds, animal bites or serious burns consult a doctor

**Stop use and ask a doctor if**

- condition persists or gets worse or lasts for more than 72 hours
- do not use longer than 1 week unless directed by a doctor

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- apply to skin as needed
- discard after single use

**Other information**

Protect from freezing and avoid excessive heat

**Inactive ingredient**

Water

**Principal Display Panel - 5 mL Vial Label**

NDC 0517-0720-01

**BETAMETHASONE**

**SODIUM PHOSPHATE and**

**BETAMETHASONE ACETATE**

Injectable Suspension, USP

30 mg*/5 mL (6 mg*/mL)

5 mL MULTIPLE DOSE VIAL

Sterile

Rx Only
PRINCIPAL DISPLAY PANEL - AMPULE LABEL

RL-4823
5 mL NDC 0409-4713-12

Preservative-Free
Rx only
1%

Lidocaine HCl
Injection, USP
50 mg/5 mL
(10 mg/mL)
Hospira, Inc.
Lake Forest, IL 60045 USA
Hospira
Principal Display Panel – Povidone-Iodine Pouch Label

3 Swabs

Povidone-Iodine

Swabsticks
dynarex®

Antiseptic/Germicide

For External Use Only

Made In Israel

Reorder No. 1202

Principal Display Panel – CURAD®

STERILE

ALCOHOL

PREP PAD

MADE With 70% isopropyl alcohol
2-PLY
PAD
OFFERS EXCELLENT CLEANSING ACTION
For external use only.
Not labeled for individual sale.
Sterile in unopened,
undamaged package.
1 MEDIUM
PREP
PAD

NDC: 76420-765-01 RX Only

Betalido™

Kit Contains
1 Betamethasone Sodium Phosphate and Betamethasone Acetate 6mg/mL (5mL)
2 Lidocaine HCl Injection, USP 1% Ampule (5mL)
1 Povidone-Iodine Swabsticks (3 Swabs)
3 Isopropyl Alcohol 70% Prep Pads
1 Pair Nitrile Powder Free Sterile Gloves (M)
1 Drape
1 Adhesive Bandage
5 Non Sterile 4x4 Gauze

Needles and Syringes Not Included
1 Dose
Single Use Only
Distributed by:
Enovachem Pharmaceuticals
Betalido™

Kit Contains
1 Betamethasone Sodium Phosphate and Betamethasone Acetate 6mg/mL (5mL)
2 Lidocaine HCl Injection, USP 1% Ampule (5mL)
1 Povidone-Iodine Swabsticks (3 Swabs)
3 Isopropyl Alcohol 70% Prep Pads
1 Pair Nitrile Powder Free Sterile Gloves (M)
1 Drape
1 Adhesive Bandage
5 Non Sterile 4x4 Gauze

Needles and Syringes Not Included

1 Dose
Single Use Only

BETALIDO KIT
betamethasone sodium phosphate, betamethasone acetate, lidocaine, povidine iodine kit

Product Information
Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:76420-765

Packaging
# | Item Code | Package Description | Marketing Start Date | Marketing End Date
--- | --- | --- | --- | ---
1 | NDC:76420-765-01 | 1 in 1 CARTON; Type 1: Convenience Kit of Co-Package | 06/13/2014 | 

Quantity of Parts
Part # | Package Quantity | Total Product Quantity
--- | --- | ---
Part 1 | 1 VIAL, MULTI-DOSE | 5 mL
Part 2 | 2 AMPULE | 10 mL
Part 3 | 1 PACKET | 0.9 mL
Part 4 | 3 POUCH | 15 mL
## BETAMETHASONE SODIUM PHOSPHATE AND BETAMETHASONE ACETATE

**betamethasone sodium phosphate and betamethasone acetate injection, suspension**

**Product Information**

<table>
<thead>
<tr>
<th>Item Code (Source)</th>
<th>NDC:0517-0720</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>INTRA-ARTICULAR, INTRAMUSCULAR, INTRALESIONAL</td>
</tr>
</tbody>
</table>

**Active Ingredient/Active Moiety**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betamethasone Sodium Phosphate (UNII: 7BK02SCL3W) (Betamethasone - UNII:9842X06Q6M)</td>
<td>Betamethasone</td>
<td>3 mg in 1 mL</td>
</tr>
<tr>
<td>Betamethasone Acetate (UNII: TI05AO53L7) (Betamethasone - UNII:9842X06Q6M)</td>
<td>Betamethasone Acetate</td>
<td>3 mg in 1 mL</td>
</tr>
</tbody>
</table>

**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Phosphate, Dibasic, Anhydrous (UNII: 22ADO53M6F)</td>
<td>7.1 mg in 1 mL</td>
</tr>
<tr>
<td>Sodium Phosphate, Monobasic, Monohydrate (UNII: 593YOG76RN)</td>
<td>3.4 mg in 1 mL</td>
</tr>
<tr>
<td>Edetate Disodium (UNII: 7FLD91C86K)</td>
<td>0.1 mg in 1 mL</td>
</tr>
<tr>
<td>Benzalkonium Chloride (UNII: F5UM2KM3W7)</td>
<td>0.2 mg in 1 mL</td>
</tr>
<tr>
<td>Water (UNII: 059QF0KO0R)</td>
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</table>

**Packaging**

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1 in 1 CARTON</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>5</td>
<td>5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
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</tbody>
</table>

**Marketing Information**

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>ANDA</td>
<td>ANDA090747</td>
<td>04/28/2010</td>
<td></td>
</tr>
</tbody>
</table>

### Part 2 of 4

**LIDOCAINE HYDROCHLORIDE**

**lidocaine hydrochloride injection, solution**

**Product Information**
### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LIDOCAINE HYDROCHLORIDE</strong> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)</td>
<td>LIDOCAINE HYDROCHLORIDE ANHYDROUS</td>
<td>10 mg in 1 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47IQ8X)</td>
<td>7 mg in 1 mL</td>
</tr>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
<tr>
<td>SODIUM HYDROXIDE (UNII: 55X04QC32I)</td>
<td></td>
</tr>
<tr>
<td>HYDROCHLORIC ACID (UNII: QTT17582CB)</td>
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</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5 mL in 1 AMPULE; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
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<th>Marketing End Date</th>
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<tbody>
<tr>
<td>ANDA</td>
<td>ANDA080408</td>
<td>09/28/1972</td>
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### Product Information

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<th>Item Code (Source)</th>
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<tr>
<td>Route of Administration</td>
<td>TOPICAL</td>
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### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Povidone-Iodine</strong> (UNII: 85H0HZU99M) (Iodine - UNII:9679TC07X4)</td>
<td>Iodine</td>
<td>10 mg in 1 mL</td>
</tr>
</tbody>
</table>
Nonoxynol-9 (UNII: 48Q180SH9T)  
Water (UNII: 059QF0KO0R)

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>1 in 1 BOX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>0.9 mL in 1 PACKET; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTC monograph final</td>
<td>part333C</td>
<td>05/10/2010</td>
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</table>

### Part 4 of 4

**ISOPROPYL ALCOHOL**  
isopropyl alcohol swab

### Product Information

<table>
<thead>
<tr>
<th>Route of Administration</th>
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</tr>
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<tbody>
<tr>
<td>TOPICAL</td>
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### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)</td>
<td>Isopropyl Alcohol</td>
<td>70 mL in 100 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
</tbody>
</table>
### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
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</thead>
<tbody>
<tr>
<td>Unapproved drug other</td>
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<td>06/13/2014</td>
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### Labeler - Asclemed USA, Inc. (059888437)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tbody>
<tr>
<td>Asclemed USA, Inc.</td>
<td></td>
<td>059888437</td>
<td>REPACK(76420-765)</td>
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Revised: 5/2016

Asclemed USA, Inc.