BETAMETHASONE DIPROPIONATE- betamethasone dipropionate cream, augmented
Asclemed USA, Inc

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use BETAMETHASONE DIPROPIONATE CREAM (augmented) safely and effectively. See full prescribing information for BETAMETHASONE DIPROPIONATE CREAM (augmented).

BETAMETHASONE DIPROPIONATE cream, for topical use
Initial U.S. Approval: 1983

RECENT MAJOR CHANGES

Warnings and Precautions	
Ophthalmic Adverse Reactions (5.2)	05/2019

INDICATIONS AND USAGE

Betamethasone dipropionate cream (augmented), 0.05% is a corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 13 years of age and older. (1)

DOSAGE AND ADMINISTRATION

- Apply a thin film to the affected skin areas once or twice daily. (2)
- Discontinue therapy when control is achieved. (2)
- Use no more than 50 g per week. (2)
- Do not use with occlusive dressings unless directed by a physician. (2)
- Avoid use on the face, groin, or axillae, or if skin atrophy is present at the treatment site. (2)
- Not for oral, ophthalmic, or intravaginal use. (2)

DOSAGE FORMS AND STRENGTHS

- Cream, 0.05% (3)

CONTRAINDICATIONS

- Hypersensitivity to any component of this medicine. (4)

WARNINGS AND PRECAUTIONS

- Effects on endocrine system: Betamethasone dipropionate cream (augmented) can cause reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency during and after withdrawal of treatment. Risk factor(s) include the use of high-potency topical corticosteroids, use over a large surface area or to areas under occlusion, prolonged use, altered skin barrier, liver failure, and use in pediatric patients. Modify use should HPA axis suppression develop. (5.1, 8.4)
- Ophthalmic Adverse Reactions: Betamethasone dipropionate cream (augmented) may increase the risk of cataracts and glaucoma. If visual symptoms occur, consider referral to an ophthalmologist for evaluation. (5.2)

ADVERSE REACTIONS

- The most common adverse reaction reported in 0.4% of adult patients is stinging. (6.1)
- The most common adverse reactions reported in 10% of pediatric patients are signs of skin atrophy, telangiectasia, bruising, shininess. (6.1, 8.4)

To report SUSPECTED ADVERSE REACTIONS, contact Taro Pharmaceuticals U.S.A., Inc. at 1-866-923-4914 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.
Revised: 10/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Betamethasone dipropionate cream (augmented) is a corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 13 years of age or older.

2 DOSAGE AND ADMINISTRATION

Apply a thin film of betamethasone dipropionate cream (augmented) to the affected skin areas once or twice daily.

Therapy should be discontinued when control is achieved. Betamethasone dipropionate cream (augmented) is a high-potency corticosteroid. Treatment with betamethasone

dipropionate cream (augmented) should not exceed 50 g per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis *[see Warnings and Precautions (5.1)].*

Betamethasone dipropionate cream (augmented) should not be used with occlusive dressings unless directed by a physician.

Avoid contact with eyes. Wash hands after each application.

Avoid use on the face, groin, or axillae, or if skin atrophy is present at the treatment site.

Betamethasone dipropionate cream (augmented) is for topical use only. It is not for oral, ophthalmic, or intravaginal use.

3 DOSAGE FORMS AND STRENGTHS

Cream, 0.05%. Each gram of betamethasone dipropionate cream USP (augmented), 0.05% contains 0.64 mg betamethasone dipropionate (equivalent to 0.5 mg betamethasone) in a white cream base.

4 CONTRAINDICATIONS

Betamethasone dipropionate cream (augmented), is contraindicated in patients who are hypersensitive to betamethasone dipropionate, to other corticosteroids, or to any ingredient in this preparation.

5 WARNINGS AND PRECAUTIONS

5.1 Effects on Endocrine System

Betamethasone dipropionate cream (augmented) can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or after withdrawal of treatment. Factors that predispose to HPA axis suppression include the use of high-potency steroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure, and young age. Evaluation for HPA axis suppression may be done by using the adrenocorticotropic hormone (ACTH) stimulation test.

Betamethasone dipropionate cream (augmented), 0.05% was applied once daily at 7 grams per day for 1 week to diseased skin, in adult subjects with psoriasis or atopic dermatitis, to study its effects on the HPA axis. The results suggested that the drug lowered adrenal corticosteroid secretion, although plasma cortisol levels did not go below the lower limit of the normal range.

In an open-label pediatric trial of 60 evaluable subjects (3 months to 12 years of age), 19 subjects showed evidence of HPA axis suppression. Four (4) subjects were tested 2 weeks after discontinuation of betamethasone dipropionate cream (augmented), 0.05%, and 3 of the 4 (75%) had complete recovery of HPA axis function. The proportion of subjects with adrenal suppression in this trial was progressively greater, the younger the age group.

If HPA axis suppression is documented, gradually withdraw the drug, reduce the

frequency of application, or substitute with a less potent corticosteroid. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Cushing's syndrome and hyperglycemia may also occur with topical corticosteroids. These events are rare and generally occur after prolonged exposure to excessively large doses, especially of high-potency topical corticosteroids.

Pediatric patients may be more susceptible to systemic toxicity due to their larger skin surface to body mass ratios *[see Use in Specific Populations (8.4)].*

5.2 Ophthalmic Adverse Reactions

Use of topical corticosteroids, including betamethasone dipropionate cream (augmented), may increase the risk of posterior subcapsular cataracts and glaucoma. Cataracts and glaucoma have been reported postmarketing with the use of topical corticosteroid products, including betamethasone dipropionate cream (augmented) *[see Adverse Reactions (6.2)]* .

Avoid contact of betamethasone dipropionate cream (augmented) with eyes. Advise patients to report any visual symptoms and consider referral to an ophthalmologist for evaluation.

5.3 Allergic Contact Dermatitis

Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. Such an observation should be corroborated with appropriate diagnostic patch testing. If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In controlled clinical trials, involving 242 adult subjects, the adverse reaction associated with the use of betamethasone dipropionate cream (augmented) reported at a frequency of 0.4% was stinging. It occurred in 1 subject.

In a controlled clinical trial involving 67 pediatric subjects from 3 months to 12 years of age, the adverse reactions associated with the use of betamethasone dipropionate cream (augmented) occurred in 7 of 67 (10%) subjects. Reported reactions included signs of skin atrophy (telangiectasia, bruising, shininess).

6.2 Postmarketing Experience

Because adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Postmarketing reports for local adverse reactions to topical corticosteroids may also

include: burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, hypertrichosis, skin atrophy, striae, and miliaria.

Hypersensitivity reactions, consisting of predominantly skin signs and symptoms, e.g., contact dermatitis, pruritus, bullous dermatitis, and erythematous rash have been reported.

Ophthalmic adverse reactions of cataracts, glaucoma, increased intraocular pressure, and central serous chorioretinopathy have been reported with the use of topical corticosteroids, including topical betamethasone products.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on betamethasone dipropionate cream (augmented) use in pregnant women to identify a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Observational studies suggest an increased risk of low birthweight infants with the use of greater than 300 grams of potent or very potent topical corticosteroid during a pregnancy. Advise pregnant women that betamethasone dipropionate cream (augmented) may increase the risk of having a low birthweight infant and to use betamethasone dipropionate cream (augmented) on the smallest area of skin and for the shortest duration possible.

In animal reproduction studies, increased malformations, including umbilical hernias, cephalocele, and cleft palate, were observed after intramuscular administration of betamethasone dipropionate to pregnant rabbits. The available data do not allow the calculation of relevant comparisons between the systemic exposure of betamethasone dipropionate in animal studies to the systemic exposure that would be expected in humans after topical use of betamethasone dipropionate cream (augmented) *(see Data)* .

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Animal Data

Betamethasone dipropionate has been shown to cause malformations in rabbits when given by the intramuscular route at doses of 0.05 mg/kg. The abnormalities observed included umbilical hernias, cephalocele, and cleft palate.

8.2 Lactation

Risk Summary

There are no data regarding the excretion of betamethasone dipropionate in breast milk, the effects on the breastfed infant, or the effects on milk production after topical application of betamethasone dipropionate cream (augmented) to women who are breastfeeding.

It is possible that topical administration of large amounts of betamethasone dipropionate could result in sufficient systemic absorption to produce detectable quantities in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for betamethasone dipropionate cream (augmented) and any potential adverse effects on the breastfed infant from betamethasone dipropionate cream (augmented) or from the underlying maternal condition.

Clinical Considerations

To minimize potential exposure to the breastfed infant via breast milk, use betamethasone dipropionate cream (augmented) on the smallest area of skin and for the shortest duration possible while breastfeeding. Advise breastfeeding women not to apply betamethasone dipropionate cream (augmented) directly to the nipple and areola to avoid direct infant exposure *[see Use in Specific Populations (8.4)]* .

8.4 Pediatric Use

Use of betamethasone dipropionate cream (augmented) in pediatric patients younger than 13 years of age is not recommended due to the potential for HPA axis suppression *[see Warnings and Precautions (5.1)]* .

In an open-label HPA axis safety trial in subjects 3 months to 12 years of age with atopic dermatitis, betamethasone dipropionate cream (augmented), 0.05% was applied twice daily for 2 to 3 weeks over a mean body surface area of 58% (range 35% to 95%). In 19 of 60 (32%) evaluable subjects, adrenal suppression was indicated by either a ≤5 mcg/dL pre-stimulation cortisol, or a cosyntropin post-stimulation cortisol ≤18 mcg/dL and/or an increase of <7 mcg/dL from the baseline cortisol. Out of the 19 subjects with HPA axis suppression, 4 subjects were tested 2 weeks after discontinuation of betamethasone dipropionate cream (augmented), and 3 of the 4 (75%) had complete recovery of HPA axis function. The proportion of subjects with adrenal suppression in this trial was progressively greater, the younger the age group.

Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of systemic toxicity when treated with topical drugs. They are, therefore, also at greater risk of HPA axis suppression and adrenal insufficiency upon the use of topical corticosteroids.

Rare systemic effects such as Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in pediatric patients, especially those with prolonged exposure to large doses of high potency topical corticosteroids.

Local adverse reactions including skin atrophy have also been reported with use of topical corticosteroids in pediatric patients.

Avoid use of betamethasone dipropionate cream (augmented) in the treatment of diaper dermatitis.

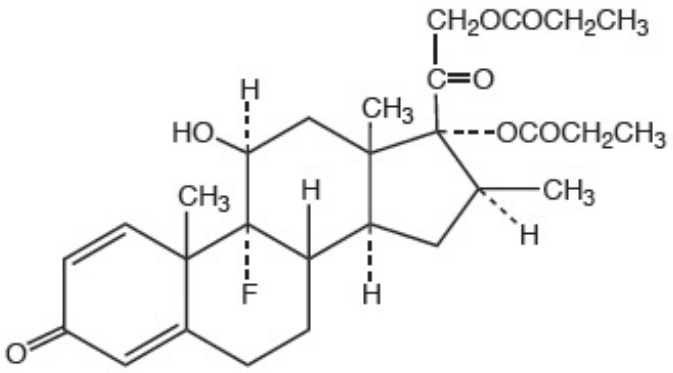
8.5 Geriatric Use

Clinical trials of betamethasone dipropionate cream (augmented) included 104 subjects who were 65 years of age and over and 8 subjects who were 75 years of age and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients. However, greater sensitivity of some older individuals cannot be ruled out.

11 DESCRIPTION

Betamethasone dipropionate cream USP (augmented), 0.05% contains betamethasone dipropionate USP, a synthetic adrenocorticosteroid, for topical use in a cream base. Betamethasone, an analog of prednisolone, has a high degree of corticosteroid activity and a slight degree of mineralocorticoid activity. Betamethasone dipropionate is the 17,21-dipropionate ester of betamethasone.

Chemically, betamethasone dipropionate is 9-fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate, with the empirical formula $C_{28}H_{37}FO_7$, a molecular weight of 504.6, and the following structural formula:



Betamethasone dipropionate is a white to creamy white, odorless crystalline powder, insoluble in water.

Each gram of betamethasone dipropionate cream USP (augmented), 0.05% contains: 0.64 mg betamethasone dipropionate USP (equivalent to 0.5 mg betamethasone) in a white cream base of carbomer homopolymer type C, ceteareth-30, chlorocresol, cyclomethicone, glyceryl oleate, propylene glycol, purified water, sodium hydroxide, sorbitol solution, white petrolatum and white wax.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Corticosteroids play a role in cellular signaling, immune function, inflammation, and protein regulation; however, the precise mechanism of action of betamethasone dipropionate cream (augmented) in corticosteroid responsive dermatoses is unknown.

12.2 Pharmacodynamics

Vasoconstrictor Assay

Trials performed with betamethasone dipropionate cream (augmented), 0.05% indicate that it is in the high range of potency as demonstrated in vasoconstrictor trials in healthy subjects when compared with other topical corticosteroids. However, similar blanching scores do not necessarily imply therapeutic equivalence.

12.3 Pharmacokinetics

No pharmacokinetics trials have been conducted with betamethasone dipropionate cream (augmented), 0.05%. The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed through normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids *[see Dosage and Administration (2)]* .

Once absorbed through the skin, topical corticosteroids enter pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees, are metabolized primarily in the liver, and excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of betamethasone dipropionate.

Betamethasone was negative in the bacterial mutagenicity assay *(Salmonella typhimurium*and *Escherichia coli),*and in the mammalian cell mutagenicity assay (CHO/HGPRT). It was positive in the *in vitro*human lymphocyte chromosome aberration assay, and equivocal in the *in vivo*mouse bone marrow micronucleus assay.

Studies in rabbits, mice, and rats using intramuscular doses up to 1, 33, and 2 mg/kg, respectively, resulted in dose-related increases in fetal resorptions in rabbits and mice.

14 CLINICAL STUDIES

The safety and efficacy of betamethasone dipropionate cream (augmented) for the treatment of corticosteroid-responsive dermatoses have been established in two randomized and active controlled trials in subjects with chronic plaque psoriasis. A total of 81 subjects who received betamethasone dipropionate cream (augmented) were included in these trials. These trials evaluated betamethasone dipropionate cream (augmented) applied once or twice daily for 14 and 21 days, respectively, on bilateral paired psoriatic lesions. Betamethasone dipropionate cream (augmented) was shown to be effective in relieving the signs and symptoms of chronic plaque psoriasis.

16 HOW SUPPLIED/STORAGE AND HANDLING

Betamethasone dipropionate cream USP (augmented), 0.05% is a white cream supplied in 15 g (NDC 76420-858-15 relabeled from NDC 51672-1310-1), 30 g (NDC 76420-858-30 relabeled from NDC 51672-1310-2) and 50 g (NDC 76420-858-50 relabeled from NDC 51672-1310-3) tubes.

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

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Inform patients of the following:

- Discontinue therapy when control is achieved, unless directed otherwise by the physician.
- Use no more than 50 grams per week.
- Avoid contact with the eyes.
- Advise patients to report any visual symptoms to their healthcare providers.
- Avoid use of betamethasone dipropionate cream (augmented) on the face, underarms, or groin areas unless directed by the physician.
- Do not occlude the treatment area with bandage or other covering, unless directed by the physician.
- Note that local reactions and skin atrophy are more likely to occur with occlusive use, prolonged use or use of higher potency corticosteroids.
- Advise a woman to use betamethasone dipropionate cream (augmented) on the smallest area of skin and for the shortest duration possible while pregnant or breastfeeding. Advise breastfeeding women not to apply betamethasone dipropionate cream (augmented) directly to the nipple and areola to avoid direct infant exposure.

Relabeled by:
Enovachem PHARMACEUTICALS
Torrance, CA 90501

Patient Information
Betamethasone Dipropionate
(bay'' ta meth' a sone dye proe' pee oh nate)
Cream (Augmented)

Important information: Betamethasone Dipropionate Cream (Augmented) is for use on skin only. Do not use betamethasone dipropionate cream (augmented) in your eyes, mouth, or vagina.

What is Betamethasone Dipropionate Cream (Augmented)?

Betamethasone dipropionate cream (augmented) is a prescription corticosteroid medicine used on the skin (topical) for the relief of redness, swelling, heat, pain (inflammation) and itching, caused by certain skin problems in people 13 years of age and older.Betamethasone dipropionate cream (augmented) should not be used in children under 13 years of age.

Do not use Betamethasone Dipropionate Cream (Augmented) if youare allergic to

betamethasone dipropionate or any of the ingredients in betamethasone dipropionate cream (augmented). See the end of this leaflet for a complete list of ingredients in betamethasone dipropionate cream (augmented).

Before using Betamethasone Dipropionate Cream (Augmented), tell your healthcare provider about all of your medical conditions, including if you:have had irritation or other skin reaction to a steroid medicine in the past.have thinning of the skin (atrophy) at the treatment site.have diabetes.have adrenal gland problems.have liver problems.have cataracts or glaucoma.are pregnant or plan to become pregnant. It is not known if betamethasone dipropionate cream (augmented) will harm your unborn baby. If you use betamethasone dipropionate cream (augmented) during pregnancy, use betamethasone dipropionate cream (augmented) on the smallest area of the skin and for the shortest time needed.are breastfeeding or plan to breastfeed. It is not known if betamethasone dipropionate cream (augmented) passes into your breast milk. Breastfeeding women should use betamethasone dipropionate cream (augmented) on the smallest area of the skin and for the shortest time needed. Do not apply betamethasone dipropionate cream (augmented) directly to the nipple and areola to avoid contact with your baby.

Tell your healthcare provider about all the medicines you take,including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especiallytell your healthcare provider if you take other corticosteroid medicines by mouth or injection or use other products on your skin or scalp that contain corticosteroids.

Do not use other products containing a steroid medicine with betamethasone dipropionate cream (augmented) without talking to your healthcare provider first.

How should I use Betamethasone Dipropionate Cream (Augmented)?Use betamethasone dipropionate cream (augmented) exactly as your healthcare provider tells you to use it.Apply a thin layer (film) of betamethasone dipropionate cream (augmented) to the affected skin area 1 or 2 times each day. Do not use more than 50 grams of betamethasone dipropionate cream (augmented) in 1 week.Do not bandage, cover, or wrap the treated skin area unless your healthcare provider tells you to.Betamethasone dipropionate cream (augmented) should not be used to treat diaper rash or redness.Avoid using betamethasone dipropionate cream (augmented) on the face, groin, or underarms (armpits) or if thinning of the skin (atrophy) is present at the treatment site.Wash your hands after applying betamethasone dipropionate cream (augmented) unless you are using the medicine to treat your hands.

What are the possible side effects of Betamethasone Dipropionate Cream (Augmented)?

Betamethasone Dipropionate Cream (Augmented) may cause serious side effects, including:Betamethasone dipropionate cream (augmented) can pass through your skin.Too much betamethasone dipropionate cream (augmented) passing through your skin can cause your adrenal glands to stop working properly. Your healthcare provider may do blood tests to check for adrenal gland problems.Cushing's syndrome, a condition that happens when your body is exposed to too much of the hormone cortisol.High blood sugar(hyperglycemia).Effects on growth and weight in children.Vision problems.Topical corticosteroids including betamethasone dipropionate cream (augmented) may increase your chance of developing cataract(s) and glaucoma. Tell your healthcare provider if you develop blurred vision or other vision problems during treatment with betamethasone dipropionate cream (augmented).Skin problems.Skin problems including, allergic reactions (contact dermatitis) may happen during treatment with betamethasone dipropionate cream (augmented). Stop using betamethasone dipropionate cream (augmented) and tell your healthcare provider if you

develop any skin reactions or have problems with healing during treatment with betamethasone dipropionate cream (augmented).

Your healthcare provider may do certain blood tests to check for side effects.

The most common side effect of betamethasone dipropionate cream (augmented) in adults includesstinging.

The most common side effects of betamethasone dipropionate cream (augmented) in children includethinning of the skin (atrophy), tiny red lines or blood vessels showing under the skin (telangiectasia), bruising and shininess.

These are not all of the possible side effects of betamethasone dipropionate cream (augmented).

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Betamethasone Dipropionate Cream (Augmented)?Store betamethasone dipropionate cream (augmented) at room temperature between 68°F to 77°F (20°C to 25°C). Protect from freezing.Keep betamethasone dipropionate cream (augmented) and all medicines out of the reach of children.

General information about the safe and effective use of Betamethasone Dipropionate Cream (Augmented).

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use betamethasone dipropionate cream (augmented) for a condition for which it was not prescribed. Do not give betamethasone dipropionate cream (augmented) to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about betamethasone dipropionate cream (augmented) that is written for health professionals.

What are the ingredients in Betamethasone Dipropionate Cream (Augmented)?

Active ingredient:betamethasone dipropionate

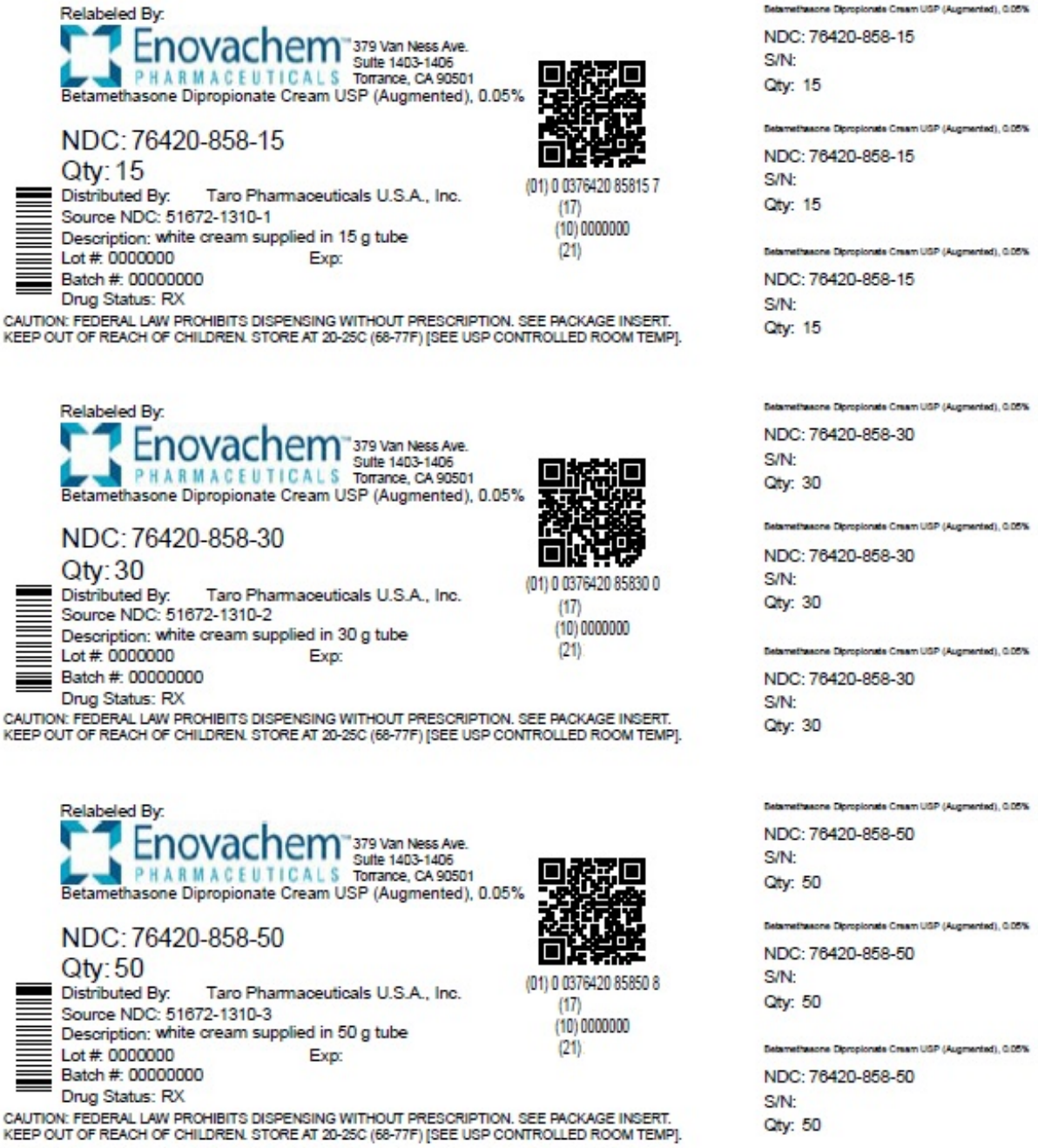
Inactive ingredients:carbomer homopolymer type C, ceteareth-30, chlorocresol, cyclomethicone, glyceryl oleate, propylene glycol, purified water, sodium hydroxide, sorbitol solution, white petrolatum and white wax.

Relabeled by:

Enovachem PHARMACEUTICALS
Torrance, CA 90501

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 12/2020

PRINCIPAL DISPLAY PANEL



BETAMETHASONE DIPROPIONATE

betamethasone dipropionate cream, augmented

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:76420-858(NDC:51672-1310)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

BETAMETHASONE DIPROPIONATE (UNII: 826Y60901U) (BETAMETHASONE - UNII:9842X06Q6M)	BETAMETHASONE	0.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CETEARETH-30 (UNII: 1R9DCZ5FOX)	
CHLOROCRESOL (UNII: 36W53O7109)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	
PETROLATUM (UNII: 4T6H12BN9U)	
WHITE WAX (UNII: 7G1J5DA97F)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76420-858-15	1 in 1 CARTON	10/11/2024	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:76420-858-30	1 in 1 CARTON	10/11/2024	
2		30 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:76420-858-50	1 in 1 CARTON	10/11/2024	
3		50 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076543	12/09/2003	

Labeler - Asclemed USA, Inc (059888437)

Establishment

Name	Address	ID/FEI	Business Operations
ASCLEMED USA INC. DBA ENOVACHEM		059888437	relabel(76420-858)

Revised: 10/2024

Asclemed USA, Inc