

# HYDROCORTISONE- hydrocortisone tablet

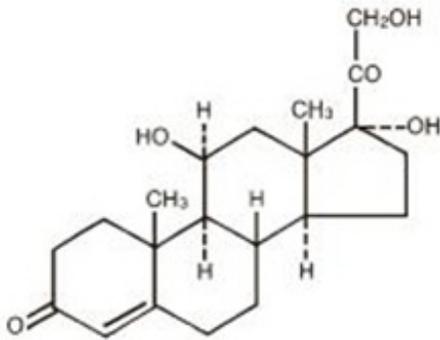
## Greenstone LLC

### Hydrocortisone tablets, USP

#### DESCRIPTION

Hydrocortisone tablets contain hydrocortisone which is a glucocorticoid. Glucocorticoids are adrenocortical steroids, both naturally occurring and synthetic, which are readily absorbed from the gastrointestinal tract. Hydrocortisone USP is white to practically white, odorless, crystalline powder with a melting point of about 215° C. It is very slightly soluble in water and in ether; sparingly soluble in acetone and in alcohol; slightly soluble in chloroform.

The chemical name for hydrocortisone is pregn-4-ene-3,20-dione,11,17,21-trihydroxy-, (11 $\beta$ )-. Its molecular weight is 362.46 and the structural formula is as outlined below.



Hydrocortisone tablets are available for oral administration in three strengths: each tablet contains either 5 mg, 10 mg, or 20 mg of hydrocortisone. Inactive ingredients: calcium stearate, corn starch, lactose, mineral oil, sorbic acid, sucrose.

#### ACTIONS

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 potent anti-inflammatory effects in disorders of many organ systems.

Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli.

#### INDICATIONS AND USAGE

Hydrocortisone tablets are indicated in the following conditions.

##### 1. Endocrine Disorders

Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the first choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy mineralocorticoid supplementation is of particular importance)

Congenital adrenal hyperplasia

Non suppurative thyroiditis

Hypercalcemia associated with cancer

## **2. Rheumatic Disorders**

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:

Psoriatic arthritis

Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)

Ankylosing spondylitis

Acute and subacute bursitis

Acute nonspecific tenosynovitis

Acute gouty arthritis

Post-traumatic osteoarthritis

Synovitis of osteoarthritis

Epicondylitis

## **3. Collagen Diseases**

During an exacerbation or as maintenance therapy in selected cases of:

Systemic lupus erythematosus

Systemic dermatomyositis (polymyositis)

Acute rheumatic carditis

## **4. Dermatologic Diseases**

Pemphigus

Bullous dermatitis herpetiformis

Severe erythema multiforme (Stevens-Johnson syndrome)

Exfoliative dermatitis

Mycosis fungoides

Severe psoriasis

Severe seborrheic dermatitis

## **5. Allergic States**

Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment:

Seasonal or perennial allergic rhinitis

Serum sickness

Bronchial asthma

Contact dermatitis

Atopic dermatitis

Drug hypersensitivity reactions

## **6. Ophthalmic Diseases**

Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as:

Allergic conjunctivitis

Keratitis

Allergic corneal marginal ulcers

Herpes zoster ophthalmicus

Iritis and iridocyclitis

Chorioretinitis

Anterior segment inflammation

Diffuse posterior uveitis and choroiditis

Optic neuritis

Sympathetic ophthalmia

## **7. Respiratory Diseases**

Symptomatic sarcoidosis

Loeffler's syndrome not manageable by other means

Berylliosis

Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy

Aspiration pneumonitis

## **8. Hematologic Disorders**

Idiopathic thrombocytopenic purpura in adults

Secondary thrombocytopenia in adults

Acquired (autoimmune) hemolytic anemia

Erythroblastopenia (RBC anemia)

Congenital (erythroid) hypoplastic anemia

## **9. Neoplastic Diseases**

For palliative management of:

Leukemias and lymphomas in adults

Acute leukemia of childhood

## **10. Edematous States**

To induce a diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus.

## **11. Gastrointestinal Diseases**

To tide the patient over a critical period of the disease in:

Ulcerative colitis

Regional enteritis

## **12. Miscellaneous**

Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy

Trichinosis with neurologic or myocardial involvement

## **CONTRAINDICATIONS**

Systemic fungal infections and known hypersensitivity to components

## **WARNINGS**

In patients on corticosteroid therapy subjected to unusual stress, increased dosage of rapidly acting corticosteroids before, during, and after the stressful situation is indicated.

Corticosteroids may mask some signs of infection, and new infections may appear during their use. Infections with any pathogen including viral, bacterial, fungal, protozoan or helminthic infections, in any location of the body, may be associated with the use of corticosteroids alone or in combination with other immunosuppressive agents that affect cellular immunity, humoral immunity, or neutrophil function.<sup>1</sup>

These infections may be mild, but can be severe and at times fatal. With increasing doses of corticosteroids, the rate of occurrence of infectious complications increases.<sup>2</sup> There may be decreased resistance and inability to localize infection when corticosteroids are used.

Prolonged 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 fungi or viruses.

## **Usage in pregnancy**

Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy, nursing mothers or women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards to the mother and embryo or fetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy, should be carefully observed for signs of hypoadrenalism.

Corticosteroids have been shown to impair fertility in male rats.

Average and large doses of hydrocortisone or cortisone 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.

Administration of live or live, attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of corticosteroids. Killed or inactivated vaccines may be administered to patients receiving immunosuppressive doses of corticosteroids; however, the response to such vaccines may be diminished. Indicated immunization procedures may be undertaken in patients receiving nonimmunosuppressive doses of corticosteroids.

The use of hydrocortisone tablets 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.

Persons who are on drugs which suppress the immune system are more susceptible to infections than healthy individuals. Chicken pox and measles, for example, can have a more serious or even fatal course in non-immune children or adults on corticosteroids. In such children or adults who have not had these diseases, particular care should be taken to avoid exposure. How the dose, route and duration of corticosteroid administration affects the risk of developing a disseminated infection is not known. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If exposed to chicken pox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated. (See the respective package inserts for complete VZIG and IG prescribing information.) If chicken pox develops, treatment with antiviral agents may be considered. 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.

## **PRECAUTIONS**

### **General Precautions**

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, hormone therapy should be reinstated.

There is an enhanced effect of corticosteroids on patients with hypothyroidism and in those with cirrhosis.

Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible corneal perforation.

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

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.

Steroids should be used with caution in nonspecific ulcerative colitis, if there is a probability of impending perforation, abscess or other pyogenic infection; diverticulitis; fresh intestinal anastomoses; active or latent peptic ulcer; renal insufficiency; hypertension; osteoporosis; and myasthenia gravis.

Growth and development of infants and children on prolonged corticosteroid therapy should be carefully observed.

Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid

therapy. Discontinuation of corticosteroids may result in clinical remission.

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.

Pheochromocytoma crisis, which can be fatal, has been reported after administration of systemic corticosteroids. In patients with suspected pheochromocytoma, consider the risk of pheochromocytoma crisis prior to administering corticosteroids.

In post marketing experience tumor lysis syndrome (TLS) has been reported in patients with malignancies, including hematological malignancies and solid tumors, following the use of systemic corticosteroids alone or in combination with other chemotherapeutic agents. Patients at high risk of TLS, such as patients with tumors that have a high proliferative rate, high tumor burden and high sensitivity to cytotoxic agents, should be monitored closely and appropriate precautions should be taken.

## **Drug Interactions**

The pharmacokinetic interactions listed below are potentially clinically important. Drugs that induce hepatic enzymes such as phenobarbital, phenytoin and rifampin may increase the clearance of corticosteroids and may require increases in corticosteroid dose to achieve the desired response. Drugs such as troleandomycin and ketoconazole may inhibit the metabolism of corticosteroids and thus decrease their clearance. Therefore, the dose of corticosteroid should be titrated to avoid steroid toxicity. Corticosteroids may increase the clearance of chronic high dose aspirin. This could lead to decreased salicylate serum levels or increase the risk of salicylate toxicity when corticosteroid is withdrawn. Aspirin should be used cautiously in conjunction with corticosteroids in patients suffering from hypoprothrombinemia. The effect of corticosteroids on oral anticoagulants is variable. There are reports of enhanced as well as diminished effects of anticoagulants when given concurrently with corticosteroids. Therefore, coagulation indices should be monitored to maintain the desired anticoagulant effect.

## **Information for the Patient**

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

## **ADVERSE REACTIONS**

### **Fluid and Electrolyte Disturbances**

- Sodium retention
- Fluid retention
- Congestive heart failure in susceptible patients
- Potassium loss
- Hypokalemic alkalosis
- Hypertension

## **Musculoskeletal**

Muscle weakness  
Steroid myopathy  
Loss of muscle mass  
Osteoporosis  
Tendon rupture, particularly of the Achilles tendon  
Vertebral compression fractures  
Aseptic necrosis of femoral and humeral heads  
Pathologic fracture of long bones

## **Gastrointestinal**

Peptic ulcer with possible perforation and hemorrhage  
Pancreatitis  
Abdominal distention  
Ulcerative esophagitis  
Increases in alanine transaminase (ALT, SGPT), aspartate transaminase (AST, SGOT) and alkaline phosphatase have been observed following corticosteroid treatment. These changes are usually small, not associated with any clinical syndrome and are reversible upon discontinuation.

## **Dermatologic**

Impaired wound healing  
Thin fragile skin  
Petechiae and ecchymoses  
Facial erythema  
Increased sweating  
May suppress reactions to skin tests

## **Neurological**

Increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment  
Convulsions  
Vertigo  
Headache  
Epidural lipomatosis

## **Endocrine**

Development of Cushingoid state  
Suppression of growth in children  
Secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness  
Menstrual irregularities  
Decreased carbohydrate tolerance  
Manifestations of latent diabetes mellitus  
Increased requirements for insulin or oral hypoglycemic agents in diabetics

## **Ophthalmic**



0074-1

**20 mg** (white, round, scored,  
imprinted CORTEF 20)

Bottles of 100

NDC 59762-  
0075-1

Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP].

## REFERENCES

- Fekety R. Infections associated with corticosteroids and immunosuppressive therapy. In: Gorbach SL, Bartlett JG, Blacklow NR, eds. *Infectious Diseases*. Philadelphia: WB Saunders Company 1992:1050-1.
- Stuck AE, Minder CE, Frey FJ. Risk of infectious complications in patients taking glucocorticoids. *Rev Infect Dis* 1989;11(6):954-63.

This product's label may have been updated. For current full prescribing information please visit [www.greenstonellc.com](http://www.greenstonellc.com)



GREENSTONE® BRAND

*Distributed by:*

---

**Greenstone LLC**

Morgantown, WV 26505 U.S.A.

LAB-0634-4.0

Revised December 2023

## PRINCIPAL DISPLAY PANEL - 5 mg Tablet Bottle Label

NDC 59762-0073-1

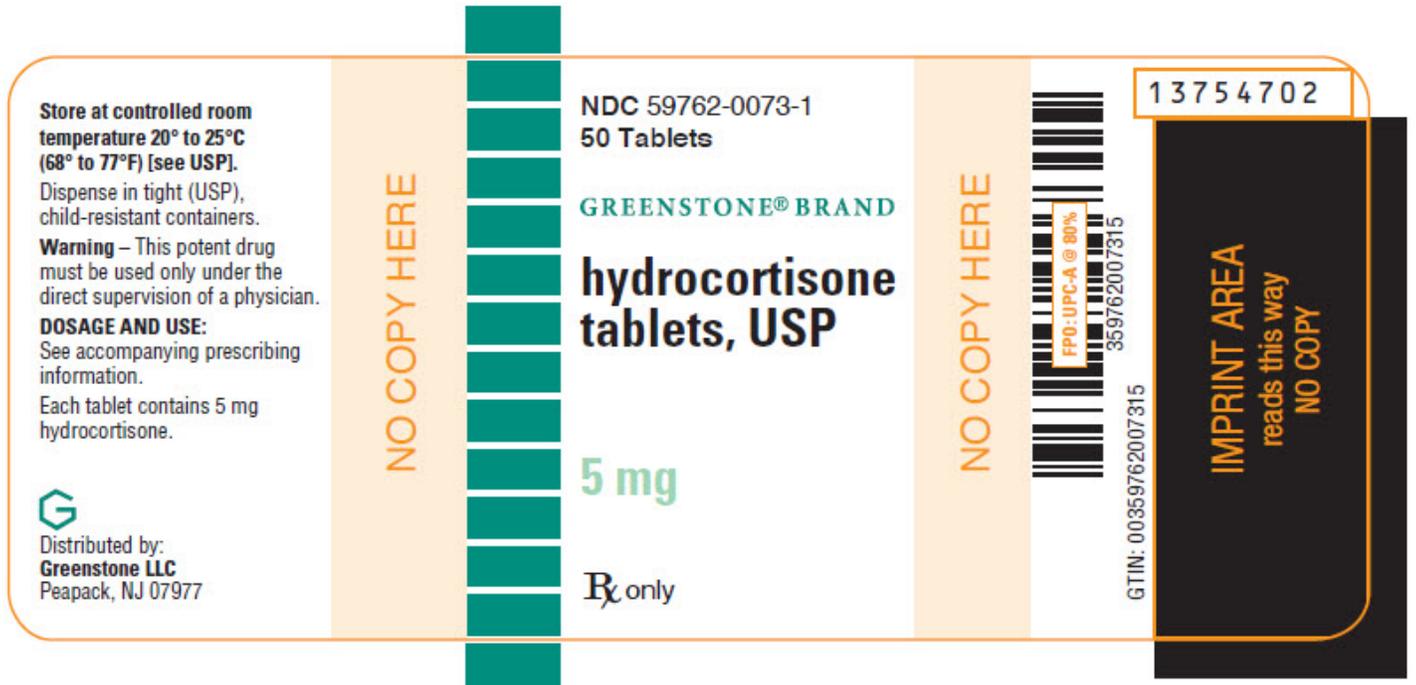
50 Tablets

GREENSTONE® BRAND

hydrocortisone  
tablets, USP

5 mg

Rx only



## PRINCIPAL DISPLAY PANEL - 10 mg Tablet Bottle Label

NDC 59762-0074-1

100 Tablets

GREENSTONE® BRAND

hydrocortisone  
tablets, USP

10 mg

Rx only

Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP].  
Dispense in tight (USP), child-resistant containers.  
**Warning** – This potent drug must be used only under the direct supervision of a physician.  
**DOSAGE AND USE:**  
See accompanying prescribing information.  
Each tablet contains 10 mg hydrocortisone.

**NO COPY HERE**

NDC 59762-0074-1  
100 Tablets

GREENSTONE® BRAND

**hydrocortisone tablets, USP**

**10 mg**

Rx only

**NO COPY HERE**

FP0:UPC-A @ 80%  
359762007414  
GTIN: 00359762007414

13754402

**IMPRINT AREA**  
reads this way  
NO COPY

**PRINCIPAL DISPLAY PANEL - 20 mg Tablet Bottle Label**

NDC 59762-0075-1  
100 Tablets

GREENSTONE® BRAND

hydrocortisone  
tablets, USP

20 mg

Rx only

Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP].  
Dispense in tight (USP), child-resistant containers.  
**Warning** – This potent drug must be used only under the direct supervision of a physician.  
**DOSAGE AND USE:**  
See accompanying prescribing information.  
Each tablet contains 20 mg hydrocortisone.

**NO COPY HERE**

NDC 59762-0075-1  
100 Tablets

GREENSTONE® BRAND

**hydrocortisone tablets, USP**

**20 mg**

Rx only

**NO COPY HERE**

FP0:UPC-A @ 80%  
359762007513  
GTIN: 00359762007513

13754802

**IMPRINT AREA**  
reads this way  
NO COPY

# HYDROCORTISONE

hydrocortisone tablet

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:59762-0073
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
CALCIUM STEARATE (UNII: 776XM7047L)	
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MINERAL OIL (UNII: T5L8T28FGP)	
SORBIC ACID (UNII: X045WJ989B)	
SUCROSE (UNII: C151H8M554)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND (half oval)	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	CORTEF;5
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59762-0073-1	50 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2013	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA AUTHORIZED GENERIC	NDA008697	02/20/2013	

# HYDROCORTISONE

hydrocortisone tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:59762-0074
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HYDROCORTISONE</b> (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CALCIUM STEARATE</b> (UNII: 776XM7047L)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>LACTOSE, UNSPECIFIED FORM</b> (UNII: J2B2A4N98G)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>SUCROSE</b> (UNII: C151H8M554)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND (half oval)	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	CORTEF;10
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59762-0074-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2013	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA AUTHORIZED GENERIC	NDA008697	02/20/2013	

## HYDROCORTISONE

hydrocortisone tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:59762-0075	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	20 mg	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>		<b>Strength</b>	
	CALCIUM STEARATE (UNII: 776XM7047L)			
	STARCH, CORN (UNII: O8232NY3SJ)			
	LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)			
	MINERAL OIL (UNII: T5L8T28FGP)			
	SORBIC ACID (UNII: X045WJ989B)			
	SUCROSE (UNII: C151H8M554)			
<b>Product Characteristics</b>				
<b>Color</b>	WHITE	<b>Score</b>	2 pieces	
<b>Shape</b>	ROUND (half oval)	<b>Size</b>	10mm	
<b>Flavor</b>		<b>Imprint Code</b>	CORTEF;20	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:59762-0075-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2013	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
NDA AUTHORIZED GENERIC	NDA008697	02/20/2013		

**Labeler** - Greenstone LLC (825560733)

**Registrant** - Pfizer Inc (113480771)