

DERMACINRX THERAZOLE PAK- clotrimazole and betamethasone dipropionate, zinc oxide
PureTek Corporation

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.

HIGHLIGHTS OF PRESCRIBING INFORMATION

DermacinRx Therazole Pak (clotrimazole and betamethasone dipropionate, zinc oxide)

These highlights do not include all the information needed to use CLOTRIMAZOLE and BETAMETHASONE DIPROPIONATE CREAM safely and effectively. See full prescribing information for CLOTRIMAZOLE and BETAMETHASONE DIPROPIONATE CREAM.

CLOTRIMAZOLE and BETAMETHASONE DIPROPIONATE cream, for topical use Initial U.S. Approval: 1984

----- **INDICATIONS AND USAGE** -----

Clotrimazole and betamethasone dipropionate cream contains a combination of clotrimazole, an azole antifungal, and betamethasone dipropionate, a corticosteroid, and is indicated for the topical treatment of symptomatic inflammatory tinea pedis, tinea cruris, and tinea corporis due to *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, and *Trichophyton rubrum* in patients 17 years and older. (1)

----- **DOSAGE AND ADMINISTRATION** -----

- Tinea pedis: Apply a thin film to the affected skin areas twice a day for 2 weeks. (2)
- Tinea cruris and tinea corporis: Apply a thin film to the affected skin area twice a day for 1 week. (2)
- Clotrimazole and betamethasone dipropionate cream should not be used longer than 2 weeks in the treatment of tinea corporis or tinea cruris, and longer than 4 weeks in the treatment of tinea pedis. (2)
- Do not use with occlusive dressings unless directed by a physician. (2)
- Not for ophthalmic, oral or intravaginal use. (2)

----- **DOSAGE FORMS AND STRENGTHS** -----

Cream, 1%/0.05% (base) (3)

Each gram of clotrimazole and betamethasone dipropionate cream, contains 10 mg of clotrimazole and 0.64 mg of betamethasone dipropionate, (equivalent to 0.5 mg of betamethasone) (3)

----- **CONTRAINDICATIONS** -----

None. (4)

----- **WARNINGS AND PRECAUTIONS** -----

- Clotrimazole and betamethasone dipropionate cream can cause reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency during and after withdrawal of the treatment. Risk factor(s) are: use of high-potency topical corticosteroid, use over a large surface area or to areas under occlusion, prolonged use, altered skin barrier, liver failure, and young age. Modify use should HPA axis suppression develop. (5.1, 8.4)
- Pediatric patients may be more susceptible to systemic toxicity. (5.1, 8.4)
- The use of clotrimazole and betamethasone dipropionate cream in the treatment of diaper dermatitis is not recommended. (5.2)

----- **ADVERSE REACTIONS** -----

Most common adverse reactions reported for clotrimazole and betamethasone dipropionate cream were paraesthesia in 1.9% of patients and rash, edema, and secondary infections each in less than 1% of patients. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Actavis at 1-800-432-8534 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 2/2019

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Purpose

Do not use on

When using this product

Stop use and ask a doctor if

Keep out of reach of children.

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Clotrimazole and betamethasone dipropionate cream is a combination of an azole antifungal and corticosteroid and is indicated for the topical treatment of symptomatic inflammatory tinea pedis, tinea cruris, and tinea corporis due to *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, and *Trichophyton rubrum* in patients 17 years and older.

2 DOSAGE AND ADMINISTRATION

Treatment of tinea corporis or tinea cruris:

- Apply a thin film of clotrimazole and betamethasone dipropionate cream into the affected skin areas twice a day for one week.
- Do not use more than 45 grams per week. Do not use with occlusive dressings.
- If a patient shows no clinical improvement after 1 week of treatment with clotrimazole and betamethasone dipropionate cream, the diagnosis should be reviewed.
- Do not use longer than 2 weeks.

Treatment of tinea pedis:

- Gently massage a sufficient amount of clotrimazole and betamethasone dipropionate cream into the affected skin areas twice a day for two weeks.
- Do not use more than 45 grams per week. Do not use with occlusive dressings.
- If a patient shows no clinical improvement after 2 week of treatment with clotrimazole and betamethasone dipropionate cream, the diagnosis should be reviewed.
- Do not use longer than 4 weeks.

Clotrimazole and betamethasone dipropionate cream is for topical use only. It is not for oral, ophthalmic, or intravaginal use.

3 DOSAGE FORMS AND STRENGTHS

Cream, 1%/0.05% (base). Each gram of clotrimazole and betamethasone dipropionate cream, USP contains 10 mg of clotrimazole, USP and 0.64 mg of betamethasone dipropionate USP, (equivalent to 0.5 mg of betamethasone) in a white to off-white hydrophilic cream.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Effects on Endocrine System

Clotrimazole and betamethasone dipropionate cream can cause reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or after withdrawal of treatment. Cushing's syndrome and hyperglycemia may also occur due to the systemic effect of corticosteroids while on treatment. Factors that predispose a patient to HPA axis suppression include the use of high-potency steroids, large treatment surface areas, prolonged use, use of occlusive dressing, altered skin barrier, liver failure, and young age.

Because of the potential for systemic corticosteroid effects, patients may need to be periodically evaluated for HPA axis suppression. This may be done by using the adrenocorticotropic hormone (ACTH) stimulation test.

In a small trial, clotrimazole and betamethasone dipropionate cream was applied using large dosages, 7 g daily for 14 days (twice a day) to the crural area of normal adult subjects. Three of the 8 normal subjects on whom clotrimazole and betamethasone dipropionate cream was applied exhibited low morning plasma cortisol levels during treatment. One of these subjects had an abnormal cosyntropin test. The effect on morning plasma cortisol was transient and subjects recovered 1 week after discontinuing dosing. In addition, 2 separate trials in pediatric subjects demonstrated adrenal suppression as determined by cosyntropin testing [*see Use in Specific Populations (8.4)*].

If HPA axis suppression is documented, gradually withdraw the drug, reduce the frequency of application, or substitute with a less potent corticosteroid.

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 Diaper Dermatitis

The use of clotrimazole and betamethasone dipropionate cream in the treatment of diaper dermatitis is not recommended.

6 ADVERSE REACTIONS

6.1 Clinical Trial 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 practice.

In clinical trials common adverse reaction reported for clotrimazole and betamethasone dipropionate cream was paresthesia in 1.9% of patients. Adverse reactions reported at a frequency less than 1% included rash, edema, and secondary infection.

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.

The following local adverse reactions have been reported with topical corticosteroids: itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, skin atrophy, striae, miliaria, capillary fragility (ecchymoses), telangiectasia, and sensitization (local reactions upon repeated application of product).

Adverse reactions reported with the use of clotrimazole are: erythema, stinging, blistering, peeling, edema, pruritus, urticaria, and general irritation of the skin.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects

Pregnancy Category C

There are no adequate and well-controlled studies with clotrimazole and betamethasone dipropionate cream in pregnant women. Therefore, clotrimazole and betamethasone dipropionate cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

There have been no teratogenic studies performed in animals or humans with the combination of clotrimazole and betamethasone dipropionate. Corticosteroids are generally teratogenic in laboratory animals when administered at relatively low dosage levels.

Studies in pregnant rats with intravaginal doses up to 100 mg/kg (15 times the maximum human dose) revealed no evidence of fetotoxicity due to clotrimazole exposure.

No increase in fetal malformations was noted in pregnant rats receiving oral (gastric tube) clotrimazole doses up to 100 mg/kg/day during gestation Days 6 to 15. However, clotrimazole dosed at 100 mg/kg/day was embryotoxic (increased resorptions), fetotoxic (reduced fetal weights), and maternally toxic (reduced body weight gain) to rats. Clotrimazole dosed at 200 mg/kg/day (30 times the maximum human dose) was maternally lethal, and therefore, fetuses were not evaluated in this group. Also in this study, doses up to 50 mg/kg/day (8 times the maximum human dose) had no adverse effects on dams or fetuses. However, in the combined fertility, teratogenicity, and postnatal development study described above, 50 mg/kg clotrimazole was associated with reduced maternal weight gain and reduced numbers of offspring reared to 4 weeks.

Oral clotrimazole doses of 25, 50, 100, and 200 mg/kg/day (2 to 15 times the maximum human dose) were not teratogenic in mice. No evidence of maternal toxicity or embryotoxicity was seen in pregnant rabbits dosed orally with 60, 120, or 180 mg/kg/day (18 to 55 times the maximum human dose).

Betamethasone dipropionate has been shown to be teratogenic in rabbits when given by the

intramuscular route at doses of 0.05 mg/kg. This dose is approximately one-fifth the maximum human dose. The abnormalities observed included umbilical hernias, cephalocele, and cleft palates.

Betamethasone dipropionate has not been tested for teratogenic potential by the dermal route of administration. Some corticosteroids have been shown to be teratogenic after dermal application to laboratory animals.

8.3 Nursing Mothers

Systemically administered corticosteroids appear in human milk and can suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when clotrimazole and betamethasone dipropionate cream is administered to a nursing woman.

8.4 Pediatric Use

The use of clotrimazole and betamethasone dipropionate cream in patients under 17 years of age is not recommended.

Adverse events consistent with corticosteroid use have been observed in pediatric patients treated with clotrimazole and betamethasone dipropionate cream. In open-label trials, 17 of 43 (39.5%) evaluable pediatric subjects (aged 12 to 16 years old) using clotrimazole and betamethasone dipropionate cream for treatment of tinea pedis demonstrated adrenal suppression as determined by cosyntropin testing. In another open-label trial, 8 of 17 (47.1%) evaluable pediatric subjects (aged 12 to 16 years old) using clotrimazole and betamethasone dipropionate cream for treatment of tinea cruris demonstrated adrenal suppression as determined by cosyntropin testing.

Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression when they are treated with topical corticosteroids. They are, therefore also at greater risk of adrenal insufficiency during and/or after withdrawal of treatment. Pediatric patients may be more susceptible than adults to skin atrophy, including striae, when they are treated with topical corticosteroids.

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in pediatric patients receiving topical corticosteroids [*see Warnings and Precautions (5.1)*].

Avoid use of clotrimazole and betamethasone dipropionate cream in the treatment of diaper dermatitis.

8.5 Geriatric Use

Clinical studies of clotrimazole and betamethasone dipropionate cream did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. However, greater sensitivity of some older individuals cannot be ruled out. The use of clotrimazole and betamethasone dipropionate cream under occlusion, such as in diaper dermatitis, is not recommended.

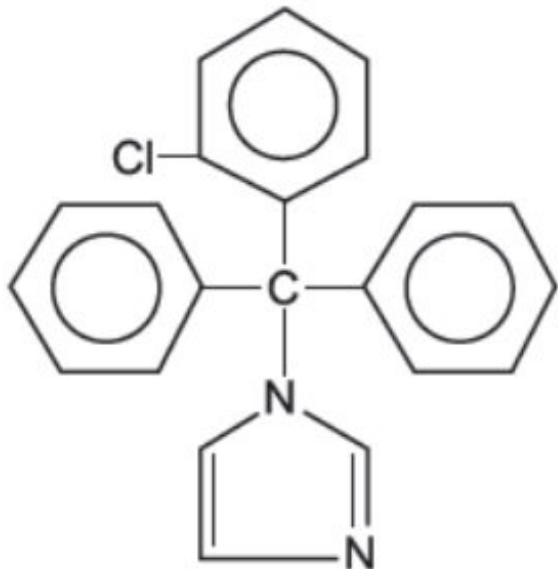
Postmarket adverse event reporting for clotrimazole and betamethasone dipropionate cream in patients aged 65 and above includes reports of skin atrophy and rare reports of skin ulceration. Caution should be exercised with the use of these corticosteroid-containing topical products on thinning skin.

11 DESCRIPTION

Clotrimazole and betamethasone dipropionate cream USP, 1%/0.05% (base), contains combinations of clotrimazole USP, an azole antifungal, and betamethasone dipropionate USP, a corticosteroid, for topical use.

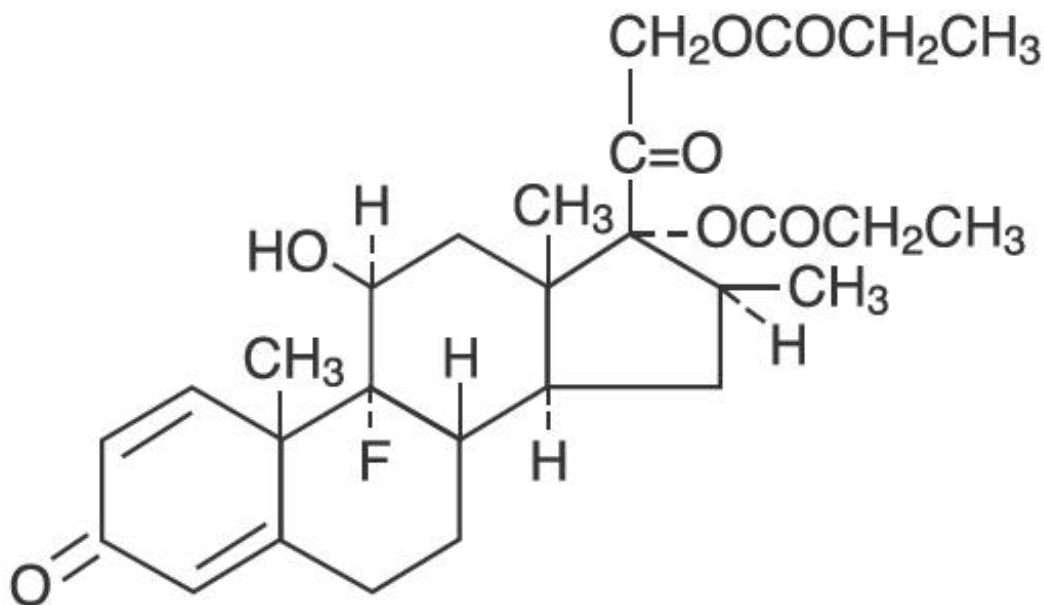
Chemically, clotrimazole, USP is 1-(*o*-Chloro- α,α -diphenylbenzyl)imidazole, with the molecular

formula $C_{22}H_{17}ClN_2$, a molecular weight of 344.84, and the following structural formula:



Clotrimazole, USP is an odorless, white crystalline powder, insoluble in water and soluble in ethanol.

Betamethasone dipropionate, USP has 9-Fluoro-11 β ,17,21-trihydroxy-16 β -methylpregna-1,4-diene-3,20-dione 17,21-dipropionate, with the molecular formula $C_{28}H_{37}FO_7$, a molecular weight of 504.59, and the following structural formula:



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

Each gram of clotrimazole and betamethasone dipropionate cream, USP contains 10 mg clotrimazole, USP and 0.64 mg betamethasone dipropionate, USP (equivalent to 0.5 mg betamethasone), in a white to off-white hydrophilic cream. Inactive ingredients: Cetareth-30, cetyl alcohol, mineral oil, propylene glycol, purified water, sodium phosphate monobasic monohydrate, stearyl alcohol and white petrolatum; benzyl alcohol as preservative.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Clotrimazole is an azole antifungal [see *Clinical Pharmacology (12.4)*].

Betamethasone dipropionate is a corticosteroid. Corticosteroids play a role in cellular signaling, immune function, inflammation, and protein regulation; however, the precise mechanism of action for the treatment of tinea pedis, tinea cruris and tinea corporis is unknown.

12.2 Pharmacodynamics

Vasoconstrictor Assay

Studies performed with clotrimazole and betamethasone dipropionate cream indicate that these topical combination antifungal/corticosteroids may have vasoconstrictor potencies in a range that is comparable to high-potency topical corticosteroids. However, similar blanching scores do not necessarily imply therapeutic equivalence.

12.3 Pharmacokinetics

Skin penetration and systemic absorption of clotrimazole and betamethasone dipropionate following topical application of clotrimazole and betamethasone dipropionate cream has not been studied.

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

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

12.4 Microbiology

Mechanism of Action

Clotrimazole, an azole antifungal agent, inhibits 14- α -demethylation of lanosterol in fungi by binding to one of the cytochrome P-450 enzymes. This leads to the accumulation of 14- α -methylsterols and reduced concentrations of ergosterol, a sterol essential for a normal fungal cytoplasmic membrane. The methylsterols may affect the electron transport system, thereby inhibiting growth of fungi.

Activity In Vitro and In Vivo

Clotrimazole has been shown to be active against most strains of the following dermatophytes, both *in vitro* and in clinical infections, *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, and *Trichophyton rubrum* [see *Indications and Usage (1)*].

Drug Resistance

Strains of dermatophytes having a natural resistance to clotrimazole have not been reported. Resistance to azoles, including clotrimazole, has been reported in some *Candida* species.

No single-step or multiple-step resistance to clotrimazole has developed during successive passages of *Trichophyton mentagrophytes*.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

There are no adequate laboratory animal studies with either the combination of clotrimazole and betamethasone dipropionate or with either component individually to evaluate carcinogenesis.

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.

Reproductive studies with betamethasone dipropionate carried out in rabbits at doses of 1 mg/kg by the intramuscular route and in mice up to 33 mg/kg by the intramuscular route indicated no impairment of fertility except for dose-related increases in fetal resorption rates in both species. These doses are approximately 5- and 38-fold the maximum human dose based on body surface areas, respectively.

In a combined study of the effects of clotrimazole on fertility, teratogenicity, and postnatal development, male and female rats were dosed orally (diet admixture) with levels of 5, 10, 25, or 50 mg/kg/day (approximately 1 to 8 times the maximum dose in a 60-kg adult based on body surface area) from 10 weeks prior to mating until 4 weeks postpartum. No adverse effects on the duration of estrous cycle, fertility, or duration of pregnancy were noted.

14 CLINICAL STUDIES

In clinical trials of tinea corporis, tinea cruris, and tinea pedis, subjects treated with clotrimazole and betamethasone dipropionate cream showed a better clinical response at the first return visit than subjects treated with clotrimazole cream. In tinea corporis and tinea cruris, the subject returned 3 to 5 days after starting treatment, and in tinea pedis, after 1 week. Mycological cure rates observed in subjects treated with clotrimazole and betamethasone dipropionate cream were as good as, or better than, in those subjects treated with clotrimazole cream. In these same clinical studies, patients treated with clotrimazole and betamethasone dipropionate cream showed better clinical responses and mycological cure rates when compared with subjects treated with betamethasone dipropionate cream.

16 HOW SUPPLIED/STORAGE AND HANDLING

Clotrimazole and betamethasone dipropionate cream, USP is available as follows:

15 gram tube in a carton (NDC 0472-0379-15)

45 gram tube in a carton (NDC 0472-0379-45)

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

17 PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (Patient Information)

Inform the patient of the following:

- Use clotrimazole and betamethasone dipropionate cream as directed by the physician. It is for external use only.
- Avoid contact with the eyes, the mouth, or intravaginally.
- Do not use clotrimazole and betamethasone dipropionate cream on the face or underarms.
- Do not use more than 45 grams of clotrimazole and betamethasone dipropionate cream per week.
- When using clotrimazole and betamethasone dipropionate cream in the groin area, patients should use the medication for 2 weeks only, and apply the cream sparingly. Patients should wear loose-fitting clothing. Notify the physician if the condition persists after 2 weeks.
- Do not use clotrimazole and betamethasone dipropionate cream for any disorder other than that for which it was prescribed.

- Do not bandage, cover or wrap the treatment area unless directed by the physician. Avoid use of clotrimazole and betamethasone dipropionate cream in the diaper area, as diapers or plastic pants may constitute occlusive dressing.
- Report any signs of local adverse reactions to the physician. Advise patients that local reactions and skin atrophy are more likely to occur with occlusive use or prolonged use.
- This medication is to be used for the full prescribed treatment time, even though the symptoms may have improved. Notify the physician if there is no improvement after 1 week of treatment for tinea cruris or tinea corporis, or after 2 weeks for tinea pedis.

Manufactured by:
G&W Laboratories, Inc.
111 Coolidge Street
South Plainfield, NJ 07080 USA

Distributed by:
Actavis Pharma, Inc.
Parsippany, NJ 07054 USA

I600-5511/14A GW7100

Revised – July 2016

PATIENT INFORMATION

Clotrimazole (kloe trim' a zole) and Betamethasone Dipropionate (bay'' ta meth' a sone dye proe' pee oh nate) Cream USP, 1%/0.05% (base)

Important information: Clotrimazole and betamethasone dipropionate cream is for use on skin only. Do not use clotrimazole and betamethasone dipropionate cream in your eyes, mouth, or vagina.

What is clotrimazole and betamethasone dipropionate cream?

- Clotrimazole and betamethasone dipropionate cream is a prescription medication used on the skin (topical) to treat fungal infections of the feet, groin, and body in people 17 years of age and older. Clotrimazole and betamethasone dipropionate cream is used for fungal infections that are inflamed and have symptoms of redness or itching.
- Clotrimazole and betamethasone dipropionate cream should not be used in children under 17 years of age.

Before using clotrimazole and betamethasone dipropionate cream, tell your healthcare provider about all your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if clotrimazole and betamethasone dipropionate cream will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if clotrimazole and betamethasone dipropionate passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take other corticosteroid medicines by mouth or use other products on your skin or scalp that contain corticosteroids.

What should I avoid while using clotrimazole and betamethasone dipropionate cream?

Clotrimazole and betamethasone dipropionate cream should not be used to treat diaper rash or redness. You should avoid applying clotrimazole and betamethasone dipropionate cream in the diaper area.

How should I use clotrimazole and betamethasone dipropionate cream?

- Use clotrimazole and betamethasone dipropionate cream exactly as your healthcare provider tells you to use it.
- Use clotrimazole and betamethasone dipropionate cream for the prescribed treatment time, even if your symptoms get better.
- Do not use more than 45 grams of clotrimazole and betamethasone dipropionate cream in 1 week.
- Do not bandage, cover, or wrap the treated area unless your healthcare provider tells you to. Wear loose-fitting clothing if you use clotrimazole and betamethasone dipropionate cream in the groin area.
- Do not use clotrimazole and betamethasone dipropionate cream on your face or underarms (armpits).
- **For treatment of fungal infections of the groin and body:**
 - Apply a thin layer of clotrimazole and betamethasone dipropionate cream to the affected skin area 2 times a day for 1 week.
 - Tell your healthcare provider if the treated skin area does not improve after 1 week of treatment.
 - Do not use clotrimazole and betamethasone dipropionate cream for longer than 2 weeks.
- **For treatment of fungal infections of the feet:**
 - Apply a thin layer of clotrimazole and betamethasone dipropionate cream to the affected skin area 2 times a day for 2 weeks.
 - Tell your healthcare provider if the treated skin area does not improve after 2 weeks of treatment. Do not use clotrimazole and betamethasone dipropionate cream longer than 4 weeks.
 - Wash your hands after applying clotrimazole and betamethasone dipropionate cream.

What are the possible side effects of clotrimazole and betamethasone dipropionate cream?

Clotrimazole and betamethasone dipropionate cream may cause serious side effects, including:

- **Clotrimazole and betamethasone dipropionate cream can pass through your skin.** Too much clotrimazole and betamethasone dipropionate cream passing through your skin can cause your adrenal glands to stop working. Your healthcare provider may do blood tests to check for adrenal gland problems.

The most common side effects of clotrimazole and betamethasone dipropionate cream include burning, tingling, rash, swelling, and infections.

These are not all the possible side effects of clotrimazole and betamethasone dipropionate cream.

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 clotrimazole and betamethasone dipropionate cream?

- Store clotrimazole and betamethasone dipropionate cream at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep clotrimazole and betamethasone dipropionate cream and all medicines out of the reach of children.

General information about the safe and effective use of clotrimazole and betamethasone dipropionate cream.

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

What are the ingredients in clotrimazole and betamethasone dipropionate cream?

Active ingredients: clotrimazole, USP and betamethasone dipropionate, USP

Inactive ingredients: Cetareth-30, cetyl alcohol, mineral oil, propylene glycol, purified water, sodium phosphate monobasic monohydrate, stearyl alcohol and white petrolatum; benzyl alcohol as preservative.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Manufactured by:
G&W Laboratories, Inc.
111 Coolidge Street
South Plainfield, NJ 07080 USA

Distributed by:
Actavis Pharma, Inc.
Parsippany, NJ 07054 USA

1600-5511/14A GW7100

Revised – July 2016

DermacinRx[®] Zinc Oxide Skin Healing Paste

Active ingredient

Zinc Oxide 20.0%
(3.0% as Calamine)

Purpose

Skin Protectant

Uses

- for the treatment and/or prevention of diaper rash
- temporarily protects and helps relieve minor skin irritation and itching due to rashes

Warnings

For external use only

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

When using this product

- do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

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

Directions

- cleanse skin with warm water and soap
- apply paste to area as needed
- for G-tubes, cleanse as above, apply thin layer and secure with drain sponge or product as directed

Other information

- protect from freezing
- avoid excessive heat

Inactive ingredients:

Aleurites Moluccana Seed Oil, Aloe Barbadensis (Aloe Vera) Leaf Juice, Bisabolol, Calcium Pantothenate (Vitamin B5), Carthamus Tinctorius (Safflower) Oleosomes, Carthamus Tinctorius (Safflower) Seed Oil, Fragrance, Maltodextrin, Modified Corn Starch, Niacinamide (Vitamin B3), Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Petrolatum, Phenoxyethanol, Pyridoxine HCl (Vitamin B6), Silica, Sodium Ascorbyl Phosphate (Vitamin C), Sodium Hyaluronate, Sodium Starch Octenylsuccinate, Tocopheryl Acetate (Vitamin E), Zingiber Officinale (Ginger) Root Extract.

DermacinRx[®] Therazole Pak (kit carton)



DERMACINRX THERAZOLE PAK
 clotrimazole and betamethasone dipropionate, zinc oxide kit

Product Information**Product Type**

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:59088-893

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-893-00	1 in 1 CARTON	08/09/2016	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	15 g
Part 2	30 PACKET	120 g

Part 1 of 2**CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE**

clotrimazole and betamethasone dipropionate cream

Product Information**Item Code (Source)**

NDC:0472-0379

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	10 mg in 1 g
BETAMETHASONE DIPROPIONATE (UNII: 826Y60901U) (BETAMETHASONE - UNII:9842X06Q6M)	BETAMETHASONE	0.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETEARETH-30 (UNII: 1R9DCZ5FOX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PETROLATUM (UNII: 4T6H12BN9U)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0472-0379-15	1 in 1 CARTON		
1		15 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	ANDA076002		

Part 2 of 2

DERMACINRX ZINC OXIDE SKIN HEALING

zinc oxide paste

Product Information

Item Code (Source)	NDC:59088-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
KUKUI NUT OIL (UNII: TP11QR7B8R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)	
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)	
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
PETROLATUM (UNII: 4T6H12BN9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

GINGER OIL (UNII: SAS9Z1SVUK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-563-01	4 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/09/2016	

Labeler - PureTek Corporation (785961046)

Establishment

Name	Address	ID/FEI	Business Operations
G&W NC Laboratories, LLC		079419931	manufacture(0472-0379)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	pack(59088-893) , manufacture(59088-563)

Revised: 11/2020

PureTek Corporation