CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-502

APPROVED DRAFT LABELING

15-502

NDC 0168-0258-46

℞ only

fougera®

CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE CREAM USP, 1%/0.05% (base)

USUAL DOSAGE: Apply a sufficient amount of cream to the affected and surrounding skin areas twice a day.
See package insert for full prescribing information.
Store between 2° and 30°C (36° and 86°F).
See crimp of tube for Lot No. and Exp. Date.

E. FOUGERA & CO.
a division of Altana Inc.
MELVILLE, NEW YORK 11747

APPROVED
JUN 5 2001

NDC 0168-0258-46

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fougera®

CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE CREAM USP, 1%/0.05% (base)

N 3 0168-0258-46 1

TO OPEN: To puncture the seal, reverse the cap and place the puncture-top onto the tube. Push down firmly until seal is open.
To close, screw the cap back onto the tube.

IMPORTANT: The opening of this product is covered by a metal tamper-resistant seal. If this seal has been punctured or is not visible, do not use and return product to place of purchase.

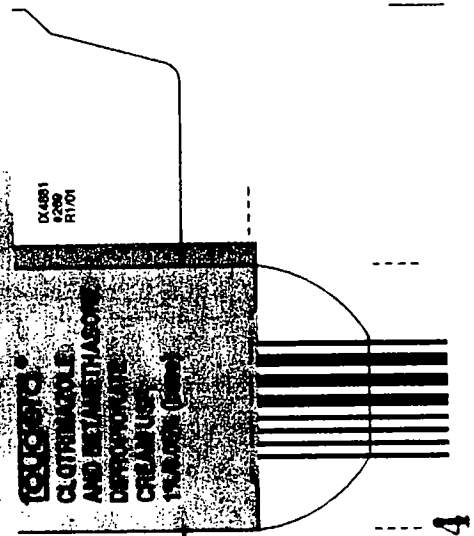
FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE. NOT RECOMMENDED FOR PATIENTS UNDER THE AGE OF 18 YEARS AND NOT RECOMMENDED FOR DIAPER DERMATITIS

NET WT 45 grams

Each gram contains 10 mg clotrimazole and 0.64 mg betamethasone dipropionate (equivalent to 0.5 mg betamethasone), in a hydrophilic emollient cream consisting of purified water, mineral oil, white petrolatum, cetearyl alcohol, ceteareth-30, propylene glycol, and monobasic sodium phosphate, (monohydrate). Phosphoric acid added when necessary to adjust pH. Benzyl alcohol added as a preservative.

ATTENTION PHARMACIST:
COMBINED INSERT- Dispense with enclosed Patient Information Leaflet.
ATTENTION PATIENT: See Patient Information Leaflet before using this product.
WARNING: Keep out of reach of children.

NET WT 45 grams



GUIDE 44

T1149
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Pharma Code- 269

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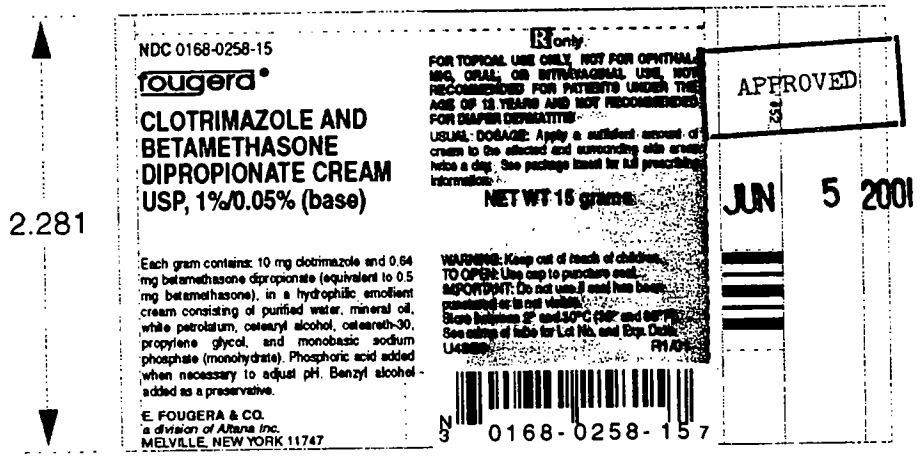
text revs per Reg 2/8/01-AA
revised layout of carton for consistncy
of text and better layoutdh 2-14



15 grams Tube Temp.

Drawing LB-518

Item #- U????
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Pharma Code-52 actual placed dh 2-14

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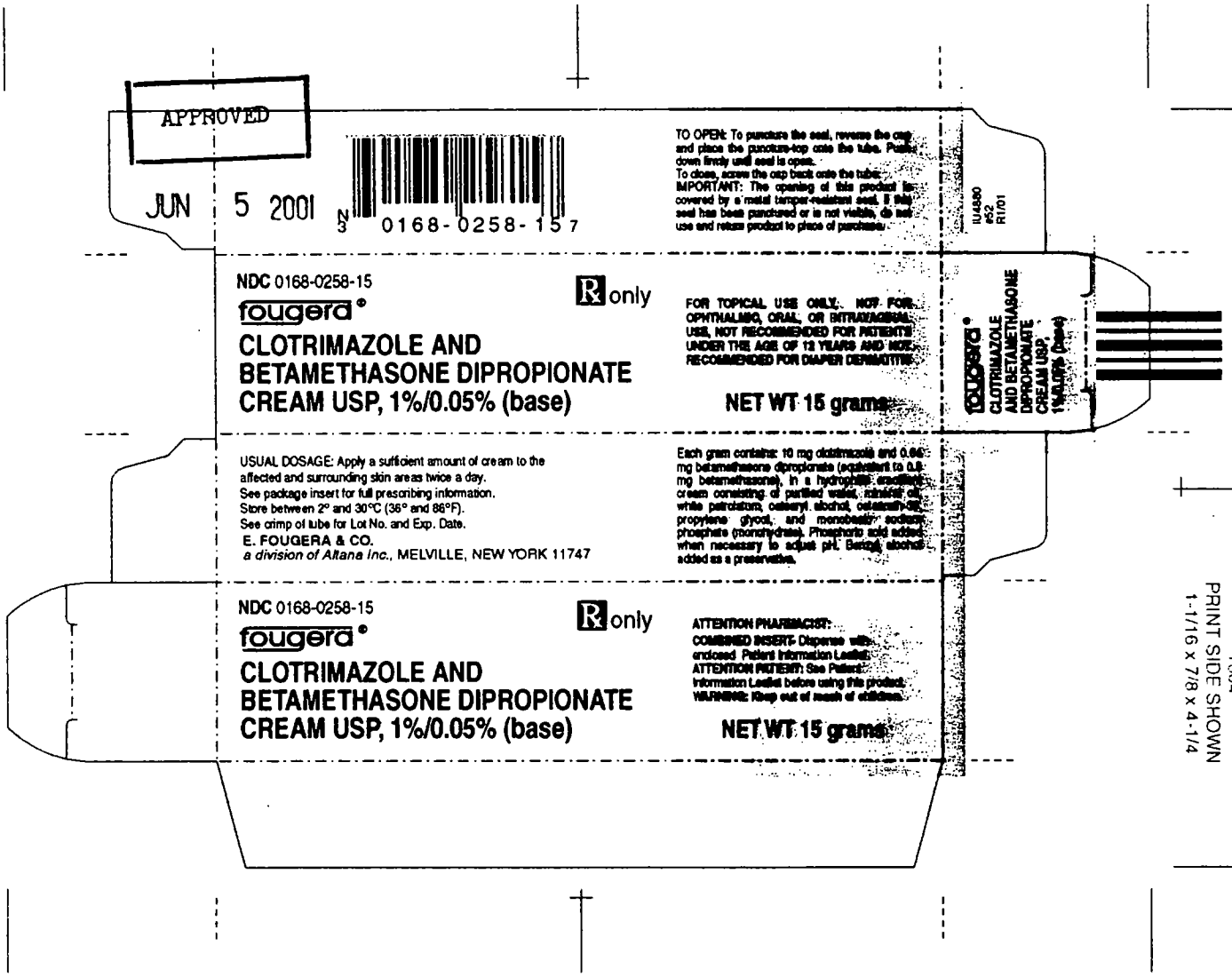
Text Revs per Reg - 2/8/ 01- AA
redesigned tube for better layout dh 2-14



Item #-IU4880
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Colors: Yellow Black
Pharma Code-52

Add WARNING statements per REG - 1/30/01- AA
Text Revs per Reg - 2/8/01 - AA

12258B R5/01
SSI -27 Dimensions: 7.00" x 7.50" COLOR: Black
Pharmacode moved per production/Spell checked-5/17/01-AA

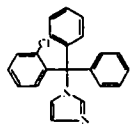
fougera® CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE CREAM USP,1%/0.05% (base)

Ronly

FOR TOPICAL USE ONLY, NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE, NOT RECOMMENDED FOR PATIENTS UNDER THE AGE OF 12 YEARS AND NOT RECOMMENDED FOR DIAPER DERMATITIS

DESCRIPTION: Clotrimazole and Betamethasone Dipropionate Cream USP, contains combinations of clotrimazole USP, a synthetic antifungal agent, and betamethasone dipropionate USP, a synthetic corticosteroid, for dermatologic use.

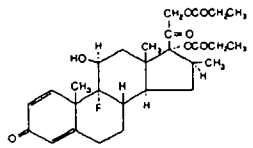
Chemically, clotrimazole is 1-(o-chloro-α,α-diphenylbenzyl)imidazole, with the empirical formula $C_{22}H_{17}ClN_2$, a molecular weight of 344.84, and the following structural formula:



APPROVED

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

Betamethasone dipropionate has the chemical name 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 504.59, and the following structural formula:



JUN 5 2001

Betamethasone dipropionate 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 and 0.64 mg betamethasone dipropionate (equivalent to 0.5 mg betamethasone), in a hydrophilic cream consisting of purified water, mineral oil, white petrolatum, cetearyl alcohol 70/30, ceteareth-30, propylene glycol, sodium phosphate monobasic, and phosphoric acid, benzyl alcohol as a preservative.

Clotrimazole and Betamethasone Dipropionate Cream USP, is smooth, uniform and white to off-white in color.

CLINICAL PHARMACOLOGY

Clotrimazole and Betamethasone Dipropionate

Clotrimazole and Betamethasone Dipropionate Cream has been shown to be at least as effective as clotrimazole alone in a different cream vehicle.

Use of corticosteroids in the treatment of a fungal infection may lead to suppression of host inflammation leading to worsening or decreased cure rate.

Clotrimazole

Skin penetration and systemic absorption of clotrimazole following topical application of Clotrimazole and Betamethasone Dipropionate Cream have not been studied. The following information was obtained using 1% clotrimazole cream and solution formulations. Six hours after the application of radioactive clotrimazole 1% cream and 1% solution onto intact and acutely inflamed skin, the concentration of clotrimazole varied from 100 mcg/cm² in the stratum corneum, to 0.5 to 1 mcg/cm² in the reticular dermis, and 0.1 mcg/cm² in the subcutis. No measurable amount of radioactivity (<0.001 mcg/mL) was found in the serum within 48 hours after application under occlusive dressing of 0.5 mL of the solution or 0.8 g of the cream. Only 0.5% or less of the applied radioactivity was excreted in the urine.

Microbiology

Mechanism of Action: Clotrimazole is an imidazole antifungal agent. Imidazoles inhibit 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 Vivo*: Clotrimazole has been shown to be active against most strains of the following dermatophytes, both *in vitro* and in clinical infections as described in the **INDICATIONS AND USAGE** section: *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, and *Trichophyton rubrum*.

Activity *In Vitro*: *In vitro*, clotrimazole has been shown to have activity against many dermatophytes, but the clinical significance of this information is unknown.

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*.

Betamethasone Dipropionate

Betamethasone dipropionate, a corticosteroid, has been shown to have topical (dermatologic) and systemic pharmacologic and metabolic effects characteristic of this class of drugs.

Pharmacokinetics: 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. (See **DOSAGE AND ADMINISTRATION** section). Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption of topical corticosteriods. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids (See **DOSAGE AND ADMINISTRATION** section).

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.

Studies performed with Clotrimazole and Betamethasone Dipropionate Cream indicate that these topical combination anti-fungal/corticosteroids may have vasoconstrictor potencies in a range that is comparable to high potency topical corticosteroids. Therefore use is not recommended in patients less than 12 years of age, in diaper dermatitis, and under occlusion.

CLINICAL STUDIES

In clinical studies of tinea corporis, tinea cruris, and tinea pedis, patients treated with Clotrimazole and Betamethasone Dipropionate Cream showed a better clinical response at the first return visit than patients treated with clotrimazole cream. In tinea corporis and tinea cruris, the patient returned 3 to 5 days after starting treatment, and in tinea pedis, after 1 week. Mycological cure rates observed in patients treated with Clotrimazole and Betamethasone Dipropionate Cream were as good as or better than in those patients 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 patients treated with betamethasone dipropionate cream.

INDICATIONS AND USAGE: Clotrimazole and Betamethasone Dipropionate Cream 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*. Effective treatment without the risks associated with topical corticosteroid use may be obtained using a topical antifungal agent that does not contain a corticosteroid, especially for noninflammatory tinea infections. The efficacy of Clotrimazole and Betamethasone Dipropionate Cream for the treatment of infections caused by zoophilic dermatophytes (e.g., *Microsporum canis*) has not been established. Several cases of treatment failure of Clotrimazole and Betamethasone Dipropionate Cream in the treatment of infections caused by *Microsporum canis* have been reported.

CONTRAINDICATIONS: Clotrimazole and Betamethasone Dipropionate Cream is contraindicated in patients who are sensitive to clotrimazole, betamethasone dipropionate, other corticosteroids or imidazoles, or to any ingredient in these preparations.

PRECAUTIONS:

General: Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Conditions which augment systemic absorption include use over large surface areas, prolonged use, and use under occlusive dressings. Patients applying Clotrimazole and Betamethasone Dipropionate Cream to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. This may be done by using the ACTH stimulation, morning plasma cortisol, and urinary free cortisol tests.

Clotrimazole and Betamethasone Dipropionate Cream was applied using large dosages, 7 g daily for 14 days (BID) to the crural area of normal subjects. Three of the eight 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 Cortrosyn test. The effect on morning plasma cortisol was transient and subjects recovered one week after discontinuing dosing.

If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid.

Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur, requiring supplemental systemic corticosteroids.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios (See **PRECAUTIONS – Pediatric Use**).

Remove this portion before dispensing

CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE CREAM USP,1%/0.05% (base)
Patient Information Leaflet

What is Clotrimazole and Betamethasone Dipropionate Cream?

Clotrimazole and Betamethasone Dipropionate Cream is a medication used on the skin to treat fungal infections of the feet, groin, and body, as diagnosed by your doctor. Clotrimazole and Betamethasone Dipropionate Cream should be used for fungal infections that are inflamed and have symptoms of redness and/or itching. Talk to your doctor if your fungal infection does not have these symptoms. Clotrimazole and Betamethasone Dipropionate Cream contains a corticosteroid. Notify your doctor if you notice side effects with the use of Clotrimazole and Betamethasone Dipropionate Cream. (see **"What are the possible side effects of Clotrimazole and Betamethasone Dipropionate Cream** below). Clotrimazole and Betamethasone Dipropionate Cream is not to be used in the eyes, in the mouth, or in the vagina.

How does Clotrimazole and Betamethasone Dipropionate Cream work?

Clotrimazole and Betamethasone Dipropionate Cream is a combination of an antifungal agent (clotrimazole) and a corticosteroid (betamethasone dipropionate). Clotrimazole works against fungus. Betamethasone dipropionate, a corticosteroid, is used to help relieve redness, swelling, itching, and other discomforts of fungal infections.

Who should NOT use Clotrimazole and Betamethasone Dipropionate Cream?

Clotrimazole and Betamethasone Dipropionate Cream is not recommended for use in patients under the age of 12 years. Clotrimazole and Betamethasone Dipropionate Cream is not recommended for use in diaper rash.

Patients who are sensitive to Clotrimazole and Betamethasone Dipropionate, other corticosteroids or imidazoles or any ingredients in the preparation should not use Clotrimazole and Betamethasone Dipropionate Cream.

How should I use Clotrimazole and Betamethasone Dipropionate Cream?

Gently massage sufficient Clotrimazole and Betamethasone Dipropionate Cream into the affected and surrounding skin areas twice a day, in the morning and evening. Treatment for 2 weeks on the groin or on the body, and for 4 weeks on the feet is recommended. The use of Clotrimazole and Betamethasone Dipropionate Cream for longer than 4 weeks is not recommended for any condition. Prolonged use of Clotrimazole and Betamethasone Dipropionate Cream may lead to unwanted side effects.

What other important information should I know about Clotrimazole and Betamethasone Dipropionate Cream?

1. This medication is to be used for the full prescribed treatment time, even though the

If irritation develops, Clotrimazole and Betamethasone Dipropionate Cream should be discontinued and appropriate therapy instituted.

THE SAFETY OF CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE CREAM HAS NOT BEEN DEMONSTRATED IN THE TREATMENT OF DIAPER DERMATITIS. ADVERSE EVENTS CONSISTANT WITH CORTICOSTEROID USE HAVE BEEN OBSERVED IN PATIENTS TREATED WITH CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE CREAM FOR DIAPER DERMATITIS. THE USE OF CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE CREAM IN THE TREATMENT OF DIAPER DERMATITIS IS NOT RECOMMENDED.

Information for Patients: Patients using Clotrimazole and Betamethasone Dipropionate Cream should receive the following information and instructions:

1. This medication is to be used as directed by the physician and is not recommended for use longer than the prescribed time period. It is for external use only. Avoid contact with the eyes, the mouth, or intravaginally.
2. 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.
3. This medication should only be used for the disorder for which it was prescribed.
4. The treated skin areas should not be bandaged, covered, or wrapped so as to be occluded. (See **DOSAGE AND ADMINISTRATION** section).
5. Any signs of local adverse reactions should be reported to your physician.
6. Patients should avoid sources of infection or reinfection.
7. When using Clotrimazole and Betamethasone Dipropionate Cream in the groin area, patients should use the medication for two weeks only, and apply the cream sparingly. Patients should wear loose-fitting clothing. Notify the physician if the condition persists after 2 weeks.
8. The safety of Clotrimazole and Betamethasone Dipropionate Cream has not been demonstrated in the treatment of diaper dermatitis. Adverse events consistent with corticosteroid use have been observed in patients treated with Clotrimazole and Betamethasone Dipropionate Cream for diaper dermatitis. The use of Clotrimazole and Betamethasone Dipropionate Cream in the treatment of diaper dermatitis is not recommended.

Laboratory Tests: If there is a lack of response to Clotrimazole and Betamethasone Dipropionate Cream, appropriate confirmation of the diagnosis, including possible mycological studies, is indicated before instituting another course of therapy.

The following tests may be helpful in evaluating HPA axis suppression due to the corticosteroid components:

Urinary free cortisol test
Morning plasma cortisol test
ACTH stimulation test

Carcinogenesis, Mutagenesis, Impairment of Fertility: There are no 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. This pattern of response is similar to that of dexamethasone and hydrocortisone.

In genotoxicity testing of clotrimazole, chromosomes of the spermatophores of Chinese hamsters, which had been exposed to five daily oral clotrimazole doses of 100 mg/kg body weight, were examined for structural changes during the metaphase.

The results of this study showed that clotrimazole had no mutagenic effect.

Reproductive studies with betamethasone dipropionate carried out in rabbits at doses of 1.0 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 human dose based on a mg/m^2 comparison, respectively. Oral doses of clotrimazole in mice resulted in decreased litter size at doses of 120 mg/kg and higher. This dose is approximately 10-fold the human dose based on a mg/m^2 comparison.

A Segment I (fertility and general reproduction) study of clotrimazole was conducted in rats. Males and females were dosed orally (diet admixture) at doses of 5, 10, 25, or 50 mg/kg/day for 10 weeks prior to mating. At 50 mg/kg (approximately 8 times the human dose based on a mg/m^2 comparison), there was an adverse effect on maternal body weight gain and rearing of the offspring. Doses of 25 mg/kg (approximately 4 times the human dose based on a mg/m^2 comparison) and lower were well tolerated and produced no adverse effects on fertility or reproduction.

Pregnancy Category C. There have been no teratogenic studies performed in animals or humans with the combination of clotrimazole and betamethasone dipropionate.

A Segment II (teratology) study in pregnant rats with intravaginal doses up to 100 mg/kg clotrimazole have revealed no evidence of harm to the fetus. This dose is approximately 17-fold the human dose based on a mg/m^2 comparison.

Segment II (teratology) studies of clotrimazole were conducted by the oral (gavage) route in rats, mice, and rabbits. In rats administered 25, 50, 100, or 200 mg/kg/day, no increase in malformations was seen at doses up to 200 mg/kg. Doses of 100 and 200 mg/kg were embryotoxic (increased resorptions) as well as maternally toxic, while doses of 25 and 50 mg/kg were well tolerated by both the dams and the fetuses. These doses were approximately 4-, 8-, 17- and 34-fold the human dose based on a mg/m^2 comparison, respectively.

In pregnant mice, clotrimazole at oral doses of 25, 50, 100, or 200 mg/kg/day was not teratogenic and was well tolerated by both the dams and the fetuses. These doses were approximately 2-, 4-, 8-, and 17-fold the human dose based on a mg/m^2 comparison, respectively. No evidence of maternal toxicity or embryotoxicity was seen in pregnant rabbits dosed orally with 60, 120, or 180 mg/kg/day. These doses were approximately 20-, 40-, and 61-fold the human dose based on a mg/m^2 comparison, respectively.

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 human dose based on a mg/m^2 comparison. 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. Other corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application to laboratory animals.

Nursing Mothers: Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could 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.

Pediatric Use: The safety of Clotrimazole and Betamethasone Dipropionate Cream has not been demonstrated in pediatric patients under 12 years of age. Adverse events consistant with corticosteroid use have been observed in patients under 12 years of age treated with Clotrimazole and Betamethasone Dipropionate Cream. **THE USE OF CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE CREAM IN THE TREATMENT OF PATIENTS UNDER 12 YEARS OF AGE OR PATIENTS WITH DIAPER DERMATITIS IS NOT RECOMMENDED.**

Because of higher ratio of skin surface to body mass, pediatric patients under the age of 12 years are at higher risk with Clotrimazole and Betamethasone Dipropionate Cream. They are at increased risk of developing Cushing's syndrome while on treatment and adrenal insufficiency after withdrawal of treatment. Adverse effects, including striae and growth retardation, have been reported with inappropriate use of Clotrimazole and Betamethasone Dipropionate Cream in infants and children (see **PRECAUTIONS** and **ADVERSE REACTIONS** sections).

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

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. Post-market adverse event reporting for Clotrimazole and Betamethasone Dipropionate Cream in patients aged 65 and above includes reports of skin atrophy and extremely rare reports of skin ulceration. Caution should be exercised with the use of these corticosteroid containing topical products on thinning skin. **THE USE OF CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE CREAM UNDER OCCLUSION, SUCH AS IN DIAPER DERMATITIS, IS NOT RECOMMENDED.**

ADVERSE REACTIONS: Adverse reactions reported for Clotrimazole and Betamethasone Dipropionate Cream in clinical trials were paresthesia in 1.9% of patients, and rash, edema, and secondary infection, each in less than 1% of patients.

The following local adverse reactions have been reported with topical corticosteroids and may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: itching, irritation, dryness, folliculitis, hypertrichosis, acneform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria. In the pediatric population, reported adverse events for Clotrimazole and Betamethasone Dipropionate Cream include growth retardation, benign intracranial hypertension, Cushing's syndrome (HPA axis suppression), and local cutaneous reactions, including skin atrophy.

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

OVERDOSAGE: Amounts greater than 45 g/week of Clotrimazole and Betamethasone Dipropionate Cream should not be used. Acute overdosage with topical application of Clotrimazole and Betamethasone Dipropionate Cream is unlikely and would not be expected to lead to life-threatening situation. Clotrimazole and Betamethasone Dipropionate Cream should not be used for longer than the prescribed time period.

Topically applied corticosteroids, such as the one contained in Clotrimazole and Betamethasone Dipropionate Cream can be absorbed in sufficient amounts to produce systemic effects. (See **PRECAUTIONS**.)

DOSAGE AND ADMINISTRATION: Gently massage sufficient Clotrimazole and Betamethasone Dipropionate Cream into the affected skin areas twice a day, in the morning and evening.

Clotrimazole and Betamethasone Dipropionate Cream should <u>not</u> be used longer than 2 weeks in the treatment of tinea corporis or tinea cruris, and amounts greater than 45 g per week of Clotrimazole and Betamethasone Dipropionate Cream should not be used. If a patient with tinea corporis or tinea cruris shows no clinical improvement after one week of treatment with Clotrimazole and Betamethasone Dipropionate Cream, the diagnosis should be reviewed. **Clotrimazole and Betamethasone Dipropionate Cream should <u>not</u> be used longer than 4 weeks in the treatment of tinea pedis, and amounts greater than 45 g per week of Clotrimazole and Betamethasone Dipropionate Cream should not be used.** If a patient with tinea pedis shows no clinical improvement after 2 weeks of treatment with Clotrimazole and Betamethasone Dipropionate Cream, the diagnosis should be reviewed.

Clotrimazole and Betamethasone Dipropionate Cream should not be used with occlusive dressings.

HOW SUPPLIED: Clotrimazole and Betamethasone Dipropionate Cream USP, 1%/0.05% (base) is supplied as follows:

NDC 0168-0258-15	15 gram tube
NDC 0168-0258-46	45 gram tube

Store between 2° and 30°C (36° and 86°F).

E. FOUGERA & CO.
a division of Altana Inc., MELVILLE, NEW YORK 11747

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#52 pharma reads

symptoms may have improved. Notify your doctor if there is no improvement after 1 week of treatment on the groin or body or after 2 weeks on the feet.
2. This medication should only be used for the disorder for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped.
4. Any signs of side effects where Clotrimazole and Betamethasone Dipropionate Cream is applied should be reported to your doctor.
5. When using Clotrimazole and Betamethasone Dipropionate Cream in the groin area, it is especially important to use the medication for two weeks only, and to apply the cream sparingly. You should tell your doctor if your problem persists after 2 weeks. You should also wear loose-fitting clothing so as to avoid tightly covering the area where Clotrimazole and Betamethasone Dipropionate Cream is applied.
6. This medication is not recommended for use in diaper rash.

What are the possible side effects of Clotrimazole and Betamethasone Dipropionate Cream?

The following side effects have been reported with topical corticosteroid medications: itching, irritation, dryness, infection of the hair follicles, increased hair, acne, change in skin color, allergic skin reaction, skin thinning, and stretch marks. In children, reported adverse events for Clotrimazole and Betamethasone Dipropionate Cream include slower growth, Cushing's syndrome (a type of hormone imbalance that can be very serious) and local skin reactions, including thinning skin and stretch marks.

Can Clotrimazole and Betamethasone Dipropionate Cream be used if I am pregnant or plan to become pregnant or if I am nursing?

Before using Clotrimazole and Betamethasone Dipropionate Cream, tell your doctor if you are pregnant or plan to become pregnant. Also, tell your doctor if you are nursing.

How should Clotrimazole and Betamethasone Dipropionate Cream be stored?

Clotrimazole and Betamethasone Dipropionate Cream should be stored between 2° and 30°C (36° and 86°F).

General advice about prescription medicines

This medication was prescribed for your particular condition. Only use Clotrimazole and Betamethasone Dipropionate Cream to treat the condition that your doctor has prescribed it for. Do not give Clotrimazole and Betamethasone Dipropionate Cream to other people. It may harm them. **Keep out of reach of children.**

This leaflet summarizes the most important information about Clotrimazole and Betamethasone Dipropionate Cream. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Clotrimazole and Betamethasone Dipropionate Cream that is written for health professionals.

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