PODIATROLE- ketoconazole 2% and urea 20%
V2 Pharma, LLC

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.

Podiatrole

(NDC 72835-302-03)

For external use only.
Not for ophthalmic use.

Rx Only

PODIATROLE DESCRIPTION

PODIATROLE is supplied as 3 components in a *kit*:

-2 TUBES OF KETOCONAZOLE CREAM 2%, 30g (60g TOTAL IN KIT) (NDC 51672-1298-2), UREA 20% CREAM, 85g

INDICATION AND USAGE

For the topical treatment of tinea corporis, tinea cruris and tinea pedis caused by Trichophyton rubrum, T. mentagrophytes and Epidermophyton floccosum; in the treatment of tinea (pityriasis) versicolor caused by Malassezia furfur (Pityrosporum orbiculare); in the treatment of cutaneous candidiasis caused by Candida spp. and in the treatment of seborrheic dermatitis. Keratolytic.

DOSAGE AND ADMINISTRATION

First apply ketoconazole cream, 2% to cover the affected and immediate surrounding area. Then apply Urea 20% cream and rub into skin until completely absorbed. Apply twice a day or as directed by your physician.

WARNINGS

FOR EXTERNAL USE ONLY. Avoid contact with eyes, lips or mucous membranes. Do not use on areas of broken skin.

CONTRAINDICATIONS

Do not use if known hypersensitivity to any of the listed ingredients of *any* of the components included on the kit.

PRECAUTIONS

Stop use and ask a doctor if redness or irritation develops. Keep this and all other medications out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

PREGNANCY

If pregnant or breast feeding, ask a health professional before use.

Store at 20°-25°C (68° to 77°F); Keep away from heat and flame. Protect from freezing. [See USP Controlled Room Temperature.]

MANUFACTURED FOR:
V2 Pharma, LLC

Portland, OR

Rx Only

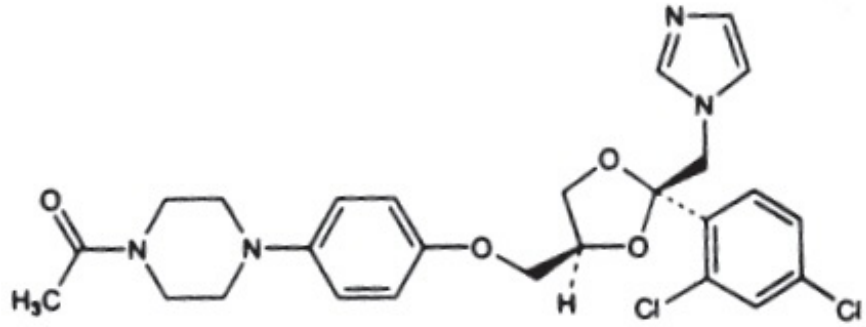
Ketoconazole cream, 2%

Rx Only

DESCRIPTION

Ketoconazole cream, 2% contains the broad-spectrum synthetic antifungal agent, ketoconazole 2%, formulated in an aqueous cream vehicle consisting of butylated hydroxyanisole (BHA), cetyl alcohol, isopropyl myristate, polysorbate 60, polysorbate 80, propylene glycol, purified water, sorbitan monostearate and stearyl alcohol. Ketoconazole is cis-1-acetyl-4-[4-[[2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl] piperazine and has the following structural formula:

Molecular Formula: $C_{26}H_{28}Cl_2N_4O_4$
Molecular Weight: 531.43



CLINICAL PHARMACOLOGY

When ketoconazole cream, 2% was applied dermally to intact or abraded skin of beagle dogs for 28 consecutive days at a dose of 80 mg, there were no detectable plasma levels using an assay method having a lower detection limit of 2 ng/mL.
After a single topical application to the chest, back and arms of normal volunteers, systemic absorption of ketoconazole was not detected at the 5 ng/mL level in blood over

a 72-hour period.
Two dermal irritancy studies, a human sensitization test, a phototoxicity study and a photoallergy study conducted in 38 male and 62 female volunteers showed no contact sensitization of the delayed hypersensitivity type, no irritation, no phototoxicity and no photoallergenic potential due to ketoconazole cream, 2%.

Microbiology

Ketoconazole is a broad spectrum synthetic antifungal agent which inhibits the in vitro growth of the following common dermatophytes and yeasts by altering the permeability of the cell membrane: dermatophytes: Trichophyton rubrum, T. mentagrophytes, T. tonsurans, Microsporum canis, M. audouini, M. gypseum and Epidermophyton floccosum; yeasts: Candida albicans, Malassezia ovale (Pityrosporum ovale) and C. tropicalis; and the organism responsible for tinea versicolor, Malassezia furfur (Pityrosporum orbiculare). Only those organisms listed in the INDICATIONS AND USAGE section have been proven to be clinically affected. Development of resistance to ketoconazole has not been reported.

Mode of Action

In vitro studies suggest that ketoconazole impairs the synthesis of ergosterol, which is a vital component of fungal cell membranes. It is postulated that the therapeutic effect of ketoconazole in seborrheic dermatitis is due to the reduction of M. ovale, but this has not been proven.

INDICATIONS AND USAGE

Ketoconazole cream, 2% is indicated for the topical treatment of tinea corporis, tinea cruris and tinea pedis caused by Trichophyton rubrum, T. mentagrophytes and Epidermophyton floccosum; in the treatment of tinea (pityriasis) versicolor caused by Malassezia furfur (Pityrosporum orbiculare); in the treatment of cutaneous candidiasis caused by Candida spp. and in the treatment of seborrheic dermatitis.

CONTRAINDICATIONS

Ketoconazole cream, 2% is contraindicated in persons who have shown hypersensitivity to the active or excipient ingredients of this formulation.

WARNINGS

Ketoconazole cream, 2% is not for ophthalmic use.

PRECAUTIONS

General

If a reaction suggesting sensitivity or chemical irritation should occur, use of the medication should be discontinued. Hepatitis (1:10,000 reported incidence) and, at high doses, lowered testosterone and ACTH induced corticosteroid serum levels have been

seen with orally administered ketoconazole; these effects have not been seen with topical ketoconazole.

Carcinogenesis, Mutagenesis, Impairment of Fertility

A long-term feeding study in Swiss Albino mice and in Wistar rats showed no evidence of oncogenic activity. The dominant lethal mutation test in male and female mice revealed that single oral doses of ketoconazole as high as 80 mg/kg produced no mutation in any stage of germ cell development. The Ames' salmonella microsomal activator assay was also negative.

Pregnancy

Teratogenic effects

Pregnancy Category C

Ketoconazole has been shown to be teratogenic (syndactylia and oligodactylia) in the rat when given orally in the diet at 80 mg/kg/day, (10 times the maximum recommended human oral dose). However, these effects may be related to maternal toxicity, which was seen at this and higher dose levels.
There are no adequate and well-controlled studies in pregnant women. Ketoconazole should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether Ketoconazole cream, 2% administered topically could result in sufficient systemic absorption to produce detectable quantities in breast milk. Nevertheless, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

During clinical trials 45 (5.0%) of 905 patients treated with ketoconazole cream, 2% and 5 (2.4%) of 208 patients treated with placebo reported side effects consisting mainly of severe irritation, pruritus and stinging. One of the patients treated with ketoconazole cream developed a painful allergic reaction.
In worldwide postmarketing experience, rare reports of contact dermatitis have been associated with ketoconazole cream or one of its excipients, namely propylene glycol.

DOSAGE AND ADMINISTRATION

Cutaneous candidiasis, tinea corporis, tinea cruris, tinea pedis, and tinea (pityriasis) versicolor

It is recommended that ketoconazole cream, 2% be applied once daily to cover the

affected and immediate surrounding area. Clinical improvement may be seen fairly soon after treatment is begun; however, candidal infections and tinea cruris and corporis should be treated for two weeks in order to reduce the possibility of recurrence. Patients with tinea versicolor usually require two weeks of treatment. Patients with tinea pedis require six weeks of treatment.

Seborrheic dermatitis

Ketoconazole cream, 2% should be applied to the affected area twice daily for four weeks or until clinical clearing.
If a patient shows no clinical improvement after the treatment period, the diagnosis should be redetermined.

Ketoconazole cream, 2% is supplied in 30 g (NDC 51672-1298-2) tubes.

STORAGE

Store at room temperature 15° to 25°C (59° to 77°F); avoid freezing and excessive heat above 40°C (104°F).

Mfd. by: Taro Pharmaceuticals Inc., Brampton, Ontario, Canada L6T 1C1
Dist. by: Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532
Revised: March, 2014
PK-2925-4
354

PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

NDC 51672-1298-2
30 g
Ketoconazole
Cream 2%
FOR DERMATOLOGIC USE ONLY.
NOT FOR OPHTHALMIC USE.
Rx only
Keep this and all medications out of the reach of children.
TARO

UREA 20% CREAM

Drug Description

Active Ingredient

Urea 20%

Purpose

Keratolytic

Inactive Ingredients

Carbomer, Fragrance, Isopropyl Myristate, Isopropyl Palmitate, Propylene Glycol, Water, Sodium Laureth Sulfate, Sodium Hydroxide, Phenoxyethanol, Stearic Acid, and Xanthan Gum.

Warnings

FOR EXTERNAL USE ONLY. Avoid contact with eyes, lips or mucous membranes. Do not use on areas of broken skin. Do not use if known hypersensitivity to any of the listed ingredients.

Precautions

Stop use and ask a doctor if redness or irritation develops. Keep this and all other medications out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Pregnancy

If pregnant or breast feeding, ask a health professional before use.

Directions

Apply to the affected areas twice a day or as directed by a physician. Rub into the skin until completely absorbed.

Store at controlled room temperature 15° - 30°C (59° - 86°F). Protect from Freezing. See Crimp and end of carton for Lot Number and Expiration Date.

PRINCIPAL DISPLAY PANEL - Kit Carton

V2 Pharma, LLC

PODIATROLE

NDC 72835-302-03 RX ONLY

PODIATROLE

ketoconazole 2% and urea 20% kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72835-302

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72835-302-02	1 in 1 CARTON	01/06/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	2 TUBE	60 g
Part 2	1 TUBE	85 g

Part 1 of 2

KETOCONAZOLE

ketoconazole cream

Product Information	
Item Code (Source)	NDC:51672-1298
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I)	KETOCONAZOLE	20 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Product Characteristics			
Color	white (White to off-white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51672-1298-2	1 in 1 CARTON		

1		30 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	ANDA075638		

Part 2 of 2

UREA

urea cream

Product Information

Item Code (Source)	3005361109455
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	17 g in 85 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	3005361109455	1 in 1 BOX		
1		85 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
unapproved drug other		10/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/06/2023	

Labeler - V2 Pharma, LLC (102457346)

Establishment

Name	Address	ID/FEI	Business Operations
V2 Pharma, LLC		102457346	label(72835-302)

Revised: 1/2023 V2 Pharma, LLC