KETOCONAZOLE- ketoconazole aerosol, foam
Bryant Ranch Prepack

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use KETOCONAZOLE FOAM safely and effectively. See full prescribing information for KETOCONAZOLE FOAM.

KETOCONAZOLE foam, 2%
For topical use
Initial U.S. Approval: 1981

INDICATIONS AND USAGE

Ketoconazole Foam, 2% is indicated for topical treatment of seborrheic dermatitis in immunocompetent patients 12 years of age and older. (1)

Limitations of Use (1)

Safety and efficacy of Ketoconazole Foam, 2% for treatment of fungal infections have not been established. (1)

DOSAGE AND ADMINISTRATION

- Ketoconazole Foam, 2% should be applied to the affected area(s) twice daily for four weeks (2).
- Ketoconazole Foam, 2% is not for ophthalmic, oral, or intravaginal use (2).

DOSAGE FORMS AND STRENGTHS

Foam: 2% ketoconazole in 50 g and 100 g containers. (3)

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

- Ketoconazole Foam, 2% may result in contact sensitization, including photoallergenicity (5.1, 6.2).
- The contents of Ketoconazole Foam, 2% are flammable. Avoid fire, flame, or smoking during and immediately following application. (5.2).

ADVERSE REACTIONS

The most common adverse reactions observed in clinical studies (incidence >1%) were application site burning and application site reaction (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Perrigo at 1-866-634-9120 or www.perrigo.com and FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

Revised: 11/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Ketoconazole Foam, 2% is indicated for the topical treatment of seborrheic dermatitis in immunocompetent patients 12 years of age and older.

Limitations of Use

Safety and efficacy of Ketoconazole Foam, 2% for treatment of fungal infections have not been established.

2 DOSAGE AND ADMINISTRATION

Ketoconazole Foam, 2% should be applied to the affected area(s) twice daily for four weeks.

Hold the container upright, and dispense Ketoconazole Foam, 2% into the cap of the can or other cool surface in an amount sufficient to cover the affected area(s). Dispensing directly onto hands is not recommended, as the foam will begin to melt immediately upon contact with warm skin. Pick up small amounts of Ketoconazole Foam, 2% with the fingertips, and gently massage into the affected area(s) until the foam disappears. For hair-bearing areas, part the hair, so that Ketoconazole Foam, 2% may be applied directly to the skin (rather than on the hair).

Avoid contact with the eyes and other mucous membranes. Ketoconazole Foam, 2% is not for ophthalmic, oral or intravaginal use.

3 DOSAGE FORMS AND STRENGTHS

Ketoconazole Foam, 2% contains 20 mg of ketoconazole, USP per gram, supplied in 50 g and 100 g containers.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Contact Sensitization

Ketoconazole Foam, 2% may result in contact sensitization, including photoallergenicity. *[see Adverse Reactions (6.2)*]

5.2 Flammable Contents

The contents of Ketoconazole Foam, 2% include alcohol and propane/butane, which are flammable. Avoid fire, flame and/or smoking during and immediately following application. Do not puncture and/or incinerate the containers. Do not expose containers to heat and/or store at temperatures above 120°F (49°C).

5.3 Systemic Effects

Hepatitis has been seen with orally administered ketoconazole (1:10,000 reported incidence). Lowered testosterone and ACTH–induced corticosteroid serum levels have been seen with high doses of orally administered ketoconazole. These effects have not been seen with topical ketoconazole.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug, and may not reflect the rates observed in practice. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse reactions that appear to be related to drug use and for approximating rates.

The safety data presented in Table 1 reflect exposure to ketoconazole foam, 2% in 672 subjects, 12 years and older with seborrheic dermatitis. Subjects applied ketoconazole foam, 2% or vehicle foam twice daily for 4 weeks to affected areas on the face, scalp, and/or chest. Adverse reactions occurring in > 1% of subjects are presented in Table 1.

Table 1: Adverse Reactions Reported by >1% Subjects in Clinical Trials

	Ketoconazole Foam, 2%	**Vehicle Foam**

Adverse Reactions	N=672 n (%)	N=497 n (%)
Subjects with an Adverse Reaction	**188 (28%)**	**122 (25%)**
Application site burning	67 (10%)	49 (10%)
Application site reaction	41 (6%)	24 (5%)

Application site reactions that were reported in <1% of subjects were dryness, erythema, irritation, paresthesia, pruritus, rash and warmth.

6.2 Dermal Safety Studies

In a photoallergenicity study, 9 of 53 subjects (17%) had reactions during the challenge period at both the irradiated and non-irradiated sites treated with ketoconazole foam, 2%. Ketoconazole Foam, 2% may cause contact sensitization.

6.3 Postmarketing Experience

The following adverse events have been identified during postmarketing use of ketoconazole foam, 2%:

Gastrointestinal disorders: Cheilitis

General disorders and administration site conditions: Application site pain and application site burn

Skin and subcutaneous tissue disorders: Skin burning sensation and erythema

Because these events 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.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on ketoconazole foam, 2% use in pregnant women to identify a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. No reproductive studies in animals have been performed with ketoconazole foam, 2%. In animal reproduction studies with pregnant mice, rats and rabbits both embryotoxic and developmental effects (structural abnormalities) were observed following oral dosing of ketoconazole during organogenesis. Assuming equivalent systemic absorption of topical and oral ketoconazole doses and a ketoconazole foam, 2% maximum recommended human dose (MRHD) of 8 grams (equivalent to 160 mg ketoconazole), embryotoxic effects were observed at 0.8 to 2.4 times the MRHD and developmental effects were observed at 4.8 times the MRHD *[see Data].*

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

15 to 20%, respectively.

Data

Animal Data

The animal multiples of human exposure calculations are based on body surface area (BSA) comparisons of oral doses administered to animals and a ketoconazole foam, 2% maximum recommended human dose (MRHD) of 8 grams (equivalent to 2.67 mg ketoconazole/kg/day for a 60 kg individual or 98.8 mg ketoconazole/m^2/day).

Embryofetal development studies have been conducted in mice, rats and rabbits with orally administered ketoconazole. When orally administered to mice on gestational days 6 through 18 (covering the period of organogenesis), ketoconazole was embryotoxic (25 mg/kg and higher; 0.8 times the MRHD based on BSA comparisons) with a high incidence of resorptions, increased number of stillbirths and delayed parturition. Delays in maturation were also observed. There was no evidence of maternal toxicity or malformations at up to 50 mg/kg (1.5 times the MRHD based on BSA comparisons). No treatment related developmental effects were observed at 10 mg/kg (0.3 times the MRHD based on BSA comparisons).

In the presence of maternal toxicity in rats, orally administered ketoconazole was both embryotoxic (40 mg/kg and higher; 2.4 times the MRHD based on BSA comparisons), including increased resorbed fetuses and stillbirths, and teratogenic (80 mg/kg and higher; 4.8 times the MRHD based on BSA comparisons), including syndactylia, oligodactylia, waved ribs and cleft palate. Additionally, 100 mg/kg (6 times the MRHD based on BSA comparisons) ketoconazole orally administered on a single day during gestation (gestational days 9 through 12) was embryotoxic (increased resorptions). This same oral dose given on gestation day 12, 13, 14 or 15 induced external malformations including cleft palate, micromelia and digital anomalies (brachydactyly, ectrodactyly, syndactyly).

In pregnant rabbits orally administered ketoconazole, evidence of embryotoxicity (increased resorptions) was observed at 10 mg/kg (1.2 times the MRHD based on BSA comparisons) and higher and an increased incidence of skeletal abnormalities was observed at 40 mg/kg (4.8 times the MRHD based on BSA comparisons).

8.2 Lactation

Risk Summary

There is no information available on the presence of ketoconazole in human milk, or the effects on the breastfed child, or the effects on milk production after topical application of ketoconazole foam, 2% to women who are breastfeeding. In animal studies ketoconazole was found in milk following oral administration. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for Ketoconazole Foam, 2% and any potential adverse effects on the breastfed infant from Ketoconazole Foam, 2% or from the underlying maternal condition.

8.3 Females and Males of Reproductive Potential

Infertility

In animal fertility studies in rats and dogs, administration of oral doses of ketoconazole between 3-day and 3-month periods resulted in infertility that was reversible *[see*

Nonclinical Toxicology (13.1)].

8.4 Pediatric Use

The safety and effectiveness of ketoconazole foam, 2% in pediatric patients less than 12 years of age have not been established.

Of the 672 subjects treated with ketoconazole foam, 2% in the clinical trials, 44 (7%) were from 12 to 17 years of age. *[See Clinical Studies (14)].*

8.5 Geriatric Use

Of the 672 subjects treated with ketoconazole foam, 2% in the clinical trials, 107 (16%) were 65 years and over.

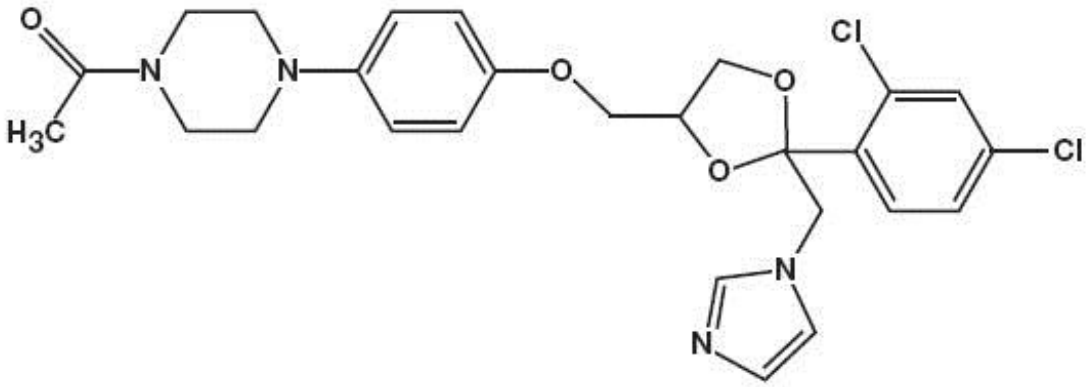
Clinical trials of ketoconazole foam, 2% did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently than younger subjects.

11 DESCRIPTION

Ketoconazole Foam, 2% contains 2% ketoconazole USP, an antifungal agent, in a thermolabile hydroethanolic foam for topical application.

The chemical name for ketoconazole is piperazine, 1-acetyl-4-[4-[[2-(2,4-dichlorophenyl) -2-(1*H*-imidazol-1-ylmethyl)-1, 3-dioxolan-4-yl]methoxy]phenyl]-, *cis*- with the molecular formula $C_{26}H_{28}Cl_2N_4O_4$ and a molecular weight of 531.43.

The following is the chemical structure:



Ketoconazole Foam, 2% contains 20 mg ketoconazole per gram in a thermolabile hydroethanolic foam vehicle consisting of cetyl alcohol, citric acid, ethanol (denatured with *tert*-butyl alcohol and brucine sulfate) 58%, polysorbate 60, potassium citrate, propylene glycol, purified water, and stearyl alcohol pressurized with a hydrocarbon (propane/butane) propellant.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of ketoconazole in the treatment of seborrheic dermatitis is not known.

12.2 Pharmacodynamics

The pharmacodynamics of Ketoconazole Foam, 2% has not been established.

12.3 Pharmacokinetics

In a bioavailability study, 12 subjects with moderate to severe seborrheic dermatitis applied 3 g of ketoconazole foam, 2% twice daily for 4 weeks. Circulating plasma levels of ketoconazole were < 6 ng/mL for a majority of subjects (75%), with a maximum level of 11 ng/mL observed in one subject.

12.4 Microbiology

Ketoconazole is an antifungal agent which inhibits the *in vitro* synthesis of ergosterol, a key sterol in the cell membrane of *Malassezia furfur*. The clinical significance of antifungal activity in the treatment of seborrheic dermatitis is not known.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic or photo-carcinogenic potential of ketoconazole foam, 2%.

In oral carcinogenicity studies in mice (18-months) and rats (24-months) at dose levels of 5, 20 and 80 mg/kg/day ketoconazole was not carcinogenic. The high dose in these studies was approximately 2.4 to 4.8 times the MRHD based on BSA comparisons. In a bacterial reverse mutation assay, ketoconazole did not express any mutagenic potential. In three *in vivo* assays (sister chromatid exchange in humans, dominant lethal and micronucleus tests in mice), ketoconazole did not exhibit any genotoxic potential.

In animal fertility studies, oral ketoconazole impaired both male and female fertility in rats in a dose and duration dependent manner. In females, oral doses up to 40 mg/kg (2.4 times the MRHD based on BSA comparisons) had no effect on fertility, while doses of 75 mg/kg (4.5 times the MRHD based on BSA comparisons) and higher decreased the pregnancy rate and number of implantation sites. In male rats, oral dosing at 200 mg/kg/day (12 times the MRHD based on BSA comparisons) for three days decreased fertility and 400 mg/kg/day (24 times the MRHD based on BSA comparisons) for three days resulted in a complete loss of fertility. When administered for longer durations (up to 3 months), decreased fertility in male rats was observed at doses as low as 24 mg/kg/day (1.4 times the MRHD based on BSA comparisons). In male beagle dogs, an oral dose of 25 mg/kg/day ketoconazole for up to 4 weeks (5.2 times the MRHD based on BSA comparisons) resulted in decreased sperm motility, decreased sperm count, increased abnormal sperm and atrophy of the testes. These effects were reversed subsequent to withdrawal of treatment.

14 CLINICAL STUDIES

The safety and efficacy of ketoconazole foam, 2% were evaluated in a randomized,

double-blind, vehicle-controlled trial in subjects 12 years and older with mild to severe seborrheic dermatitis. In the trial, 427 subjects received ketoconazole foam, 2% and 420 subjects received vehicle foam. Subjects applied ketoconazole foam, 2% or vehicle foam twice daily for 4 weeks to affected areas on the face, scalp, and/or chest. The overall disease severity in terms of erythema, scaling, and induration was assessed at Baseline and week 4 on a 5-point Investigator's Static Global Assessment (ISGA) scale.

Treatment success was defined as achieving a Week 4 (end of treatment) ISGA score of 0 (clear) or 1 (majority of lesions have individual scores for scaling, erythema, and induration that averages 1 [minimal or faint]) and at least two grades of improvement from baseline. The results are presented in Table 2. The database was not large enough to assess whether there were differences in effects in age, gender, or race subgroups.

Table 2: Efficacy Results

Number of Subjects	**Ketoconazole Foam, 2% N = 427 n (%)**	**Vehicle Foam N = 420 n (%)**
Subjects Achieving Treatment Success	239 (56%)	176 (42%)

16 HOW SUPPLIED/STORAGE AND HANDLING

Ketoconazole Foam, 2% contains 20 mg of ketoconazole, USP per gram. The thermolabile hydroethanolic foam is available as follows:

NDC 63629-8677-1

100 g aluminum can

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature].

Do not store under refrigerated conditions.

Contents are flammable. Do not expose containers to heat and/or store at temperatures above 49°C (120°F). Do not store in direct sunlight.

Contents under pressure. Do not puncture and/or incinerate container.

Keep out of reach of children.

Repackaged/Relabeled by:

Bryant Ranch Prepack, Inc.

Burbank, CA 91504

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Patient Package Insert).

Instruct patients on a proper use of Ketoconazole Foam, 2%.

•Avoid fire, flame and/or smoking during and immediately following

application.•Do not apply Ketoconazole Foam, 2% directly to hands. Dispense onto a cool surface, and apply to the affected areas using the fingertips.•Wash their hands after application•Ketoconazole Foam, 2% may cause skin irritation (application site burning and/or reactions)•Instruct a patient to contact a health care provider if the area of application shows signs of increased irritation and report any signs of adverse reactions.

Made in Israel

Manufactured By Perrigo

Yeruham, Israel

Distributed By

Perrigo®

Allegan, MI 49010

www.perrigo.com

Rev 08-18

5K200RCJ3

Instructions for Use

Ketoconazole Foam, 2%

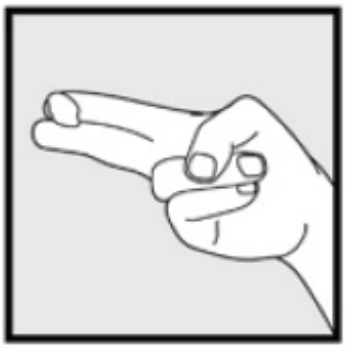
Important Information: Ketoconazole Foam, 2% is for use on the skin only. Do not use Ketoconazole Foam, 2% in your eyes, mouth or vagina.

Step 1: Remove the clear cap from the Ketoconazole Foam, 2% can.

Step 2: Hold the can upright and firmly press the nozzle to dispense Ketoconazole Foam, 2% into the clear cap.•Dispense enough Ketoconazole Foam, 2% to cover the entire affected area(s).

•If the can seems warm or the foam seems runny, run the can under cold water.

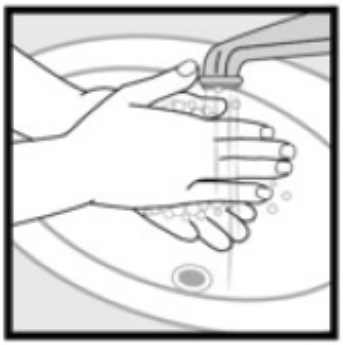
Step 3: Pick up small amounts of Ketoconazole Foam, 2% with your fingertips and gently rub the foam into the affected area(s) until the foam disappears.



•If you are treating areas such as your scalp, part the hair so that Ketoconazole Foam,

2% may be applied directly to the skin.

Step 4: Wash your hands after applying Ketoconazole Foam, 2%.•Throw away any of the unused medicine that is left in the cap.



How should I store Ketoconazole Foam, 2%?

•Store Ketoconazole Foam, 2% at room temperature between 68°F to 77°F (20°C to 25°C).•Do not store the Ketoconazole Foam, 2% can in the refrigerator or freezer.•Keep Ketoconazole Foam, 2% away from heat. Never throw the can into a fire, even if the can is empty.•Do not store Ketoconazole Foam, 2% at temperatures above 120°F (49°C).•Do not break through (puncture) the Ketoconazole Foam, 2% can.

Keep Ketoconazole Foam, 2% and all medicines out of the reach of children.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Rx Only

Made in Israel

Manufactured By Perrigo

Yeruham, Israel

Distributed By

Perrigo®

Allegan, MI 49010

www.perrigo.com

Rev 08-18

PATIENT INFORMATION

Ketoconazole Foam, 2%

Important Information: Ketoconazole Foam, 2% is for use on the skin only. Do not use Ketoconazole Foam, 2% in your eyes, mouth or vagina.

What is Ketoconazole Foam, 2%?

Ketoconazole Foam, 2% is a prescription medicine used on the skin (topical) to treat seborrheic dermatitis in people 12 years of age and older with a normal immune system.

It is not known if Ketoconazole Foam, 2% is safe and effective when used to treat fungal infections.

It is not known if Ketoconazole Foam, 2% is safe and effective in children less than 12 years of age.

Before using Ketoconazole Foam, 2%, tell your healthcare provider about all of your medical conditions, including if you:

•are pregnant or plan to become pregnant. It is not known if Ketoconazole Foam, 2% will harm your unborn baby.•are breastfeeding or plan to breastfeed. It is not known if Ketoconazole Foam, 2% passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with Ketoconazole Foam, 2%.

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

How should I use Ketoconazole Foam, 2%?

Use Ketoconazole Foam, 2% exactly as your healthcare provider tells you to use it. See the detailed “Instructions for Use” at the end of this leaflet for directions about how to apply Ketoconazole Foam, 2% the right way.•Apply Ketoconazole Foam, 2% to the affected skin area(s) 2 times each day for 4 weeks. You should apply enough Ketoconazole Foam, 2% to cover the entire affected area(s).•Talk to your healthcare provider if your skin does not improve after 4 weeks of treatment with Ketoconazole Foam, 2%.•Dispense Ketoconazole Foam, 2% directly into the cap. **Do not** dispense Ketoconazole Foam, 2% directly onto your hands, because the foam will begin to melt on contact with warm skin.•Wash your hands after applying Ketoconazole Foam, 2%.

What should I avoid while using Ketoconazole Foam, 2%?

•**Ketoconazole Foam, 2% is flammable.** Avoid fire, flames, or smoking during and right after you apply Ketoconazole Foam, 2% to your skin.•Avoid getting Ketoconazole Foam, 2% in or near your eyes, mouth, lips or vagina. If you get Ketoconazole Foam, 2% on your lips or in your eyes, mouth or vagina, rinse well with water.

What are the possible side effects of Ketoconazole Foam, 2%?

Ketoconazole Foam, 2% may cause serious side effects, including:

•**Skin irritation at the application area(s), including skin reactions caused by exposure to light.** Tell your healthcare provider if you develop skin irritation during

treatment with Ketoconazole Foam, 2%.

The most common side effects of Ketoconazole Foam, 2% include, burning, dryness, redness, irritation, numbness, itching, rash and warmth at the application site.

These are not all of the possible side effects of Ketoconazole Foam, 2%.

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 Ketoconazole Foam, 2%?

•Store Ketoconazole Foam, 2% at room temperature between 68°F to 77°F (20°C to 25°C).•Do not store the Ketoconazole Foam, 2% can in the refrigerator or freezer.•Keep Ketoconazole Foam, 2% away from heat. Never throw the Ketoconazole Foam, 2% can into a fire, even if the can is empty.•Do not store Ketoconazole Foam, 2% at temperatures above 120°F (49°C).•Do not break through (puncture) the Ketoconazole Foam, 2% can.**Keep Ketoconazole Foam, 2% and all medicines out of the reach of children.**

General information about the safe and effective use of Ketoconazole Foam, 2%.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Ketoconazole Foam, 2% for a condition for which it was not prescribed. Do not give Ketoconazole Foam, 2% to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Ketoconazole Foam, 2% that is written for health professionals.

What are the ingredients in Ketoconazole Foam, 2%?

Active ingredient: ketoconazole

Inactive Ingredients: cetyl alcohol, citric acid, ethanol (denatured with *tert*-butyl alcohol and brucine sulfate) 58%, polysorbate 60, potassium citrate, propylene glycol, purified water, and stearyl alcohol pressurized with a hydrocarbon (propane/butane) propellant

For more information, call Perrigo at 1-866-634-9120

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

Ketoconazole 2%, Foam, #100

Each gram contains: Ketoconazole Foam, 2% contains 20 mg of ketoconazole, USP per gram

Avoid contact with eyes. Keep out of the reach of children. Do not store in diect sunlight.

Do not store in the refrigerator. Store at 20-25°C (68-77°F)[See USP Controlled Room Temperature].

For topical use only. Not for ophthalmic, oral or intravaginal use.

WARNING: Flammable. Avoid fire, flame or smoking during and immediately following application.

NDC 63629-8677-1

Ketoconazole Foam

2%

BRP PHARMACEUTICALS

Rx only

100 grams

Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504 USA

Manufactured by:
Padagis

KETOCONAZOLE

ketoconazole aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63629-8677(NDC:45802-532)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I)	KETOCONAZOLE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
ALCOHOL (UNII: 3K9958V90M)	
BRUCINE SULFATE (UNII: KY7O12XPOQ)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
BUTANE (UNII: 6LV4FOR43R)	
PROPANE (UNII: T75W9911L6)	

Packaging

			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63629-8677-1	1 in 1 CARTON	08/30/2011	
1		100 g in 1 CANISTER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091550	08/30/2011	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-8677) , RELABEL(63629-8677)

Revised: 11/2023 Bryant Ranch Prepack