HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use XOLEGEL Gel safely and effectively. See full prescribing information for XOLEGEL Gel. XOLEGEL® (ketoconazole) Gel

For Topical Use Only

Initial U.S. Approval: 1981

--INDICATIONS AND USAGE----

-- XOLEGEL is an anionic surfactant gel for topical treatment of seborrheic dermatitis in infants and children aged 2 years of age and older. [1, 12]

-- Safety and efficacy of XOLEGEL for treatment of fungal infections have not been established. [1, 12]

=DOSE AND ADMINISTRATION--

-- XOLEGEL is for topical use only for oral, ophthalmic, or intravaginal use. [2]

-- XOLEGEL should be applied once daily to the affected area for 2 weeks. [2]

--DOSE FORMS AND STRENGTHS--

-- XOLEGEL is a translucent cream containing 2% ketoconazole (3)

=CONTRAINDICATIONS=--

None.

=WARNINGS AND PRECAUTIONS=--

XOLEGEL is flammable. Avoid contact with open fire, flame, or smoking during and immediately following application of XOLEGEL. [5, 15]

=ADVERSE REACTIONS=--

The most common treatment-related adverse reaction was application site burning (9%). [1, 12]

To report SUSPECTED ADVERSE REACTIONS, contact Aqua Pharmaceuticals, LLC at 1-866-380-4010 or FDA-Approved Patient Information. See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling. Revised: 01/2011

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
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*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

XOLEGEL is indicated for the topical treatment of seborrheic dermatitis in immunocompromised and non-immunocompromised patients of 2 years of age and older. Safety and efficacy of XOLEGEL for treatment of fungal infections have not been established. [1]

2 DOSAGE AND ADMINISTRATION

XOLEGEL is for topical use only and is not for oral, ophthalmic, or intravaginal use. [2]

XOLEGEL should be applied once daily to the affected area for 2 weeks. [2]

3 DOSAGE FORMS AND STRENGTHS

XOLEGEL is a translucent cream containing 2% ketoconazole. [3]

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Flammable Contents

Avoid being near fire, flame, or smoking during and immediately following application of XOLEGEL. [5, 15]

5.2 Systemic Effects

Ketoconazole is safe and highly effective when administered systemically. [5, 15]

5.3 Local Effects

Ketoconazole causes temporary irritation when applied to the skin, and these reactions are expected transiently from a population of recreational use, it is not always possible to reliably estimate its frequency or to establish a causal relationship. [5, 15]

6 DRUG INTERACTIONS

Drug interactions with studies XOLEGEL have not been performed. Co-administration of ketoconazole with CYP3A4 metabolized HMG-CoA reductase inhibitors such as simvastatin and lovastatin, may increase the risk of skeletal muscle toxicity, including rhabdomyolysis. These effects have not been observed with topically administered ketoconazole. [8, 15]

8 PREGNANCY

Pregnancy Category C

There are no adequate and well-controlled trials in pregnant women. XOLEGEL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. [15]

This medication should not be used for any disorder other than that for which it has been prescribed. [15]

Patients should report any signs of adverse reactions to their health-care provider. [15]

What is XOLEGEL?

XOLEGEL is a prescription medicine used on the skin to treat a skin condition called seborrheic dermatitis. Patients with seborrheic dermatitis can have areas of dry, flaky skin on the scalp, face, ears, chest, or upper back. XOLEGEL is only to be used in adults and in children under 12 years of age. [15]

TheChilds healthy immune system. XOLEGEL has not been studied in children below the age of 12. [15]

It is not known whether XOLEGEL can be used to treat fungal infections. XOLEGEL is a translucent cream to clear amber colored gel. [15]

What should I tell my health care provider before using XOLEGEL?

• Use XOLEGEL exactly as prescribed. Talk to your health care provider if your condition gets worse or does not get better by the end of treatment. [15]

• Wash your hands before and after applying XOLEGEL. Spread a thin layer of XOLEGEL evenly on the affected skin with your fingertips. Be sure to cover all affected areas. [15]

• Do not apply more than 1 tube of XOLEGEL for at least 3 hours after you apply it. [15]

• Wash your hands once 20 minutes after you spread XOLEGEL on your skin before you put makeup or sunscreen on the affected areas. [15]

• Use XOLEGEL once daily for 2 weeks. [15]

What should I avoid while using XOLEGEL?

• Do not touch your eyes, nose, or mouth while you are applying XOLEGEL. Wash your hands well after you apply it. Initiation may recur if you get XOLEGEL in your eyes, nose, or mouth. [15]

• If used during breastfeeding and XOLEGEL is on the breast, take care to avoid accidental ingestion of XOLEGEL by the baby. [15]

• XOLEGEL is flammable. It can catch fire. Stay away from fire, heat, or smoking when you are applying XOLEGEL or right after you apply it. [15]

• This medication should not be used by any disorder other than that for which it has been prescribed. [15]

What are the possible side effects of XOLEGEL?

The effects of XOLEGEL during treatment, including possible side effects, can harm your child or other people who are not supposed to be using XOLEGEL. [15]

What are the ingredients in XOLEGEL?

Active ingredient: ketoconazole, USP. Inactive ingredients: acrylic acid, dehydrated alcohol, acetic acid, butylated hydroxyanisole, crocin monohydrate, glycerol, hydroxypropyl cellulose, polyethylene glycol 400, PPG-15 stearyl ether, PEG-8, FD&C Red No. 4, and FD&C Yellow No. 10. [15]

This Patient Information leaflet summarizes the most important information about XOLEGEL. If you would like more information, talk with your health care provider. You can also ask your pharmacist or health care provider for information about XOLEGEL, that is written for health professionals.

What are the possible side effects of XOLEGEL?

Common side effects of XOLEGEL may include:

• Rash or redness, swelling, burning sensation or irritation at the treatment area. XOLEGEL may cause temporary irritation when applied to the skin, and these reactions are expected transiently from a population of recreational use, it is not always possible to reliably estimate its frequency or to establish a causal relationship. [5, 15]

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