ERTACZO® (sertaconazole nitrate) cream, 2%, is indicated for the topical treatment of interdigital tinea pedis in immunocompetent patients 12 years of age and older caused by Epidermophyton floccosum [see Clinical Studies (14)].

ERTACZO cream, 2%, should be applied to the affected and immediate surrounding area(s) twice daily for 4 weeks. (2)

Not for ophthalmic, oral, or intravaginal use. (2)

DOSAGE FORMS AND STRENGTHS

Cream, 2%. (3)

CONTRAINDICATIONS

None. (4)

ADVERSE REACTIONS

Most common adverse reactions observed in clinical trials (incidence >2%) were contact dermatitis, dry skin, burning skin, application site skin tenderness. (6.1)

Reproduction studies have not been performed with ERTACZO cream, 2%. Sertaconazole nitrate did not produce any evidence of maternal toxicity, embryotoxicity, or teratogenicity in rats and rabbits at an oral dose of 160 mg/kg/day [40 times [rats] and 80 times [rabbits] the maximum recommended human dose based on a body surface area (BSA) comparison].

A reduction in live birth indices and an increase in the number of still-born pups were seen at doses of 80 and 160 mg/kg/day sertaconazole nitrate in an oral peri- and postnatal development study in rats.

8.3 Nursing Mothers

It is not known if sertaconazole is excreted in human milk. Because many drugs are excreted into human milk, caution should be exercised when prescribing ERTACZO cream, 2%, to a nursing woman.

8.4 Pediatric Use

The efficacy and safety of ERTACZO cream, 2%, have not been established in pediatric patients below the age of 12 years.

8.5 Geriatric Use

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

11 DESCRIPTION

ERTACZO (sertaconazole nitrate) cream, 2%, is for topical application. It contains ERTACZO® (sertaconazole nitrate) cream, 2%, is indicated for the topical treatment of interdigital tinea pedis in immunocompetent patients 12 years of age and older caused by Epidermophyton floccosum [see Clinical Studies (14)].

ERTACZO cream, 2%, is an azole antifungal indicated for the topical treatment of interdigital tinea pedis in immunocompetent patients 12 years of age and older caused by Trichophyton rubrum, Trichophyton mentagrophytes, and Epidermophyton floccosum. (1)

ERTACZO cream, 2% should be applied to the affected and immediate surrounding area(s) twice daily for 4 weeks. (2)

Not for ophthalmic, oral, or intravaginal use. (2)
Treatment outcomes are summarized in the table below.

<table>
<thead>
<tr>
<th>Treatment Outcomes as Percent (%) of Total Subjects</th>
<th>Trial 1</th>
<th>Trial 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sertaconazole</td>
<td>Vehicle</td>
<td>Sertaconazole</td>
</tr>
<tr>
<td>Complete Cure* (Primary Efficacy Variable)</td>
<td>13/99 (13.1%)</td>
<td>3/9 2 (3.3%)</td>
</tr>
<tr>
<td>Effective Treatment**</td>
<td>32/99 (32.5%)</td>
<td>11/92 (12.0%)</td>
</tr>
<tr>
<td>Mycological Cure***</td>
<td>49/99 (49.5%)</td>
<td>18/92 (19.6%)</td>
</tr>
</tbody>
</table>

* Complete Cure – Patients who had complete clearing of signs and symptoms and mycological cure.
** Effective Treatment – Patients who had minimal residual signs and symptoms of interdigital tinea pedis and/or onychomycosis were excluded from the trial. Two weeks after completion of therapy (6 weeks after beginning therapy), subjects were evaluated for signs and symptoms related to interdigital tinea pedis.
*** Mycological Cure – Patients who had both negative microscopic KOH preparation and negative fungal culture.

In clinical trials, complete cure in sertaconazole-treated subjects was achieved in 32 of 160 (20%) subjects with Trichophyton rubrum, in 7 of 28 (25%) subjects with Trichophyton mentagrophytes, and in 1 of 13 (15%) subjects with Epidermophyton floccosum.

16 HOW SUPPLIED/DOSAGE AND HANDLING
ERTACZO cream, 2%, is white in color and supplied in tubes in the following sizes:
- 60-gm tube
  [NDC 0187-5115-60]

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
Advertise the patient to read the FDA-approved patient labeling (Patient Information).

The patient should be instructed to:
- Use ERTACZO cream, 2%, as directed by the physician. The hands should be washed after applying the medication to the affected area(s). Avoid contact with the eyes, mouth, vagina, and other mucous membranes exposed to fungi.
- Dry the affected area(s) thoroughly before application, if you wish to use ERTACZO cream, 2%, after bathing.
- Use the medication for the full treatment time recommended by the physician, even though symptoms may have improved.
- Inform the physician if the area of application shows signs of increased irritation, redness, itching, burning, blistering, swelling, or oozing.
- Avoid the use of occlusive dressings unless otherwise directed by the physician.
- Do not use this medication for any disorder other than that for which it was prescribed.

What are the possible side effects of ERTACZO cream?
-The most common side effects of ERTACZO cream include: redness, itching, dry skin, burning, blistering, swelling, drainage, and skin tenderness at the treated skin areas. Tell your healthcare provider if you have any of these skin reactions. These are not all the possible side effects of ERTACZO 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 ERTACZO cream?
- Store ERTACZO cream at room temperature between 68° to 77°F (20° to 25°C).
- Keep ERTACZO cream and all medicines out of reach of children.

What is ERTACZO cream?
ERTACZO cream is a prescription medicine used on the skin (topical) to treat athlete's foot (that is between the toes (interdigital tinea pedis) in people 12 years of age and older with normal immune systems.

It is not known if ERTACZO cream is safe and effective in children under 12 years of age.

What should I tell my healthcare provider before using ERTACZO cream?
Before using ERTACZO cream, tell your healthcare provider about all of your medical conditions, including if you:
- have any allergies
- are pregnant or plan to become pregnant. It is not known if ERTACZO cream will harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if ERTACZO cream passes into your breast milk.

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

How should I use ERTACZO cream?
- Use ERTACZO cream exactly as your healthcare provider tells you to use it.
- Use ERTACZO cream for the full treatment time, even if your symptoms improve.
- If you take a bath or shower, dry the affected skin areas well before you apply ERTACZO cream.
- Apply ERTACZO cream 2 times a day for 4 weeks to the affected skin areas between your toes and to the healthy skin around the affected areas.
- Wash your hands after you apply ERTACZO cream.
- Do not cover the treated skin areas with bandages unless your healthcare provider tells you to.

What are the ingredients in ERTACZO cream?
- Inactive ingredients: sertaconazole nitrate
- Inactive ingredients: ethylene glycol, glyceryl isostearate, glycolized saturated glyceraldehydes, light mineral oil, methylparaben, polyethylene glycol palmitostearate, polyoxyethylene saturated glyceraldehydes, purified water, and sorbic acid.

VEALENT
Manufactured for:
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San Antonio, TX 78215

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