SERTACIDE Cream (Sertaconazole nitrate)

**Composition**

**SERTACIDE Cream**

Sertaconazole Nitrate Ph. Eur .................. 2.0% w/w

In a cream base ..................................... q.s.

Benzyl alcohol IP............................... 1.0% w/w (As preservative)

**Dosage Form**

Cream

**Pharmacology**

**Pharmacodynamics**

Sertaconazole is an antifungal that belongs to the imidazole class of antifungals and exhibits activity similar to that of other imidazoles. It is believed that they act primarily by inhibiting the cytochrome P450-dependent synthesis of ergosterol. Ergosterol is a key component of the cell membrane of fungi, and lack of this component leads to fungal cell injury, primarily by leakage of key constituents in the cytoplasm from the cell.

In clinical infections, sertaconazole nitrate has been shown to be active against isolates of dermatophytes (e.g. *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*).

Additionally sertaconazole has demonstrated broad spectrum of antifungal activity both *in vitro* and in experimental *in vivo* models, which includes opportunistic filamentous fungi (e.g. *Aspergillus*, *Alternaria*, *Scopulariopsis*, *Fusarium*), and pathogenic yeasts such as *Malassezia furfur*, *Candida albicans*, *Candida tropicalis*, *Torulopsis*, and *trichosporon*. Activity has also been observed against *Trichomonas* and some gram-positive organisms (staphylococci, streptococci).

**Pharmacokinetics**

Sertaconazole achieves high epidermal concentrations following cutaneous application. Cutaneous absorption was 64% of the dose at 12 hours and 72% at 24 hours following topical application of 2%
cream. Systemic absorption is minimal to undetectable. The drug was undetectable in serum or urine samples from healthy subjects for up to 24 hours with 16 g of sertaconazole 2% cream.

In a multiple-dose pharmacokinetic study that included 5 male patients with interdigital tinea pedis (range of diseased area, 42-140 cm\(^2\); mean, 93 cm\(^2\)), sertaconazole nitrate cream, 2%, was topically applied to the diseased skin (0.5 grams sertaconazole nitrate per 100 cm\(^2\)) every 12 hours for a total of 13 doses. Sertaconazole concentrations in plasma, measured by serial blood sampling for 72 hours after the thirteenth dose, were below the limit of quantitation (2.5 ng/mL) of the analytical method used.

### Indications

**SERTACIDE Cream**, 2%, is indicated for the topical treatment of superficial fungal infections of skin including tinea pedis.

### Dosage And Administration

In the treatment of superficial fungal infections of skin **SERTACIDE Cream**, 2%, should be applied twice daily for 2 weeks.

In the treatment of interdigital tinea pedis, **SERTACIDE Cream**, 2%, should be applied twice daily for 4 weeks.

Sufficient **SERTACIDE Cream**, 2%, should be applied to cover both, the affected area as well as the immediately surrounding healthy skin. If a patient shows no clinical improvement 2 weeks after the treatment period, the diagnosis should be reviewed.

### Contraindications

**SERTACIDE Cream**, 2%, is contraindicated in patients having a known or suspected sensitivity to sertaconazole nitrate or any of its components or to other imidazoles.

### Warnings And Precautions

**SERTACIDE Cream**, 2%, is not for oral, ophthalmic, or intravaginal use.

**SERTACIDE Cream**, 2%, is intended for topical dermatological use only. If irritation or sensitivity develops with the use of **SERTACIDE Cream**, 2%, treatment should be discontinued and appropriate therapy instituted. Diagnosis of the disease should be confirmed either by direct microscopic examination of infected superficial epidermal tissue in a solution of potassium hydroxide or by culture on an appropriate medium.

Physicians should exercise caution when prescribing **SERTACIDE Cream**, 2%, to patients known to be sensitive to imidazole antifungal, since cross-reactivity may occur.

### Drug Interactions

Potential interactions between sertaconazole nitrate cream, 2%, and other drugs, or laboratory tests have not been systematically evaluated.
**Pregnancy Category C**

There are no adequate and well-controlled studies that have been conducted on topically applied sertaconazole nitrate cream 2%, in pregnant women.

Oral reproduction studies in rats and rabbits did not produce any evidence of maternal toxicity, embryotoxicity or teratogenicity of sertaconazole nitrate at an oral dose of 160mg/kg/day (40 times in rats and 80 times in rabbits compared to the maximum recommended human dose on a body surface area basis).

Because animal reproduction studies are not always predictive of human response, SERTACIDE Cream, 2%, should be used during pregnancy only if clearly needed.

**Lactation**

It is not known if sertaconazole is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when prescribing SERTACIDE Cream, 2%, to a nursing mother.

** Pediatric Use**

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

**Geriatric Use**

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

**Undesirable Effects**

In clinical trials, cutaneous adverse events occurred in 7 of 297 (2%) patients (severe in two cases) receiving sertaconazole nitrate cream, 2%, and in 7 of 291 (2%) patients (severe in two cases) receiving vehicle. The reported cutaneous adverse events included contact dermatitis, dry skin, burning skin, application site reaction, and skin tenderness.

In a dermal sensitization study, 8 of 202 evaluable patients tested with sertaconazole nitrate cream, 2%, and 4 of 202 evaluable patients tested with vehicle, exhibited a slight erythematous reaction in the challenge phase. There was no evidence of cumulative irritation or contact sensitization in a repeated insult patch test involving 202 healthy volunteers.

In non-U.S. post-marketing surveillance for sertaconazole nitrate cream, 2%, the cutaneous adverse events reported were contact dermatitis, erythema, pruritus, vesiculation, desquamation, and hyperpigmentation.
Overdosage

Overdose with sertaconazole nitrate cream, 2%, has not been reported to date.

Shelf Life

2 years

Storage And Handling Instructions

Store in a cool place. Do not freeze

Packaging Information

SERTACIDE Cream: Tube of 10 g

Last Updated: August 2012
Last Reviewed: May 2016

SERTACIDE Cream

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