

# Sertazol<sup>®</sup> Cream

Sertaconazole Nitrate 2%

## COMPOSITION:

Sertazol<sup>®</sup> Cream : Each gram cream contains Sertaconazole Nitrate BP 20 mg.

## PHARMACOLOGY:

Sertaconazole is an antifungal that belongs to the imidazole class of antifungals. While the exact mechanism of action of this class of antifungals is not known, 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. Lack of this component leads to fungal cell injury primarily by leakage of key constituents in the cytoplasm from the cell.

## INDICATION:

Sertazol<sup>®</sup> Cream is 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*.

## DOSE & ADMINISTRATION:

In the treatment of interdigital tinea pedis, Sertazol<sup>®</sup> Cream should be applied twice daily for 4 weeks. Sufficient amount of Sertazol<sup>®</sup> Cream should be applied to cover both the affected areas between the toes and the immediately surrounding healthy skin of patients with interdigital tinea pedis. Not for ophthalmic, oral, or intravaginal use.

## CONTRA-INDICATION:

Sertazol<sup>®</sup> Cream is contraindicated in patients who have a known or suspected sensitivity to sertaconazole nitrate or any of its components or to other imidazoles.

## WARNING AND PRECAUTION:

Sertazol<sup>®</sup> Cream is for use on the skin only. If irritation develops, treatment should be discontinued and appropriate therapy instituted. Physicians should exercise caution when prescribing Sertazol<sup>®</sup> Cream to patients known to be sensitive to azole antifungals, since cross-reactivity may occur.

## SIDE EFFECTS:

Most common adverse reactions observed in clinical trials were contact dermatitis, dry skin, burning skin, application site skin tenderness.

## USE IN PREGNANCY & LACTATION:

Pregnancy Category C. There are no adequate & well-controlled studies conducted with Sertazol<sup>®</sup> Cream in pregnant women. Sertazol<sup>®</sup> Cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known if Sertazol<sup>®</sup> Cream is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when prescribing Sertazol<sup>®</sup> Cream to a nursing woman.

## USE IN CHILDREN & ADOLESCENTS:

Pediatric Use The efficacy and safety of Sertazol<sup>®</sup> Cream have not been established in pediatric patients below the age of 12 years. Geriatric Use Clinical trials of Sertazol<sup>®</sup> Cream did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

## DRUG INTERACTION:

Potential interactions between Sertazol<sup>®</sup> Cream and other drugs have not been systematically evaluated.

## OVERDOSE:

Overdosage with Sertazol<sup>®</sup> Cream has not been reported to date.

## STORAGE:

Store in a dry and cool place below 30°C temperature and keep away from light and moisture. Keep out of reach of children.

## PACKING:

Sertazol<sup>®</sup> Cream: Each box contains 20 gm cream in a tube.



Manufactured by

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