

## SERIVA

**For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.**  
Abbreviated Prescribing information for SERIVA (Sertaconazole Nitrate Cream I.P. 2% w/w)

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### PHARMACOLOGICAL PROPERTIES:

**Mechanism of action:** The mechanism of antifungal action of sertaconazole nitrate is similar to that of other imidazoles, in that it inhibits fungal biosynthesis of ergosterol, resulting in disorganization of the fungal plasma membrane and altered permeability.

**DOSAGE AND ADMINISTRATION:** As directed by the physician.

**CONTRAINDICATION:** In patients who have a known or suspected sensitivity to sertaconazole nitrate or any of its components or to other imidazoles.

**WARNINGS & PRECAUTIONS:** *Warning:* Sertaconazole nitrate cream, 2%, is not indicated for ophthalmic, oral or intravaginal use. *Precautions:* Sertaconazole nitrate cream, 2%, is for use on the skin only. If irritation or sensitivity develops with the use of SERIVA, 2%, treatment should be discontinued and appropriate therapy instituted. Physicians should exercise caution when prescribing SERIVA, 2%, to patients known to be sensitive to imidazole antifungals, since cross-reactivity may occur.

**DRUG INTERACTION:** Potential interactions between Sertaconazole nitrate Cream, 2%, and other drugs or laboratory tests have not been systematically evaluated.

**ADVERSE REACTIONS:** In clinical trials, cutaneous adverse events occurred in 7 of 297 (2%) patients (2 of them severe) receiving Sertaconazole nitrate cream, 2% and in 7 of 291 (2%) patients (2 of them severe) receiving vehicle. These 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 post-marketing surveillance for sertaconazole nitrate cream, 2%, the following cutaneous adverse events were reported: contact dermatitis, erythema, pruritus, vesiculation, desquamation, and hyperpigmentation.

### Marketed BY:

Manufactured in India by:

Glenmark Pharmaceuticals Ltd.

Glenmark House, HDO-Corp Bldg, Wing-A, B.D.Sawant Marg,

Chakala, Andheri (East) – Mumbai – 400099.

At: Village – Saini Majra, Ropar Road, Nalagarh, Dist. Solan (H.P.) – 174101.

**IN/ SERIVA CREAM 2% w/w/Dec 20/02/ABPI**

(Additional information is available on request)