

PIL – Proposed Pristine

ZALAIN VAGINAL SUPPOSITORY 300 MG

Pharmacological Action

Sertaconazole is a new topical broad-spectrum antifungal. It acts against pathogenic yeasts (*Candida albicans*, *C. tropicalis*, *C. spp.*, *Pityrosporum orbiculare*), dermatophytes (*Trichophyton*, *Epidermophyton* and *Microsporum*) and gram-positive bacteria (*Staphylococcus* and *Streptococcus*).

Composition

Per vaginal suppository

Sertaconazole nitrate	0.3g
Excipients, q.s.	3.0g

Indications

Local treatment of vaginal candidiasis

Dosage

One vaginal suppository in the evening, to be inserted deeply into the vagina, preferably while lying down. If symptoms persist, repeat with a second vaginal suppository seven days after the first insertion.

Contraindications

Known hypersensitivity to any imidazole antimycotic or to any of the excipients.
Concomitant use of contraceptive diaphragm.

Interactions

The concomitant use with contraceptive diaphragm may cause the sheath or diaphragm to break during the insertion of the vaginal suppository (See Contraindications)
The concomitant use with local spermicidal contraception is not recommended as the spermicide may be inactivated.

Precautions during treatment

Upon confirmation of diagnosis, etiological factors causing the infection should be investigated, and patients should be counseled so as to avoid future recurrence.

Use soaps which are of neutral or alkaline pH when washing the outer genitals, as lower pH favours candidiasis.

Practise good personal hygiene; wear preferably cotton underclothes; avoid vaginal douches.

If mycosis occurs on the vulvar or perianal areas, apply an antifungal cream on these areas.

Consider the treatment of sexual partner wherever applicable for each specific case.

Do not interrupt treatment during menstruation.

Concomitant treatment for any bacterial infection associated with candidiasis is advisable.

In case of local intolerance or allergic reaction, stop treatment.

Side-effects

With the absence of systemic absorption of sertaconazole after the application of a vaginal suppository, side effects are unlikely to occur.

However, there may be the rare occasions of allergic reactions and the manifestation of local intolerance such as a feeling of burning sensation or exacerbation of pruritus which generally disappears on discontinuation of treatment.

Use during pregnancy and lactation

No embryotoxic or teratogenic effects have been observed in animal studies.

No teratogenic and lactation studies have been done in humans.

Storage

Keep in a cool, dry place with temperature below 30°C.

Presentation

Zalain Vaginal Suppository 300mg x 1's

Keep out of reach of children

Product Owner:

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