

YSP ECONAZOLE NITRATE PESSARY 150mg

Ingredient(s):

Each pessary contains:

Econazole Nitrate 150mg
Benzethonium chloride (as preservative) 1mg

Pharmacodynamics:

Econazole is an imidazole antifungal agent. It acts by inhibiting the biosynthesis of ergosterol or other sterols, damaging the fungal cell membrane and altering its permeability. As a result, loss of essential intracellular elements occurs.

Econazole also inhibits the biosynthesis of triglycerides and phospholipids by fungi. In addition, econazole inhibits oxidative and peroxidative enzyme activity, resulting in intracellular build up of toxic concentrations of hydrogen peroxide, which may contribute to the deterioration of subcellular organelles and cellular necrosis. In *Candida albicans*, econazole inhibits transformation of blastopores into invasive mycelial form.

Econazole exhibits antifungal activity against a wide variety of fungi, including dermatophytes, pathogenic yeasts, and moulds. Susceptible pathogenic organisms include *C. albicans* and other *Candida* species, *T. rubrum*, *T. metagrophytes*, *E. floccosum*, and *M. furfur*.

Pharmacokinetics:

Following vaginal application of econazole nitrate, about 7% of the dose was absorbed with the maximum plasma level occurring within 24 to 48 hours.

In rabbits, the highest concentration of econazole occurred in the liver, adrenals and gastrointestinal tract 24 hours after vaginal administration.

Econazole is believed to be metabolized principally by oxidative O-dealkylation and oxidative N-dealkylation. The major metabolite is α -(2,4-dichlorophenyl)-1H-imidazole ethanol, derived by O-dealkylation. Approximately 40% of an oral dose is recovered in the urine and 30% in the feces over 5 days.

Indication(s):

Local treatment of vulvovaginal candidiasis (Moniliasis).

Dosage and Administration:

With the patient in the supine position, insert 1 pessary high into the vagina at bedtime for 3 consecutive days. To be dispensed on physician's prescription.

Route of Administration:

Intravaginal administration

Contraindication(s):

Hypersensitivity to econazole or any of the product's component.

Precaution(s) / Warning(s):

1. If marked irritation or sensitization occurs during intravaginal use, discontinue econazole therapy.
2. Intractable candidiasis may be presenting symptoms of unrecognized diabetes. Appropriate urine/blood studies may be indicated in patients not responding to treatment.
3. During the vaginal treatment period, it may be advisable to instruct the patient to abstain from intercourse or, alternatively, to recommend the use of a condom.
4. Pregnancy: Since econazole is absorbed in small amounts from the human vagina, it should not be used in the first trimester of pregnancy unless deemed essential to the patient's welfare.

Interaction with Other Medicament(s):

None has been reported.

Side Effect(s) / Adverse Reaction(s):

Econazole nitrate is usually well tolerated. Adverse effects are limited to occasional local skin irritations manifested by erythema, pruritus, and burning or stinging sensation; cessation of therapy is rarely warranted.

Symptoms and Treatment for Overdosage, and Antidote(s):

Overdosage of econazole in humans has not been reported to date.

Shelf-Life:

3 years from the date of manufacture.

Storage Condition(s):

Store at temperature below 25°C. Protect from light and moisture.

Product Description & Packing(s):

White to off-white spindle shaped pessary.

10 pessaries per strip, 5 strips per box.

10 pessaries per strip, 10 strips per box.

3 pessaries per strip, 1 strip per box.

YSP ECONAZOLE NITRATE PESARI 150mg

Bahan Aktif:

Setiap pesari mengandungi:

Econazole Nitrate 150mg

Benzethonium chloride (as preservative) 1mg

Indikasi:

Rawatan kandidiasis vulvovaginal (Moniliasis).

Dos:

Masukkan satu pesari ke dalam vagina tiap-tiap malam berturut-turut tiga hari, dengan pesakit dalam keadaan terlentang. Digunakan seperti yang diarahkan oleh doktor.



Manufacturer and Product Registration Holder:
Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)
Lot 3, 5, 7, 12 & 14, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru Bangi,
43000 Kajang, Selangor, Malaysia.
Ordering Line: 1 800 88 3027
Product Info: 1 800 88 3679