

Ecorex®

Econazole Nitrate

Composition:

Econazole Nitrate

Excipients: Vaginal cream: Isopropyl myristate, stearic acid, cetyl alcohol, polyoxyl 40 stearate, butylhydroxytoluene, methyl parahydroxybenzoate, sodium laurilsulfate, propylene glycol and purified water.

Vaginal ovules: Colloidal anhydrous silica and hard fat.

Properties:

Ecorex® is a triazole fungicide, designated to be used as gynecological-topical anti-infective.

Econazole nitrate is poorly absorbed after vaginal application.

Mechanism of action:

Econazole nitrate acts by damaging cell membranes. The permeability of the fungal cell is increased. Sub-cellular membranes in the cytoplasm are damaged. The site of action is most probably the unsaturated fatty acid acyl moiety of membrane phospholipids.

Antimicrobial activity:

Econazole nitrate has a broad spectrum of antimycotic activity, including: Dermatophytes (e.g. *Trichophyton rubrum*, *T. mentagrophytes*, *T. tonsurans*, *Microsporum canis*, *M. audouinii*, *M. gypsum* and *Epidermophyton floccosum*), yeasts (e.g. *Candida albicans*, *Malassezia furfur* (the organism responsible for Tinea versicolor)), and molds. A clinically relevant action against gram-positive bacteria has also been found.

Indications:

Ecorex® is indicated for the treatment of vulvovaginal mycoses and mycotic balanitis.

Dosage and administration:

Females

Ecorex® 150 mg Ovules: One ovule is inserted high into the vagina once daily at bedtime for three consecutive days. In event of relapse or if the culture examination one week after treatment is positive, a second round of treatment should be undertaken.

Ecorex® 50 mg Ovules: One ovule is inserted high into the vagina once daily at bedtime for not less than 14 consecutive days. Treatment should be continued for the full course even if the subjective symptoms (proteins, leucorrhea) disappear.

Ecorex® Vaginal Cream: 1 applicatorful is administered intravaginally once daily at bedtime for not less than 14 consecutive days. Treatment should be continued for the full course even if the subjective symptoms (pruritus, leucorrhea) disappear.

Male-sexual partners

Apply the cream to the glans and prepuce once a day for 14 consecutive days.

* It is necessary to treat the partner to avoid "ping-pong" infections.

Contraindications:

Hypersensitivity to econazole nitrate or any of the ingredients.

Drug interactions:

None known.

Warnings:

- Econazole nitrate may damage rubber contraceptive diaphragms or latex condoms and decrease their efficacy.
- Econazole nitrate should not be used in conjunction with other internal or external treatment of the genitalia.
- If marked irritation or sensitivity occurs, the treatment should be discontinued.
- Patients with sensitivity to imidazole have also reported sensitivity to econazole nitrate.

vity to econazole nitrate.

- Not for ophthalmic or oral use.

Precautions:

Pregnancy: Category C; econazole nitrate should not be used in the first trimester of pregnancy unless the physician considers it essential to the welfare of the patient. It may be used during the second and third trimester if the potential benefit outweighs the possible risks to the fetus.

Lactation: It is not known whether econazole nitrate is excreted in human milk. Caution should be exercised when used by nursing mothers.

Adverse effects:

Rare reports of adverse events such as: Irritation, redness, itching and burning.

Overdosage:

Not reported. In the event of accidental ingestion, nausea, vomiting and diarrhea may occur. If necessary treat symptomatically.

Information for the patient:

- Use of the applicator of **Ecorex®** vaginal cream:
 - Remove the cap on the tube and screw on the applicator.
 - Fill the applicator by squeezing the tube.
 - Remove the applicator from the tube and replace the cap.
 - Insert the filled applicator deep into the vagina and empty it by pressing the plunger.
 - The applicator should be cleaned with soap and washed with water thoroughly before use.
- Econazole nitrate dose not influence the ability to drive and to use machines.

Presentations:

Ecorex® 150 mg Ovules: Each ovule contains 150 mg Econazole Nitrate USP in packs of 3 ovules.

Ecorex® 50 mg Ovules: Each ovule contains 50 mg Econazole Nitrate USP in packs of 15 ovules.

Ecorex® Vaginal Cream: Each gram of the cream contains 10 mg Econazole Nitrate USP in a tube of 78 g.

Storage conditions:

Store up to 30°C.

- * Some presentations may not be available in certain countries.

(This is a medicament - keep medicaments out of the reach of children)

* Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
* Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
* The doctor and the pharmacist are experts in medicine, its benefits and risks.
* Do not by yourself interrupt the period of treatment prescribed for you.
* Do not repeat the same prescription without consulting your doctor.

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