

IFENEC®

1% vaginal cream, ovules ECONAZOLE

COMPOSITION

Vaginal cream - 100 g of cream contain: Econazole nitrate 1.0 g. Excipients: Benzoic Acid, Hard fats, Butylated Hydroxyanisole, Liquid paraffin, Polyoxoethylenglycol palmitate stearate, Purified water.

Vaginal ovules - Each vaginal ovule contains: Econazole nitrate 150 mg. Excipients: Semi-synthetic glycerides.

PHARMACOTHERAPEUTIC CATEGORY - Antimycotic for topical treatment in vulvo-vaginal infections even when complicated by gram-positive bacterial superinfections.

INDICATIONS - Mycotic vulvo-vaginal infections even when complicated by gram-positive bacterial superinfections.

CONTRA-INDICATIONS - Known individual hypersensitivity towards the product's components.

PRECAUTIONS FOR THE USE - During the first trimester of pregnancy the product should be used when clearly necessary, and under direct medical supervision.

INTERACTIONS - Clinical trials and extensive therapeutic use did not show any interactions or incompatibilities with other medicaments.

It is advisable to inform the physician of any simultaneous assumption of other drugs.

SPECIAL WARNINGS - No known effects on vigilance (driving vehicles or operating machinery).

POSOLOGY AND METHOD OF ADMINISTRATION

Vaginal cream - In the evening before going to bed, deeply insert into the vagina, preferably lying down, the entire amount (around 5cc) of vaginal cream contained in a filled applicator, each day for 15-day period; the treatment should be continued even after the disappearance of prurigo and leucorrhoea.

150-mg vaginal ovules - In the evening before going to bed, and for 3 consecutive days, insert into the vagina, preferably lying down, a vaginal ovule. A second therapeutic cycle should be carried out in the event of a recurrence or when a control culture is found to be positive even after a week of therapy.

It is recommended that the partner be concomitantly treated with Ifenec vaginal cream. Following an accurate cleansing with warm water, the cream is applied on genitalia once daily for 15 consecutive days. (NOTE: Ifenec does not stain the underwear).

OVERDOSAGE - To date, there have been no reports of overdosage in man.

UNDESIRABLE EFFECTS - In hypersensitive patients local mild irritations or sensitisation phenomena may occur; as well as pelvic cramps, cutaneous eruptions and headache. In these events the physician should consider the opportunity to discontinue the administration of the product and adopt another therapy. If, after administration, side effects not reported in this leaflet appear, they should be communicated to the physician.

For further information on the product, please refer to your pharmacist.

CAUTION: Do not use the medicine after the expiry date marked on the carton.

STORAGE - Store at temperature not exceeding 25°C.

PACKAGING - **1% Vaginal cream:** tube of 78 g with applicator. **Vaginal ovules:** 3 - 6 ovules 150 mg.

KEEP OUT OF THE REACH OF CHILDREN

Manufacturer: **Italfarmaco S.p.A.**

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