Gyno-Travogen Ovule

Qualitative and Quantitative Composition
1 ovule contains 600 mg isoconazole nitrate

Indications
Gyno-Travogen suppository is indicated in fungal infections of the vagina including mixed infections with gram-positive bacteria.

Dosage and method of administration
Dosage
1-day treatment: 1 vaginal suppository (containing 600 mg isoconazole) is used as one single dose.

Method of administration
The ovulum must be inserted deep into the vagina. This is best done in the lying position in the evening before going to sleep. The enclosed finger stalls should be used to assist insertion. The treatment is not to be carried out during menstruation.

Contraindications
Hypersensitivity to the active substance or to any of the excipients.

Special warnings and precautions for use
For treatment of the external genital region or for simultaneous prophylactic treatment of the partner it is recommended to use Travogen cream.

During treatment and in the following week vaginal douching should be avoided.

To avoid renewed infection, personal linen (face-cloth, towels, underwear – preferably of cotton) should be changed daily and boiled.

Some of the excipients in Gyno-Travogen suppository may reduce the effectiveness of latex products such as condoms and diaphragms.

Interaction with other medicinal products and other forms of interaction
No interaction studies have been performed.

Concomitant treatment with intra-vaginal isoconazole nitrate and coumarin type anticoagulants (e.g., warfarin) might lead to increased plasma levels of the anticoagulant.

Fertility, pregnancy and lactation
Pregnancy
The experience with the use of isoconazole-containing preparations during pregnancy does not indicate a teratogenic risk in humans.

Lactation
It is unknown whether isoconazole/isoconazole nitrate is excreted in human milk. A risk of exposure to the suckling child cannot be excluded.

Fertility
Preclinical data did not indicate any risk on fertility.

Undesirable effects
Summary of the safety profile
In clinical studies, most frequently observed adverse reactions included application site irritation, application site burning and application site pruritus with Gyno-Travogen formulations.

Tabulated list of adverse reactions
Frequencies of adverse reactions observed in clinical studies and given in the table below are defined according to the MedDRA frequency convention: common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); frequency not known (cannot be estimated from the available data). The ADRs identified only during post-marketing surveillance, and for which a frequency could not be estimated, are listed under "not known".

System Organ Class	**Frequencies of Reported Events Observed in Clinical Studies Isoconazole Nitrate Cream for vaginal indications**			**Identified during post-approval use of Isoconazole for vaginal indications**
	Common	**Uncommon**	**Rare**	**Frequency not known**
Gastrointestinal disorders		nausea		
General disorders and administration site reaction	application site burning application site pruritus application site irritation		application site eczema	application site vesicles
Nervous system disorders		dizziness headache		
Reproductive system and breast disorders		vaginal discharge		vulvovaginal pain vulvovaginal swelling vulvovaginal erythema
Immune system disorders				application site hypersensitivity

Pharmacological Properties
Pharmacodynamic Properties
Gyno-Travogen is effective both against dermatophytes, yeasts and yeast-like fungi and moulds and against gram-positive bacteria.

Incompatibilities
Not applicable.

Storage conditions
Store below 30 °C
No special requirements

Presentation
1 ovule and 2 finger stalls

Manufacturer
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