

Fentizol[®] VT 600

Fenticonazole Nitrate BP

COMPOSITION

Each vaginal tablet contains Fenticonazole Nitrate BP 600 mg.

PHARMACOLOGY

Fenticonazole is a potent broad-spectrum antimycotic agent. It exerts fungistatic and fungicidal actions on dermatophytes, pathogenic yeasts, dimorphous fungi and molds. In addition, Fenticonazole is active against gram-positive bacteria and is therefore indicated in mycoses associated with bacterial super infections.

Fenticonazole is also active, both in vitro and in vivo, against *Trichomonas vaginalis*.

Fenticonazole exerts its unique antimycotic action through following three ways:

- Inhibiting the biosynthesis of ergosterol leading to the damage of fungal cell membrane.
- Causing certain changes in oxidative and peroxidative enzyme activities inside fungal cell. This leads to an intracellular build-up of toxic concentrations of hydrogen peroxide resulting in cell necrosis.
- Inhibiting the secretion of aspartic proteases (responsible for pathogenicity) by *Candida albicans*.

The amount of Fenticonazole absorbed by the transcutaneous route is negligible.

INDICATION

Fentizol[®] VT 600 is indicated for:

- Genital candidiasis (vulvovaginitis, colpitis, infectious fluor)
- Trichomoniasis
- Vaginal infections sustained by mixed forms of *Trichomonas vaginalis* and *Candida albicans*.

DOSAGE AND ADMINISTRATION

Fentizol[®] VT 600 is used in *Trichomonas* or mixed (*Trichomonas* and *Candida albicans*) vaginal infections:

One 600 mg VT (followed by a second administration 24 hours later, if necessary).

Candida albicans infections:

One single 600 mg VT administration in the evening. Should the symptoms persist, a second administration may be repeated after three days.

The tablet must be introduced deep into the vagina and pushed well up to the fornix. To avoid re-infection, it is recommended that the partner undergoes concurrent treatment with Fenticonazole Cream or similar Azole Cream.

OVERDOSE & PRECAUTION

As systemic absorption is very low, the possibility of overdose is rare. In case of accidental swallowing, emesis or gastric lavage should be done. After vomiting, active charcoal along with water/lemon juice and laxative should be given to the patient.

SIDE EFFECTS

After intravaginal administration slight transient burning (which usually disappears rapidly) may occasionally happen. Prolonged topical application may cause sensitisation reactions.

Fenticonazole is generally well tolerated by the mucous membranes; only exceptionally mild and transient erythematous reactions have been reported. After topical application or intravaginal administration, a slight burning sensation may occur, usually subsiding soon. Should more persistent irritation occur or resistant micro-organism develop, suspend the treatment and seek the doctor's advice. Due to poor absorption of Fenticonazole, no systemic effects should occur, provided the above instructions are carefully observed.

CONTRAINDICATION

Contraindicated in case of hypersensitivity to Fenticonazole and other Imidazoles.

USE IN PREGNANCY AND LACTATION

It is not recommended in pregnancy. Safety in breastfeeding has not been established.

USE IN CHILDREN

Fenticonazole Nitrate is not recommended for children.

STORAGE CONDITION

store below 25°C in dry place. Keep away from light. Keep out of reach of children.

HOW SUPPLIED

Fentizol[®] VT 600: Each box contains 1 Tablet in Alu-Alu blister with an applicator.

DIRECTION FOR USE

- Pull out plunger "A" until it stops. Place a vaginal tablet into the applicator "B".
- Insert applicator containing the tablet carefully as deeply as possible into the vagina (best lying on your back)
- Push plunger "A" until it stops, thereby depositing the tablet into the vagina. Remove the applicator.
- After use, remove plunger "A" completely by pulling it out of the applicator "B". Then wash it in warm (not boiling) soapy water, rinse & dry carefully.

Note: Pregnant woman must follow physician's instructions.



SQUARE