



SHARIF
Pharmaceuticals Ltd.

Fentigal

Fenticonazole Nitrate BP

COMPOSITION:

Fentigal cream: Each gram cream contains Fenticonazole Nitrate BP 20 mg.

Fentigal tablet VT 600: Each vaginal tablet contains Fenticonazole Nitrate BP 600 mg.

PHARMACOLOGY:

Fenticonazole is an imidazole antifungal, active against a range of organisms including *dermatophyte pathogens*, *Malassezia furfur* (Tinea versicolor) and *Candida albicans*.

It inhibits the production of a chemical called ergosterol, which is a component of the fungal cell membrane. Damage to this membrane cannot be repaired and this interferes with the fungal cell's ability to reproduce, hence the infection is controlled.

INDICATION:

Treatment of vulvovaginal candidiasis.

DOSAGE & APPLICATION:

Fentigal cream-

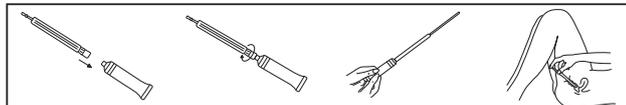
Route of application : Intravaginal

Adults: One applicator full (about 5 g) is to be administered into the vagina in the morning and evening for three days.

Children: The use of Fenticonazole in children is not recommended.

How to apply Fentigal

Follow the instructions in the diagrams below:



1. Screw the applicator onto the tube in place of the cap.
2. Squeeze the tube gently at its lower end, so as to fill the applicator. If there is a certain resistance in the piston, pull it delicately. Unless otherwise prescribed by the physician, the applicator must be completely filled.
3. Remove the applicator from the tube, which should be closed with the cap.
4. In a lying down position, with knees raised and spread apart, delicately insert the applicator into the vagina as deeply as possible. Push the piston in completely, then pull out the applicator without touching the piston.

Take care to ensure that the applicator is always perfectly clean.

After each use, wash it carefully with warm water and soap. If your doctor advises sterilization of the applicator, for a particular reason, follow his instructions. Do not use water which is hotter than 50°C, or solvents. Then dry the applicator and store in its container.

Always wash your hands with mild soap and warm water afterwards. Fentigal is not greasy, does not soil and can easily be removed with water.

Fentigal Tablet-

Fentigal 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.

DIRECTION FOR USE

1. Pull out plunger "A" until it stops. Place a vaginal tablet into the applicator "B".
2. Insert applicator containing the tablet carefully as deeply as possible into the vagina (best lying on your back).
3. Push plunger "A" until it stops, thereby depositing the tablet into the vagina. Remove the applicator.
4. 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

CONTRAINDICATIONS:

Hypersensitivity to Fenticonazole or any component of the formulation.

PRECAUTIONS:

The product should not be used in conjunction with barrier contraceptives.

SIDE EFFECTS:

After intravaginal administration, slight transient burning may occasionally occur, which usually disappears rapidly.

USE IN PREGNANCY AND LACTATION:

Since there is no experience of use during pregnancy or lactation, So Fenticonazole should not be used without physician's advice.

DRUG INTERACTION:

Not investigated. Since systemic absorption of Fenticonazole after application is low, interactions with other drugs are unlikely.

STORAGE:

Store in a cool and dry place. Protect from light. Keep away from children.

PACKING:

Fentigal cream: Each tube contains 20/30/50/60 g of cream with an applicator.

Fentigal tablet VT 600: Each box contains 1 tablet in Alu-Alu blister with an applicator.

Manufactured by:



Sharif Pharmaceuticals Ltd.

Rugganj, Narayanganj, Bangladesh.