Fungidal® BT

Miconazole Nitrate BP

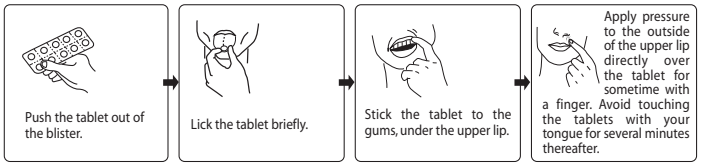
COMPOSITION
Fungidal® BT: Each buccal tablet contains Miconazole Nitrate BP 10 mg.

PHARMACOLOGY
The active ingredient of **Fungidal® BT** buccal tablet is Miconazole which is a synthetic imidazole anti-fungal agent with a broad spectrum of activity against pathogenic fungi (including yeast and dermatophytes) and gram-positive bacteria (*Staphylococcus* and *Streptococcus spp*). It may act by interfering with the permeability of the fungal cell membranes. When administered orally, Miconazole is incompletely absorbed from the gastrointestinal tract, peak plasma levels of about 1 µgm per ml have been achieved after a dose of 1 gm per day. Miconazole is inactivated in the body and 10-20% of an oral dose is excreted in the urine, mainly as metabolites, within 6 days. About 50% of an oral dose may be excreted unchanged in the faeces.

INDICATION
For the treatment and prevention of Oropharyngeal & Esophageal Candidiasis.

DOSAGE
1 tablet daily (apply in the morning) for 7 days. Miconazole should be applied to the gingiva in the morning, i.e. above the eye tooth, once daily, for one week. Do not swallow. A second week of treatment may be indicated.
The use of Miconazole in children below the age of 7 is not recommended.

METHOD OF ADMINISTRATION
Once a tablet is removed from the blister, it should be used immediately.



SIDE EFFECT
Nausea and taste perversion are common side effects experienced with Miconazole buccal tablet. Allergic reaction is rarely observed. Mouth irritation, oral numbness, vomiting, diarrhoea & dizziness are uncommon side effects.

CONTRAINDICATION
Known hypersensitivity to Miconazole Nitrate or to any of the other ingredients of the product.

PRECAUTION
Harmful effects are not expected following accidental ingestion of the Miconazole buccal tablet. However, reapplication of a new tablet may be required. In cases of reduced salivary production, tablet erosion may be prolonged or inhibited. A minimal salivary production is required to guarantee complete disintegration of the tablet and release of the active drug substance.

OVERDOSE
No cases of overdose were reported. As one Miconazole patient package contains a total of only 70 mg of Miconazole Nitrate, which excludes the possibility of overdose.

DRUG INTERACTION
Miconazole administered systemically is known to inhibit CYP3A4/2C9. Due to limited systemic availability after Miconazole buccal tablet application, clinically relevant interactions are unlikely to occur. However, in patients on oral anticoagulants, such as warfarin, caution should be exercised and anticoagulant effects should be monitored.

USE IN PREGNANCY AND LACTATION
Pregnancy: There are no adequate data from the use of Miconazole Nitrate in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Caution should be exercised when prescribing to pregnant women.
Lactation: No adequate data on excretion of Miconazole Nitrate in human milk are available. Caution should be exercised when prescribing to breastfeeding women.

STORAGE
Store below 25°C and in a dry place, protected from light and moisture. Keep all medicines out of reach of children.

HOW SUPPLIED
Fungidal® BT: Each box contains 3 x 10 tablets in blister pack.

Manufactured by :
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

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