

# Fungata

Fluconazole USP

## COMPOSITION

**Fungata 50 mg Capsule:** Each capsule contains Fluconazole USP 50 mg

**Fungata 150 mg Capsule:** Each capsule contains Fluconazole USP 150 mg

**Fungata Powder for Suspension 35 ml:** Each 5 ml reconstituted suspension contains Fluconazole USP 50 mg.

## PHARMACOLOGY

Fluconazole is a triazole antifungal drug which acts by inhibition of the ergosterol component of the fungal cell membrane. It is active against a broad spectrum of fungal pathogens and is available for oral use. Fluconazole acts by inhibiting the synthesis of ergosterol, a major component of the cell membrane of yeast and fungi.

Fluconazole is normally administered orally. Following oral administration, absorption is rapid and extensive, with >90% of the dose being absorbed. Bioavailability is the same in the fasting and fed states. The bioavailability of Fluconazole is unaffected by gastric P<sup>H</sup>. The plasma half life is approximately 30h. The plasma protein binding of Fluconazole is low, at 11 % and the drug is widely distributed throughout the body. Most of the dose of Fluconazole is excreted unchanged in the urine, the remainder of the dose being eliminated in the urine as metabolites.

## INDICATION

It is indicated in the treatment of acute or recurrent vaginal candidiasis, mucosal candidiasis (e.g. oropharyngeal candidiasis, oesophagitis, candiduria), systemic candidiasis and cryptococcal infections (including meningitis).

## DOSAGE AND ADMINISTRATION

Acute or recurrent vaginal candidiasis : a single dose of 150 mg.  
Mucosal candidiasis (except vaginal) : 50 mg daily (100 mg daily in unusually difficult infections) given for 7-14 days in oropharyngeal candidiasis; for 14-30 days in other mucosal infections (e. g. oesophagitis, candiduria). Systemic candidiasis and cryptococcal infections (including meningitis) - 400 mg initially then 200 mg daily; increased if necessary to 400 mg daily; treatment continued according to response.

Child over 1 year - superficial candidal infections, 1-2 mg/kg body weight daily; systemic candidiasis and cryptococcal infections, 3-6 mg/kg body weight daily (in serious life threatening infections up to 12 mg/kg body weight daily has been given to children aged 5-13 years - max. 400 mg daily).

## **CONTRAINDICATION**

It is contraindicated to patients hypersensitive to this drug and in advanced liver disease.

## **PRECAUTION**

Caution should be taken in renal impairment, pregnancy and breast feeding and in raised liver enzymes. The use of Fluconazole in lactating mothers is not recommended.

## **SIDE EFFECTS**

Nausea, abdominal discomfort, diarrhoea and flatulence, occasionally abnormalities of liver enzymes; rarely rash; angioedema, and anaphylaxis reported.

## **DRUG INTERACTION**

Rifampicin reduces plasma concentration of Fluconazole. Effect of nicoumalone. phenytoin and warfarin is enhanced. Plasma concentrations of sulphonylureas & theophylline is possibly increased.

## **STORAGE**

Storing Cool and dry place, protected from light. Keep out of the reach of children.

## **COMMERCIAL PACK**

**Fungata 50 mg Capsule:** Each box containing 5x10's capsules in blister pack.

**Fungata 150 mg Capsule:** Each box containing 2x10's capsules in blister pack.

**Fungata Powder for suspension 35 ml:** Each amber color glass bottle contains of dry powder for preparation of 35 ml suspension.

Manufactured by



For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.