

AFSC KIT

(Fluconazole 150 mg Tablets, Secnidazole 1 gm Tablets & Azithromycin 1 gm Tablets)

Composition

Each kit contains:

Two Secnidazole 1 gm Tablets
One Azithromycin 1 gm Tablets
One Fluconazole 150 mg Tablets

Pharmacological action

Azithromycin:

The mode of action of azithromycin is inhibition of protein synthesis in bacteria by binding to the 50s ribosomal subunit and preventing translocation of peptides.

Fluconazole

Fluconazole, a member of the triazole class of antifungal agents, is a potent and selective inhibitor of fungal enzymes necessary for the synthesis of ergosterol.

Secnidazole

Secnidazole is the first nitroimidazole to offer a 3-day antiprotozoal activity from one single dose. With its prolonged half life, secnidazole offers an effective treatment and thus ensures improved patient compliance because of the short duration of treatment with excellent therapeutic efficacy.

Therapeutic Indications

AFSC Kit is indicated for the syndromic management of abnormal vaginal discharge and other related sexually transmitted infections such as gonorrhoea, chlamydial infections, bacterial vaginosis, trichomoniasis and vulvo-vaginal candidiasis.

Contra Indications

Azithromycin:

The use of azithromycin is contraindicated in patients with hypersensitivity to azithromycin, to other macrolide antibiotics, or to any of the excipients.

Fluconazole:

Fluconazole 150 should not be used in patients with known hypersensitivity to Fluconazole or to relatedazole compounds or to any of the other ingredients. Co-administration of terfenadine or cisapride is contra-indicated in patients receiving fluconazole.

Secnidazole:

Secnidazole is contraindicated for those patients who are hypersensitive to imidazole derivatives.

Side Effects

Azithromycin:

Uncommon: Vaginitis, Dizziness/vertigo, convulsions, headache, somnolence, disturbances of smell and/or taste.; Rare: Candidiasis; Thrombocytopenia, haemolytic anaemia. Anaphylaxis, including oedema (rarely fatal).

Fluconazole:

Headache, Convulsions, Nausea and Vomiting, Abdominal pain, Diarrhoea, dry mouth, increased sweating, Hepatic Necrosis

Secnidazole:

may cause dizziness, headache, nausea, vomiting, reduced appetite, sweating, hypersalivation, tachycardia, palpitations, difficulty in micturition, urinary retention, and tremor's, anxiety fear, confusion, psychotic states, restlessness and insomnia. Hypertension and ventricular arrhythmias may occur.

Drug interactions:

Azithromycin:

- * Concurrent use of macrolides and warfarin is associated with increased anticoagulant effects.
- * Close monitoring for liver enzyme abnormalities and hearing impairment, is warranted when coadministered with nelfinavir.
- * Careful monitoring of patients is advised with concurrent use of azithromycin and following drugs:

Digoxin: Elevated digoxin levels.

Ergotamine or Dihydroergotamine: Acute ergot toxicity characterized by severe peripheral vasospasm and dysesthesia.

Terfenadine, cyclosporine, hexobarbital, and phenytoin concentrations.

Fluconazole:

- * Clinically significant hypoglycemia may be precipitated when concomitantly used with oral hypoglycemic agents.
- * On coadministration, fluconazole increases the plasma concentrations of phenytoin.
- * Concurrent use with astemizole or other drugs metabolized by the cytochrome P450 system may be associated with elevations in serum levels of these drugs.
- * Uveitis is reported with coadministration of fluconazole and rifabutin.
- * Nephrotoxicity is reported with coadministration of fluconazole and tacrolimus.
- * Coadministration of midazolam and fluconazole might result in substantial increases in midazolam concentrations and psychomotor effects.

Secnidazole:

- * Nitroimidazoles might impair the metabolism or excretion of several drugs including warfarin, phenytoin, lithium, ciclosporin, and fluorouracil, and increase incidence of adverse effects.
- * When coadministered with alcohol, secnidazole may provoke a disulfiram-like reaction in some patients.

Warning & Precautions:

Azithromycin

Rare serious allergic reactions including angioneurotic oedema and anaphylaxis (rarely fatal), have been reported. Some of these reactions with azithromycin have resulted in recurrent symptoms and required a longer period of observation and treatment.

Fluconazole

Patients with rare hereditary problems of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Secnidazole

Patients should be advised not to take alcohol during treatment with secnidazole (because of possibility of antabuse effect) Administration of secnidazole should be avoided to patients with a history of blood dyscrasia.

Use in Pregnancy and lactation

Fiazec kit containing azithromycin, fluconazole and secnidazole is not recommended for use during pregnancy and lactation.

Dosage & Route of Administration

Route of administration:

Oral

AFSC Kit is meant for one day's treatment as single dose of Secnidazole, Azithromycin, and Fluconazole.

Both partners should take one combi kit each for proper results:

2 Secnidazole tablets (White colored biconvex capsule shaped tablets) to be taken as a single dose after meals

1 Azithromycin tablet (Pink colored biconvex capsule shaped tablet) as a single oral dose 1 hour before or 2 hours after the meal, preferably on an empty stomach

1 Fluconazole tablet (pink colored flat and round shaped tablet) as a single oral dose with or without meals.

Overdose and Treatment

Azithromycin

Adverse events experienced in higher than recommended doses were similar to those seen at normal doses. Characteristic symptoms of an overdose of macrolide antibiotics were: reversible hearing loss, severe nausea, vomiting and diarrhoea. In case of an overdose lavage and general supporting measures are indicated.

Fluconazole

There have been reports of overdose with fluconazole and in one case a 42 year-old patient infected with human immunodeficiency virus developed hallucinations and exhibited paranoid behaviour after reportedly ingesting 8200mg of fluconazole, unverified by his physician. The patient was admitted to the hospital and his condition resolved within 48 hours.

As fluconazole is largely excreted in the urine, forced volume diuresis would probably increase the elimination rate. A three hour haemodialysis session decreases plasma levels by approximately 50%.

Secnidazole

Patients should be advised not to take alcohol during treatment with secnidazole (because of possibility of antabuse effect). Administration of secnidazole should be avoided to patients with a history of blood dyscrasia.

Identification

Two Secnidazole tablets (White colored biconvex capsule shaped film coated tablets), One Azithromycin tablet (Pink colored biconvex capsule shaped film coated tablet), One Fluconazole tablet (pink colored flat and round shaped uncoated tablet).

Storage Condition

Store in a cool and dry place, protected from light.

Shelf Life:

2 year from date of manufacturing.

Presentation

Each kit contains 4 tablets and each carton contains 10 kits packed along with a pack insert.

Pack Size: 1x4's Tablets

Manufactured in India by

Impact Health Care Pvt. Ltd.

At: 81-B, EP/II, Phase I, Jharmajri, Baddi,

Distt. Solan (H.P.)



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