

SUMMARY OF PRODUCT CHARACTERISTICS

1.NAME OF THE MEDICINAL PRODUCT

AZFLOSEC KIT

Combipack of Azithromycin 1000 mg, fluconazole 150 mg and Secnidazole 1000 mg Tablets

2.QUALITATIVE AND QUANTITATIVE COMPOSITION

(A) 1 Azithromycin Tablets USP 1000 mg

Each film coated tablet contains:

Azithromycin Dihydrate USP

Azithromycin (Anhydrous) 1000 mg

Excipients Q.S.

Colour: Titanium Dioxide BP

(B) 1 Fluconazole Tablets USP

150 mg Each uncoated tablet

contains:

Fluconazole USP..... 150 mg

Excipients Q.S.

(C) 2 Secnidazole Tablets

1000 mg Each film coated

tablet contains:

Secnidazole.....1000 mg

Excipients Q.S.

Colour: Quinoline Yellow & Titanium Dioxide

3.PHARMACEUTICAL FORM

Film coated and uncoated Tablets

4.CLINICAL PARTICULARS

4.1 Therapeutic indications

Secnidazole Tablets

Secnidazole is primarily indicated in condition like amoebiasis, giardiasis, trichomoniasis, urethritis and vaginitis.

Azithromycin Tablet

Azithromycin is effective against susceptible bacteria causing otitis media (infection of the middle ear) tonsillitis, laryngitis, bronchitis, pneumonia and sinusitis. It also is effective against several sexually transmitted infectious disease such as nongonococcal urethritis and cervicitis.

Fluconazole Tablet

For the treatment of fungal infections.

4.2 Posology and method of administration

Posology

Secnidazole 1g – Take 2 tablets as single dose with food to avoid gastrointestinal side

effects Azithromycin 1g – Take 1 tablet as single dose at least 1 hour before or 2 hours after meal.

Fluconazole 150mg – Take 1 tablet as a single dose with secnidazole or alone

Method of administration

For oral use.

4.3 Contraindications

Secnidazole 1g: Pregnancy, lactation, hypersensitivity

Azithromycin 1g: Azithromycin is contraindicated in condition like hepatic impairment, hypersensitivity.

Fluconazole 150mg: Hypersensitivity.

4.4 Special warnings and precautions for use

Secnidazole Tablets

Alcoholic drinks and alcohol containing medicines should be avoided during secnidazole treatment. Do not administer to subject with a history of blood dyscrasia.

Azithromycin Tablet

Azithromycin should be used with caution in patients with illness or any allergy, especially allergies to drug, liver disease, jaundice, history of colitis or stomach problems or kidney disease. This drug should be used only if clearly needed during pregnancy or lactation.

Fluconazole Tablet

Fluconazole should be used with caution in patients with liver disease, kidney disease or of any drug allergy. This medication should be used only when clearly needed during pregnancy. Avoid fluconazole during lactation.

4.5 Interaction with other medicinal products and other forms of interaction

Secnidazole Tablets

Potentiate anticoagulant effect of warfarin. Concurrent disulfiram may cause antabuse like effects cimetidine prolongs half life.

Azithromycin Tablet

Azithromycin is known to interact with other drugs like aluminum hydroxide and oxide, astemizole, cyclosporine A, digoxin, terfenadine, theophylline, triazolam. These interactions are sometimes beneficial and sometimes may pose threats to life. Always consult your physician for the change of dose regimen or an alternative drug of choice that may strictly be required.

Fluconazole Tablet

Fluconazole is known to interact with other drugs like alfentanil (HCL), Aliskiren, Alprazolam, Amitriptyline (HCL), Artesunate, astemizole, bosentan, celecoxib, chlorpropamide, cisapride, cyclosporine A, fosphenytoin, hydrochlorthiazide, loratadine, losartan (K), nortriptyline(HCL), phenytoin(Na), Quetiapine, Repaglinidine, rifabutin, rifampicin, ritonavir , sacchromyces, silfapyridine, silphamethaxazole, terfenadine theophylline, torasemide, warfarin (Na), zidovudine.

These interactions are sometimes beneficial and sometimes may pose threats to life. Always consult your physician for the change of dose regimen or an alternative drug of choice that may strictly be required.

4.6 Fertility, pregnancy and lactation

Secnidazole Tablets

Secnodazole may be prescribed in pregnancy after the first trimester. As with other similar drugs, secnidazole should be not be administrate during the first trimester of pregnancy or during lactation because secnidazole is found in placenta and breast milk.

Azithromycin Tablet

Caution when used during pregnancy and lactation.

Category B: Either animal – reproduction studies have not demonstrate a foetal risk but there are no controlled studies in pregnant women or animal – reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the 1st trimester (and there is no evidence of a risk in later trimester).

Fluconazole Tablet

There are no adequate studies in pregnant women. There are reports of harmful effect to the fetus when high dose fluconazole was administrating to pregnant women for a few months. Use of

fluconazole during pregnancy is not usually recommended. Nursing mothers: fluconazole is secreted in breast milk. Use of fluconazole by nursing mothers is not recommended.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Vaginal itching, Taste change, Vomiting, Vaginal infection, Headache, Dizziness, Stomach pain, Nausea, Indigestion, Diarrhea, Loss of appetite

Reporting of suspected adverse reactions:

Healthcare professionals are requested to report any suspected adverse reactions via the national Pharmacovigilance Electronic Reporting Systems to the respective national regulatory authorities.

4.9 Overdose

In the event of overdose, symptomatic treatment (with supportive measures and Gastric lavage if clinically indicated) should be instituted.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: R06AE07

Secnidazole:

~~Synthetic derivative of the nitro imidazole series. Essentially tissular amoebicide.~~

Active against *Entamoeba histolytica* and *Giardia lamblia*.

Azithromycin:

General properties:

Pharmacotherapeutic group: antibacterials for systemic use; macrolids; azithromycin, ATC code: J01FA10

Mode of action:

Azithromycin is an azalide, a sub-class of the macrolid antibiotics. By binding to the 50S- ribosomal sub-unit, azithromycin avoids the translocation of peptide chains from one side of the ribosome to the other. As a consequence of this, RNA-dependent protein synthesis in sensitive organisms is prevented.

Mechanism of resistance:

Resistance to azithromycin may be inherent or acquired. There are three main mechanisms of resistance in bacteria: target site alteration, alteration in antibiotic transport and modification of the antibiotic. Complete cross resistance exists among *Streptococcus pneumoniae*, beta-haemolytic streptococcus of group A, *Enterococcus faecalis* and *Staphylococcus aureus*, including methicillin resistant *S. aureus* (MRSA) to erythromycin, azithromycin, other macrolides and lincosamides.

Fluconazole:

ATC classification

Pharmacotherapeutic group: Antimycotics for systemic use, triazole derivatives, ATC code: J02AC01.

Mode of action

Fluconazole is a triazole antifungal agent. Its primary mode of action is the inhibition of fungal cytochrome P-450-mediated 14 alpha-lanosterol demethylation, an essential step in fungal ergosterol biosynthesis. The accumulation of 14 alpha-methyl sterols correlates with the subsequent loss of ergosterol in the fungal cell membrane and may be responsible for the antifungal activity of fluconazole. Fluconazole has been shown to be more selective for fungal cytochrome P-450 enzymes than for various mammalian cytochrome P-450 enzyme systems. Fluconazole 50 mg daily given up to

28 days has been shown not to effect testosterone plasma concentrations in males or steroid concentration in females of child-bearing age. Fluconazole 200 mg to 400 mg daily has no clinically significant effect on endogenous steroid levels or on ACTH stimulated response in healthy male

volunteers. Interaction studies with antipyrine indicate that single or multiple doses of fluconazole 50 mg do not affect its metabolism.

Mechanism(s) of resistance

Candida spp have developed a number of resistance mechanisms to azole antifungal agents. Fungal strains which have developed one or more of these resistance mechanisms are known to exhibit high minimum inhibitory concentrations (MICs) to fluconazole which impacts adversely efficacy in vivo and clinically.

There have been reports of super infection with *Candida* species other than *C. albicans*, which are often inherently not susceptible to fluconazole (e.g. *Candida krusei*). Such cases may require alternative antifungal therapy.

5.2 Pharmacokinetic properties

The pharmacokinetics of fluconazole are similar following IV administration. The drug is rapidly and almost completely absorbed from the GI tract, and there is no evidence of first-pass metabolism. Oral bioavailability of fluconazole exceeds 90% in healthy, fasting, adults; peak plasma concentrations of the drug generally are attained within 1-2 hours after oral administration.

The rate and extent of GI absorption of fluconazole are affected by food. Azithromycin is an azalide antibiotic with unique pharmacokinetic properties that result in extremely high and prolonged tissue and phagocyte concentrations. These are unique properties.

Allow it to be administered in various respiratory tract and AIDS-related opportunistic infections. The bioavailability of Secnidazole approaches 90 – 100%. Peak serum levels of Secnidazole after a single 500mg oral dose range between 9 and 13 mg and occur 0.33 to 3 hours after the dose.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Croscarmellose Sodium,
Microcrystalline Cellulose PH 101,
Dibasic Calcium Phosphate Dihydrate,
Pregelatinized Starch,
PVPK 30,
Croscarmellose Sodium,
Sodium Lauryl sulphate,
Magnesium Stearate,
Titanium Dioxide Aqueous
Purified talc
Anhydrous Colloidal Silicon Dioxide
Maize Starch
Sodium Benzoate
Quinoline
Yellow Non Aqueous (Coating)
Titanium Dioxide

6.2. Incompatibilities

Not Applicable

6.3. Shelf life

36 Months.

6.4. Special precautions for storage

Store below 30°C.

Protect from light and Moisture.

6.5. Nature and contents of container

Aluminium - PVC Blister Pack

Each Combi kit Contains

1 Azithromycin Tablets USP 1000mg,
1 Fluconazole Tablets USP 500 mg and
2 Secnidazole Tablet 1000 mg.
are packed in one carton pack.

4 Tablets are blister packed with Aluminium -PVC; such 1 blister are packed in one carton pack.

6.6. Special precautions for disposal

No special requirements

**7.MARKET AUTHORIZATION HOLDER
TRIDENT LIFELINE LIMITED**

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8. MARKET AUTHORIZATION NUMBER

H2026/CTD12959/28298

9. DATE OF REGISTRATION/RENEWAL

18 February 2026

10. DATE OF REVISION OF THE TEXT

18 February 2026