SUMMARY OF PRODUCT CHARACTERISTICS

AZFLOSEC KIT (Azithromycin 1,000 mg / Fluconazole 150 mg / Secnidazole 1,000 mg Combipack)

1. NAME OF THE MEDICINAL PRODUCT

AZFLOSEC KIT (Azithromycin Tablets USP 1,000 mg / Fluconazole Tablets USP 150 mg / Secnidazole Tablets 1,000 mg Combipack)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each AZFLOSEC KIT contains:

- Azithromycin 1,000 mg (as Azithromycin Tablets USP) — one tablet
- Fluconazole 150 mg (as Fluconazole Tablets USP) — one tablet
- Secnidazole 1,000 mg — two tablets (500 mg each)

Excipients with known effect:

None of the excipients in this combination are subject to a specific excipient warning.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Combipack of tablets.

Azithromycin tablet: White to off-white, film-coated tablet.

Fluconazole tablet: White to off-white, film-coated tablet.

Secnidazole tablets: White to off-white, uncoated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

AZFLOSEC KIT is indicated for the single-dose treatment of mixed genital tract infections in adults where concurrent bacterial, protozoal and fungal infections are clinically suspected or confirmed susceptible to the components, specifically:

- Sexually transmitted infections caused by susceptible organisms including: gonorrhoea (Neisseria gonorrhoeae), chlamydia (Chlamydia trachomatis), trichomoniasis (Trichomonas vaginalis), and vulvovaginal candidiasis (Candida species).
- Mixed pelvic infections where the combined use of azithromycin (antibacterial), secnidazole (antiprotozoal/antibacterial) and fluconazole (antifungal) is considered clinically appropriate.

Consideration should be given to official guidance on the appropriate use of antibacterial and antifungal agents.

4.2 Posology and method of administration

Adults

All three tablets are taken simultaneously on the same day as a single-dose regimen. The recommended administration sequence is:

- Secnidazole 1,000 mg: Two tablets (500 mg each) taken together as a single dose, with food.
- Azithromycin 1,000 mg: One tablet taken as a single dose, at least 1 hour before or 2 hours after a meal.
- Fluconazole 150 mg: One tablet taken as a single dose, with or without food.

Renal impairment

Azithromycin: No dose adjustment is required in mild to moderate renal impairment; use with caution in severe renal impairment (GFR <10 ml/min). Fluconazole: No dose adjustment for single-dose therapy. Secnidazole: Use with caution; limited data in severe renal impairment.

Hepatic impairment

This combination is contraindicated in severe hepatic impairment. Use with caution in mild to moderate hepatic impairment.

Paediatric population
Safety and efficacy in patients under 18 years of age have not been established for this combination. Not recommended in the paediatric population.

Method of administration
Oral. Each component is taken as a single oral dose.

4.3 Contraindications

- Hypersensitivity to azithromycin, other macrolide or ketolide antibiotics, or to any of the excipients listed in section 6.1.
- Hypersensitivity to fluconazole, other azole antifungal agents, or to any of the excipients listed in section 6.1.
- Hypersensitivity to secnidazole, other nitroimidazole derivatives (e.g. metronidazole, tinidazole), or to any of the excipients listed in section 6.1.
- Severe hepatic impairment.
- Concomitant use with alcohol during and for at least 48 hours after secnidazole administration (risk of disulfiram-like reaction).
- Concomitant use with terfenadine (risk of potentially fatal cardiac arrhythmias — QT prolongation) with azithromycin or fluconazole.
- Concomitant use with cisapride, pimozide or astemizole with fluconazole.
- Concomitant use with ergot alkaloids (dihydroergotamine, ergotamine) with azithromycin — risk of ergotism.
- Pregnancy (especially the first trimester) — secnidazole and fluconazole are contraindicated; azithromycin should be used in pregnancy only when clearly necessary.

4.4 Special warnings and precautions for use

Alcohol avoidance — secnidazole
Alcohol must be avoided during and for at least 48 hours after secnidazole administration, due to the risk of disulfiram-like reactions (flushing, nausea, vomiting, abdominal cramps, tachycardia). All alcohol-containing beverages and medicines should be avoided.

Cardiac effects — azithromycin
Azithromycin has been associated with prolongation of the QT interval and cases of torsades de pointes. Azithromycin should be used with caution in patients with known risk factors for QT interval prolongation, including: congenital or documented acquired QT prolongation; concomitant use of drugs known to prolong the QT interval; hypokalaemia or hypomagnesaemia; clinically significant bradycardia, cardiac arrhythmia or severe cardiac insufficiency; elderly patients.

Hepatic effects — azithromycin
Abnormal liver function, hepatitis, cholestatic jaundice, hepatic necrosis and hepatic failure — some of which have resulted in death — have been reported with azithromycin. Liver function tests should be considered if signs or symptoms of liver disease develop. Azithromycin should be discontinued and not restarted if hepatic dysfunction develops.

Hepatic effects — fluconazole
Fluconazole has been associated with rare cases of serious hepatic toxicity, including fatalities, primarily in patients with serious underlying medical conditions. In cases of fluconazole-associated hepatic dysfunction, these symptoms have usually been reversible upon discontinuation of therapy.

Neurotoxicity — secnidazole
As with other nitroimidazoles, convulsive seizures and peripheral neuropathy have been reported with prolonged use. AZFLOSEC KIT is intended for single-dose use only; prolonged use should be avoided.

Haematological monitoring
Use with caution in patients with a history of blood dyscrasias, as azithromycin and secnidazole may affect the haematopoietic system. Periodic blood count monitoring is recommended if repeated treatment is considered.

Superinfection
As with all antibiotic therapy, prolonged or repeated use may result in overgrowth of non-susceptible organisms including Candida. Should a superinfection occur, appropriate therapy should be initiated.

Drug resistance and treatment failure

Antibiotic resistance to azithromycin among Neisseria gonorrhoeae is increasingly reported. Where possible, susceptibility testing should guide therapy. If no clinical improvement is observed within 3–5 days of single-dose treatment, patients should seek further medical assessment.

4.5 Interaction with other medicinal products and other forms of interaction

Azithromycin interactions

Antacids:

Aluminium- and magnesium-containing antacids reduce peak plasma levels of azithromycin; separate administration by at least 1–2 hours.

Digoxin:

Azithromycin may increase digoxin levels; monitor digoxin concentrations.

Ciclosporin:

Azithromycin may elevate ciclosporin levels; monitor renal function and ciclosporin concentrations.

Theophylline:

May interact with azithromycin; monitor theophylline levels.

QT-prolonging drugs (antiarrhythmics, terfenadine, cisapride, pimozide):

Concomitant use increases the risk of serious cardiac arrhythmias. Terfenadine is contraindicated. Avoid concomitant use with other QT-prolonging agents where possible.

Ergot alkaloids:

Concomitant use of azithromycin and ergotamine or dihydroergotamine is contraindicated due to risk of ergot toxicity.

Fluconazole interactions

Fluconazole is a potent inhibitor of CYP2C9 and CYP3A4, and a moderate inhibitor of CYP2C19. Co-administration with drugs metabolised by these enzymes may result in significantly increased plasma concentrations of those drugs.

Warfarin and other anticoagulants (CYP2C9):

Fluconazole significantly increases warfarin anticoagulant effects; PT/INR must be closely monitored.

Phenytoin (CYP2C9):

Fluconazole markedly increases phenytoin plasma concentrations; monitor phenytoin levels.

Sulfonylureas (CYP2C9):

Blood glucose-lowering effect may be enhanced; monitor blood glucose.

Rifampicin (CYP3A4 inducer):

Rifampicin reduces fluconazole plasma concentrations; adjustment may be needed.

Cisapride, pimozide, astemizole, quinidine (contraindicated):

Fluconazole increases plasma concentrations of these drugs, resulting in a risk of QT prolongation and potentially fatal arrhythmias.

Terfenadine (contraindicated):

May result in serious cardiac arrhythmias.

Tacrolimus, ciclosporin (CYP3A4):

Fluconazole increases plasma concentrations; monitor levels and renal function.

Statins (CYP3A4):

Fluconazole may increase statin concentrations and the risk of myopathy; caution required.

Secnidazole interactions

Warfarin and oral anticoagulants:

Secnidazole may potentiate the anticoagulant effect of warfarin; PT/INR should be monitored closely.

Alcohol (contraindicated):

May cause disulfiram-like reaction (flushing, nausea, vomiting, tachycardia).

Cimetidine:

May increase plasma concentrations of nitroimidazoles; use with caution.

4.6 Fertility, pregnancy and lactation

Pregnancy

Azithromycin: Limited human data; azithromycin should be used during pregnancy only when clearly necessary and potential benefits outweigh the potential risk to the foetus. Animal studies did not show evidence of teratogenicity.

Fluconazole: A pattern of birth defects (craniosynostosis, cleft palate, femoral bowing, thin ribs, long bone abnormalities) has been reported in infants born to women receiving fluconazole 400–800 mg/day during most or all of the first trimester. These effects may be dose-related. AZFLOSEC KIT contains a single 150 mg dose; however, high-dose systemic exposure and teratogenic risk cannot be fully excluded. Fluconazole should not be used during pregnancy unless clearly necessary.

Secnidazole: Nitroimidazoles have mutagenic effects in bacteria and carcinogenic effects in rodents; the clinical relevance of these findings to humans following a single dose is unclear. AZFLOSEC KIT should not be used during the first trimester of pregnancy; use in later pregnancy should be restricted to situations where the benefit clearly outweighs the risk.

Breast-feeding

Azithromycin: Azithromycin is excreted in breast milk. If azithromycin is required by a nursing mother, breast-feeding may need to be interrupted. Fluconazole: Fluconazole is excreted in breast milk at concentrations similar to plasma. Breast-feeding is not recommended during and for 5 days after fluconazole treatment. Secnidazole: Secnidazole is excreted in breast milk. Breast-feeding should be discontinued during treatment and for at least 48 hours after secnidazole administration.

Fertility

No relevant data on the effect of this combination on human fertility are available.

4.7 Effects on ability to drive and use machines

AZFLOSEC KIT has no or negligible influence on the ability to drive and use machines. However, dizziness and somnolence may occur with individual components; patients should be cautioned accordingly.

4.8 Undesirable effects

Summary of the safety profile

The adverse reaction profile of AZFLOSEC KIT reflects the combined profiles of its individual components. Common adverse reactions include gastrointestinal symptoms (nausea, vomiting, diarrhoea, abdominal pain), headache, dizziness, taste disturbances, and vaginal discomfort.

System Organ Class	Common (≥1/100 to <1/10)	Uncommon / Rare
Infections and infestations	Vaginal candidiasis (fluconazole paradox — treatment failure)	Oral candidiasis, superinfection
Blood and lymphatic disorders		Leucopenia, thrombocytopenia (azithromycin/secnidazole, rare)
Immune system disorders		Hypersensitivity reactions including anaphylaxis (rare)
Nervous system disorders	Headache, dizziness	Paraesthesia, convulsions (secnidazole, rare); peripheral neuropathy (rare, prolonged use)
Cardiac disorders		QT prolongation, palpitations (azithromycin); torsades de pointes (rare)
Gastrointestinal disorders	Nausea, vomiting, diarrhoea, abdominal pain, dyspepsia	Metallic/bitter taste (secnidazole, very common); flatulence, constipation
Hepatobiliary disorders	Elevated liver enzymes (mild)	Hepatitis, cholestatic jaundice, hepatic failure (rare)
Skin and subcutaneous tissue disorders	Rash, pruritus	Urticaria, angioedema, SJS, TEN (rare)
Reproductive system	Vaginal discomfort, discharge	
General disorders	Fatigue, asthenia	

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

Symptoms

Azithromycin: Nausea, vomiting, diarrhoea, temporary hearing loss. Fluconazole: Nausea, vomiting, diarrhoea, hallucination, paranoid behaviour. Secnidazole: Nausea, vomiting, dizziness, ataxia, peripheral neuropathy.

Treatment

In case of overdose, gastric lavage may be considered if clinically indicated (within 1 hour of ingestion). Symptomatic and supportive treatment should be instituted. There are no specific antidotes. Haemodialysis may enhance elimination of fluconazole and secnidazole in severe overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

AZFLOSEC KIT is a fixed-dose combipack providing three distinct pharmacological mechanisms for the simultaneous treatment of mixed genital tract infections.

Azithromycin:

A macrolide antibiotic. Inhibits bacterial protein synthesis by binding reversibly to the 50S ribosomal subunit, blocking the translocation step of the elongation cycle. Bacteriostatic at standard concentrations; bactericidal at higher concentrations against some pathogens. Active against Neisseria gonorrhoeae (with increasing resistance in some regions) and Chlamydia trachomatis. ATC code: J01FA10.

Fluconazole:

A triazole antifungal. Inhibits fungal sterol synthesis by selectively inhibiting the cytochrome P450-dependent enzyme lanosterol 14-α-demethylase, preventing conversion of lanosterol to ergosterol — the principal sterol of the fungal cell membrane. Active against Candida species and many other fungi. ATC code: J02AC01.

Secnidazole:

A second-generation nitroimidazole derivative with antiprotozoal and antibacterial activity. After reductive activation within susceptible micro-organisms, the reactive intermediates interact with DNA, causing strand breakage and inhibiting DNA replication. Active against Trichomonas vaginalis, Giardia lamblia, Entamoeba histolytica and anaerobic bacteria including Gardnerella vaginalis and Bacteroides species. ATC code: P01AB07.

5.2 Pharmacokinetic properties

Azithromycin

Oral bioavailability approximately 37%; Tmax approximately 2–3 hours. Widely distributed in tissues; tissue concentrations are markedly higher than plasma concentrations (apparent volume of distribution approximately 31 L/kg). Plasma protein binding approximately 7–51% (concentration dependent). Terminal half-life approximately 68 hours (due to tissue redistribution). Metabolised by the liver via N-demethylation; eliminated primarily in bile.

Fluconazole

Oral bioavailability >90%; Tmax 1–2 hours. Volume of distribution approximately 0.65 L/kg. Plasma protein binding approximately 11–12%. Terminal half-life approximately 30 hours (single dose of 150 mg). Primarily excreted unchanged in urine (approximately 80% of dose). Not significantly metabolised by the cytochrome P450 system at the 150 mg dose.

Secnidazole

Well absorbed orally; Tmax approximately 4 hours after a single 2 g dose. Volume of distribution approximately 42 L. Plasma protein binding <15%. Terminal half-life approximately 17–29 hours. Metabolised by the liver; excreted mainly in urine as metabolites.

5.3 Preclinical safety data

No additional preclinical safety concerns have been identified for this combination beyond those established for the individual components at therapeutic doses. Azithromycin: No mutagenic potential; no evidence of genotoxicity. Fluconazole: No evidence of mutagenic potential; carcinogenicity studies at high doses showed increased hepatocellular adenomas in rats. Secnidazole: As with other nitroimidazoles, mutagenic effects have

been demonstrated in bacteria and carcinogenic effects in rodents at very high doses; the relevance of these findings to short-term single-dose human use is considered remote.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Azithromycin tablet:

Croscarmellose sodium, microcrystalline cellulose, dibasic calcium phosphate dihydrate, pregelatinized starch, povidone, sodium lauryl sulphate, magnesium stearate, titanium dioxide (film coat).

Fluconazole tablet:

Croscarmellose sodium, microcrystalline cellulose, dibasic calcium phosphate dihydrate, pregelatinized starch, povidone, sodium lauryl sulphate, magnesium stearate, titanium dioxide (film coat).

Secnidazole tablets:

Croscarmellose sodium, microcrystalline cellulose, dibasic calcium phosphate dihydrate, pregelatinized starch, povidone, sodium lauryl sulphate, magnesium stearate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture. Keep out of the reach and sight of children.

6.5 Nature and contents of container

Combipack containing: 1 film-coated azithromycin tablet (1,000 mg), 1 film-coated fluconazole tablet (150 mg), and 2 secnidazole tablets (500 mg each), packaged together in a single blister or carton with package insert.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

TRIDENT LIFELINE LIMITED

2004, II Floor, North Extension, Falsawadi,

Ring Road, Surat – 395003, Gujarat, India.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2026/CTD12959/28298

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

16.02.2026

10. DATE OF REVISION OF THE TEXT

16.02.2026