SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

VAGID KIT

(A Combikit of Fluconazole Tablets USP 150 mg, Azithromycin Tablets USP 1 g & Secnidazole Tablets 1 g)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Combikit Contains:

Fluconazole Tablets USP (1 Tablet)

Each uncoated tablet contains:

Fluconazole USP….150 mg

Excipients .....Q. S.

Azithromycin Tablets USP (1 Tablet)

Each film coated tablet contains:

Azithromycin USP (As Dihydrate) equivalent to Azithromycin….1 g

Excipients .....Q. S.

Secnidazole Tablets (2 Tablets)

Each Film Coated Tablet Contains:

Secnidazole…..... 1 g

Excipients .....Q. S.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Form: Tablets

Description:

Azithromycin Tablets USP 1g - Yellow coloured, elongated, biconvex, film coated tablets.

Fluconazole Tablets USP 150 mg - Pink colour, round, biconvex, both sides plain uncoated tablets.

Secnidazole Tablets 1g - White, elongated, biconvex, film coated tablets, having both sides plain.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

- Trichomoniasis
- Bacterial Vaginosis
- Vaginal discharge due to candidiasis
- Infections or mixed infections with chlamydia and Neisseria

4.2 Posology and method of administration

One Tablet of Azithromycin 1 g to be taken one hour before lunch

One Tablet of Fluconazole 150 to be taken after lunch

Two Tablets of Secnidazole to be taken immediately after dinner

4.3 Contraindications

A COMBIKIT contains three chemotherapeutic agents Azithromycin, Secnidazole and Fluconazole. These 3 drugs do not cause drug interaction when given together on the same day concomitantly. However, like any therapeutic agents Azithromycin, Secnidazole and Fluconazole have known contraindications, which must be known before A COMBIKIT is prescribed.

4.4 Special warnings and precautions for use:

You should not use this combikit if you have ever had jaundice or liver problems caused by taking this medicine. You should not use azithromycin if you are allergic to it or to similar drugs such as clarithromycin, erythromycin, or telithromycin. You may need to take only one dose of fluconazole, or you may need to take fluconazole for several weeks or longer. The length of your treatment depends on your condition and on how well you respond to fluconazole.

4.5 Interaction with other medicinal products and other forms of interactions

Fluconazole (in A COMBIKIT) can interact with oral hypoglycemics, coumarins, phenytoin, cyclosporine, rifampicin, theophylline, astemizole, rifabutin, tacrolimus, terfenadine, cisapride and short-acting benzodiazepines.

Azithromycin (in A COMBIKIT) absorption can be reduced by antacids having magnesium or aluminium. Elevation of serum levels of digoxin, ergot derivatives, Triazolam and drugs metabolized by liver cytochrome P450 can occur with azithromycin.

Secnidazole (in A COMBIKIT) can potentiate the action of anticoagulants.

4.6 Pregnancy and Lactation

Azithromycin: Azithromycin may be safe to use during pregnancy and while breastfeeding
Secnidazole: The drug should not be administered during the first trimester of pregnancy or lactation.

Pregnant and lactating women should seek physician's advice before using this product.

4.7 Effects on Ability to Drive and Use Machines

Not applicable.

4.8 Undesirable effects

The majority of side effects are mild and transient. Diarrhea, nausea, abnormal taste, dyspepsia, abdominal pain, headache, pseudomembrance colitis can occur.

4.9 Overdose

These include wheezing; chest tightness; fever; itching; bad cough; blue or gray skin color; seizures; or swelling of face, lips, tongue, or throat, very bad dizziness or passing out, fast heartbeat. If you think there was an overdose, call your local poison control center or ER right away.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Azithromycin: Macrolides

Fluconazole: Antimycotics for systemic use, triazole derivatives

Secnidazole: Antiamoebics

ATC code:

Azithromycin: J01FA10

Fluconazole: J02AC01

Secnidazole: P01AB07

VAGID KIT is a combination of three medicines: Fluconazole, Azithromycin and Secnidazole. Fluconazole is an antifungal which works by preventing the formation of the fungal protective covering which is essential for the survival of the fungi in the human body. Azithromycin is an antibiotic which stops bacterial growth by inhibiting synthesis of essential proteins required by bacteria to carry out vital functions. Secnidazole is also an antibiotic which kills the infection-causing bacteria and other microorganisms, by damaging their DNA. This medication works by decreasing ergosterol production by disrupting the activity of cytochrome P450, inhibiting the

formation of the cell membrane of susceptible fungi like Candida and Microsporum

5.2 Pharmacokinetic properties:

Azithromycin:

Absorption: After oral administration the bioavailability of azithromycin is approximately 37%. Peak plasma levels are reached after 2-3 hours (C after a max single dose of 500 mg orally was approximately 0.4 mg/1).

Distribution: Kinetic studies have shown markedly higher azithromycin levels in tissue than in plasma (up to 50 times the maximum observed concentration in plasma) indicating that the active substance is heavily tissue bound (steady state distribution volume of approximately 31 l/kg). Concentrations in target tissues such as lung, tonsil, and prostate exceed the MIC90 for likely pathogens after a single dose of 500 mg.

In experimental in vitro and in vivo studies azithromycin accumulates in the phagocytes, freeing is stimulated by active phagocytosis. In animal studies this process appeared to contribute to the accumulation of azithromycin in the tissue. In the serum the protein binding of azithromycin is variable and depending on the serum concentration varies from 50% in 0.05 mg/1 to 12% in 0.5 mg/1.

Excretion: Plasma terminal elimination half-life closely reflects the tissue depletion half-life of 2 to 4 days. About 12% of an intravenously administered dose is excreted in the urine unchanged over a period of 3 days; the majority in the first 24 hours. Biliary excretion of azithromycin, predominantly in unchanged form, is a major route of elimination.

Fluconazole:

Absorption: After oral administration fluconazole is well absorbed and plasma levels (and systemic bioavailability) are over 90% of the levels achieved after intravenous administration. Oral administration is not affected by concomitant food intake. Peak plasma concentrations in the fasting state occur between 0.5 – 1.5 hours post-dose with a plasma elimination half-life of approximately 30 hours. Plasma concentrations are proportional to dose. Ninety percent steady-state levels are reached by day 4 – 5 with multiple once daily dosing. The administration of a loading dose on the first day, double that of the normal daily dose, raises plasma levels to approximate to 90% steady-state levels by the second day.

Distribution: The apparent volume of distribution approximates to total body water. Plasma protein binding is low (11- 12%). Fluconazole achieves good penetration in all body fluids studied. The levels of fluconazole in saliva and sputum are similar to plasma levels. In patients with fungal meningitis, fluconazole levels in the CSF are approximately 80% of the corresponding plasma levels.

Biotransformation: Fluconazole is metabolised only to a minor extent. Of a radioactive dose, only

11% is excreted in a changed form in the urine. Fluconazole is a selective inhibitor of the isozymes CYP2C9 and CYP3A4. Fluconazole is also an inhibitor of the isozyme CYP2C19.

Elimination: Plasma elimination half-life for fluconazole is approximately 30 hours. The major route of excretion is renal, with approximately 80% of the administered dose appearing in the urine as unchanged drug. Fluconazole clearance is proportional to creatinine clearance. There is no evidence of circulating metabolites.

Secnidazole:

A single oral dose of 2 g of Secnidazole in healthy adult female subjects, following an overnight fast and admixed with (4 oz) of applesauce, resulted in a mean (SD) secnidazole peak plasma concentration (C) of 45.4 (7.64) mcg/mL and mean (SD)max systemic exposure (AUC0-inf) of 1331.6 (230.16) mcghr/mL. Median (range) time to peak concentration (T) was 4.0 (3.0-4.0) hours. Following administration of the max 2-g dose, mean secnidazole plasma concentrations decreased to 22.1 mcg/mL at 24 hours, 9.2 mcg/mL at 48 hours, 3.8 mcg/mL at 72 hours, and 1.4 mcg/mL at 96 hours.

5.3 Preclinical safety data

Not Available

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Corn Starch, Hypromellose, Magnesium Stearate, Talc, Colloidal Silicon Dioxide, Crospovidone, Tulsion 339, Sodium Lauryl Sulfate, Titanium Dioxide, Polyethylene Glycol 6000, Tartrazine Lake, Microcrystalline cellulose (101), Polyvinyl pyrrolidone (K-30), Methyl paraben, Propyl paraben, Croscarmellose sodium, Colour: Erythrosine Lake, Sodium starch glycolate, Purified water

6.2 Incompatibilities

Not known

6.3 Shelf Life

36 months

6.4 Special precautions for storage

Store at temperature below 30°C.

6.5 Nature and content of container

VAGID KIT is a combikit containing 1 Tablet of Azithromycin Tablets USP 1 g, 1 Tablet of Fluconazole Tablets USP 150 mg & 2 Tablets of Secnidazole Tablets 1 g is packed in clear PVC/Alu blister in a combikit along with pack insert.

7.0 Marketing Authorization Holder & Manufacturing Site Addresses:

Bliss GVS Pharma Ltd.
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Plot No. 1, Pharmacity, Selaqui, Dehradun 248011 (U.K.), India.

8.0 Marketing Authorization Number

FDA/SD.243-112164

9.0 Date of First Authorization or Renewal

November 2024

10.0 Date of Revision of the Text

Nov 2024