SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Dysen Forte Tablet, Secnidazole 1000 mg/Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Secnidazole ……1000 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A white coloured film coated tablet, oblong in shape, one side engraved with a bisection line while the other side is engraved with NQ.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Secnidazole is indicated for the treatment of intestinal amoebiasis, hepatic amoebiasis, giardiasis, urethritis and vaginitis due to Trichomonas vaginalis.

4.2 Posology and Method of Administration

The dose should preferably be taken during a meal.

Acute Intestinal Amoebiasis and Giardiasis:

Adults: Single dose treatment of two Dysen Forte Tablets (2 g).

Children: 30 mg/kg body weight as a single dose.

Hepatic Amoebiasis (5-day treatment):

Adults: One and a half (1½) tablets of 1000 mg (1.5 g) as a single dose for 5 days.

Children: 30 mg/kg body weight once a day or in divided doses before meals for 5 days.

In supportive hepatic amoebiasis, Secnidazole therapy should be complemented by abscess drainage.

Urogenital Trichomoniasis and Bacterial Vaginosis:

Single dose treatment of two Secnidazole Tablets (2 g). The male partner should also be treated with the same dose.

4.3 Contraindications

The product should not be administered during the first trimester of pregnancy or during lactation, and in patients with hypersensitivity to imidazole derivatives.

4.4 Special Warnings and Precautions for Use

Avoid alcohol during treatment. Do not associate with Disulfiram. Avoid during first trimester of pregnancy. Do not administer to subjects with a history of blood dyscrasia or severe liver disorder.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Oral anticoagulants (described for Warfarin): Potentiation of the oral anticoagulant and increased risk of haemorrhage by lowering of its hepatic catabolism. More frequent determination of the prothrombin time and monitoring of the International Normalised Ratio (INR) is recommended. Adjustment of the oral anticoagulant dose during Secnidazole treatment and 8 days after its withdrawal is necessary.

Disulfiram: Administration of Secnidazole with Disulfiram is not recommended; confusional state and paranoid reactions may occur.

Avoid alcohol during treatment with Secnidazole.

4.6 Fertility, Pregnancy and Lactation

Pregnancy: Secnidazole may be prescribed in pregnancy after the first trimester. As with other similar drugs, Secnidazole should not be administered during the first trimester of pregnancy because Secnidazole is found in the placenta.

Lactation: Secnidazole should not be administered during lactation because Secnidazole is found in breast milk.

4.7 Effects on Ability to Drive and Use Machines

No adverse effects have been observed. However, in the event that dizziness or other adverse effects occur that could prevent the carrying out of these activities, patients should avoid driving and the use of potentially hazardous machinery.

4.8 Undesirable Effects

The side effects of Secnidazole are the same as those of other nitroimidazole derivatives. The following side effects may be observed with Secnidazole as with all nitroimidazole derivatives and are rarely serious.

Most frequent side effects: Gastrointestinal disturbances, nausea, epigastric pain, metallic taste, glossitis, and stomatitis.

Occasional side effects: Urticaria, moderate leukopenia which is reversible on treatment discontinuation.

Rare side effects: Vertigo, ataxia and motor incoordination, paraesthesia, and peripheral neuropathy.

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.

Health care professionals are asked to report any suspected adverse reactions via the https://pv.pharmacyboardkenya.org

4.9 Overdose

Symptoms: Expected symptoms are drowsiness, dizziness, headache, ataxia, skin rashes, pruritus, and transient epileptiform seizures.

Treatment: There is no specific treatment for gross overdosage. The treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Antimicrobial and antiprotozoal agent; Nitroimidazole derivative.

ATC Code: P01AB07

Mechanism of Action: Secnidazole is a synthetic derivative of the nitroimidazole series. It is a nitroimidazole antiprotozoal agent with antibacterial action; it is characterised with bactericidal (against gram-positive and gram-negative anaerobe bacteria) and amoebicidal (intraluminal and extraluminal) effects. Secnidazole is particularly active against Trichomonas vaginalis, Entamoeba histolytica and Giardia lamblia. By entering the bacterial cell, Secnidazole is activated as a consequence of the reduction of the 5-nitro group; as a result, it interacts with cellular DNA, causing damage to its spiral structure, fibre destruction, inhibition of nucleotide synthesis and cell death.

5.2 Pharmacokinetic Properties

After oral intake, Secnidazole is rapidly and fully absorbed from the gastrointestinal tract. Plasma drug concentrations are linear over the therapeutic dose range of 0.5 to 2 g. Protein binding accounts for only about 15% of total plasma drug concentration and the volume of distribution is low (49.2 L). The maximum serum level is obtained 3 hours following oral administration of 2 g Secnidazole. The bioavailability is about 80%. Secnidazole passes through the blood-brain barrier and enters breast milk. The elimination half-life of Secnidazole is approximately 25 hours, which allows simplification of the drug dosage regimen, making it more convenient for patients. The metabolism of Secnidazole is not well described but, as with metronidazole, the drug

probably undergoes oxidation in the liver. Secnidazole and a hydroxymethyl metabolite are detected in urine as glucuronide conjugates. The parent drug is cleared slowly from the body. Secnidazole is eliminated via urine (50% of the administered dose is excreted within 12 hours). Secnidazole crosses the placental barrier and can be found in maternal milk.

5.3 Preclinical Safety Data

No data for carcinogenicity, mutagenicity or fertility abnormalities with the use of Secnidazole, and no teratogenic effects have been observed during animal testing. However, in view of the absence of human data, it is not recommended for use during pregnancy.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Core: Polyvinyl Pyrrolidone K-30, Maize Starch, Ac-Di-Sol, Talcum Powder, Magnesium Stearate, Aerosil #200, Isopropyl Alcohol.

Coating Agents: HPMC, Polyvinyl Pyrrolidone K-30, Talcum Powder, Titanium Dioxide, PEG 6000, Isopropyl Alcohol, De-Ionised Water.

6.2 Incompatibilities

None.

6.3 Shelf Life

48 months.

6.4 Special Precautions for Storage

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

6.5 Nature and Contents of Container

Secnidazole 1000 mg tablet for commercial use is available in Alu-PVC blister pack of 2 tablets as a single pack.

6.6 Special Precautions for Disposal and Other Handling

No special requirements. Any unused product or waste material should be disposed of properly.

7. MARKETING AUTHORISATION HOLDER

Nabiqasim Industries (Pvt.) Ltd.

17/24, Korangi Industrial Area, Korangi, Karachi – Pakistan.

8. MARKETING AUTHORISATION NUMBER(S)

019174

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

16 April 1996.

10. DATE OF REVISION OF THE TEXT

February 2020.