SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

NAME OF THE MEDICINAL PRODUCTS:

- Dysen forte tablets
- Dysen Suspension 750mg/Bottle

The International Non– Proprietary Name (INN): Secnidazole

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

COMPOSITION:
Tablet:
Each film coated tablet contains:
Secnidazole …1000mg
In-House Specs.

Dry Suspension:
Each bottle (30mL) contains:
Secnidazole as granules for Oral Suspension … 750mg
In-House Specs.

Dry Suspension:
Each bottle (30mL) contains:
Secnidazole as granules for Oral Suspension … 500mg
In-House Specs.

PHARMACEUTICAL FORM:
Tablets and Dry Suspension
Product name: Dysen Forte Tablet
The International Non– Proprietary Name (INN): Secnidazole

For a full list of excipients, see section 6.1.

Description:

3. PHARMACEUTICAL FORM:

Dysen Forte Tablet:
A white colored film coated tablet, oblong in shape, one side engraved bisection while other engraved with NQ.

Dysen Suspension 750mg/Bottle:
A white to off-white colored dry powder gives pink colored, Strawberry flavored suspension when constituted with water.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:
Dysen is indicated for the treatment of Intestinal amoebiasis, Hepatiocamoebiasis, 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 to two Dysen Forte tablets (2g).

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

Hepatic Amoebiasis (5 Day treatment):

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

Children: 30mg/kg body weight once a day or in divided doses before meals for 5 days. In supportive hepariamoebiasis, Secnidazole therapy should be complemented by abscess drainage.

4.3 Contraindications:
The product should not be administered during first trimester of pregnancy or during lactation, hypersensitivity of 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.

4.5 Interaction with other medicinal products and other forms of interaction:
Contraindicated combination therapy
With Disulfiram: Delirious episodes, confusion
With Alcohol: hotness, redness, vomiting, tachycardia.
Oral anticoagulant (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 INR.Adjustment of the oral anticoagulant dose during secnidazole treatment, and 8days after withdrawal.

4.6. Fertility, Pregnancy and Lactation
Pregnancy Category C:

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 or during lactation because secnidazole is found in placenta and breast milk.

4.7 Effects on ability to drive and use machines:
None known

4.8 Undesirable effects:

The side effects of secnidazole are same as that of other nitroimidazole derivatives.

- Most frequently: digestive disorders with abdominal pain, change in taste (metallic), glossitis, and stomatitis.
- Utricaria.
- Moderate leukopenia,reversible upon withdrawal of treatment, most rarely, dizziness,lack of coordination and ataxia, paraesthesia, sensitive and motor polyneuritis with secnidazole.Rare cases of digestive disorders have been reported (nausea, vomiting, gastric pain)

4.9 Overdosage:

Symptoms: Expected symptoms are drowsiness, dizziness headache. Ataxia, skin rashed, pruritis, transient epileptiform seizure.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties and Pharmacokinetic properties:

Pharmacotherapeutic group: Antiretroviral Agents
ATC Code: P01AB07

Pharmacodynamics:
Mechanism of Action / Pharmacodynamics:

Secnidazole and other 5-nitroimidazoles possess selective activity against many anaerobic Gram-positive and Gram-negative bacteria and protozoa. In general, secnidazole and metronidazole were approximately equipotent in activity against *Bacteroides fragilis*, Trichomonas vaginalis andEntamoeba histolytica, in *in vitro* studies. In 1 study, secnidazole was more potent than metronidazole against Giardia lamblia *(G. intestinalis, G. duodenalis)*.

Secnidazole was as effective as metronidazole and tinidazole in eradicating *G. lamblia, T. vaginalis* and *E. histolytica* from the majority of infected patients. Bacterial or protozoal resistance develops rarely to the 5-nitroimidazoles.

5.2Pharmacokinetics:

Secnidazole is rapidly and completely absorbed after oral administration. Plasma drug concentrations are linear over the therapeutic dose range of 0.5 to 2g. Protein binding accounts for only about 15% of total plasma drug concentration and the volume of distribution is low (49.2L). The concentration of secnidazole which remains in the plasma

for at least 48 hours after a single 2g dose appears to be well within the range corresponding to minimum inhibitory concentration values reported by most investigators for in vitro sensitivity of B. fragilis, E. histolyticaand T. vaginalis.

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 and, in 1 trial, only 10 to 25% of a single 2g dose was recovered in urine after 72 hours. The terminal elimination half-life (t1/2β) of secnidazole ranged from about 17 to 29 hours and was longer in men (20 hours) than in women (14 hours) in 1 study. The expression of cytochrome P450 isoenzymes does not appear to be influenced by secnidazole.

5.3 Preclinical safety data:

Not available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dysen Forte Tablet:
Polyvinyl Pyrrolidone K-30
Maize Starch
Ac-Di-Sol
Talcum Powder
Magnesium Stearate
Aerosil #200
Isopropyl Alcohol
Coating Material:
H P M C 606
Polyvinyl Pyrrolidone K-30
Talcum Powder
Titanium Dioxide
P E G 6000#
Isopropyl Alcohol
De-Ionized Water

Dysen Suspension 750mg/Bottle:
Sugar Pharma Grade
Aspartame
Sodium Citrate
Methyl Paraben
Sodium Carboxy Methyl Cellulose
Titanium Dioxide
Aerosil # 200
Rose Pink Color
Encapsulated Strawberry Flavour

6.2 Incompatibilities:

None

6.3 Shelf life:
Dysen Forte Tablet: 48 months

Dysen Suspension 750mg/Bottle: 36 months

6.4 Special precautions for storage:

Protect from heat, light.
Store below 30°C.Keep away from children.

6.5 Nature and contents of container

Dysen Forte Tablet:
Alu/PVC blister
Dysen Suspension 750mg/Bottle: Amber Glass Bottle

6.6 Special precautions for disposal and other handling

Dysen Forte Tablet:
Dysen Suspension 750mg/Bottle: Shake before use.

7. MARKETING AUTHORISATION HOLDER (S):

Nabiqasim Industries (Pvt.) Ltd.
17/24, Korangi Industrial Area,
Karachi – Pakistan.

8. MARKETING AUTHORISATION NUMBERS:

Dysen Forte Tablet: 019177

Dysen Suspension 750mg/bottle: 009906

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORISATION:
Dysen Forte Tablet:
First Authorization: 16th April, 1996.
Renewal: 23rd February,2011.

Dysen Suspension 750mg/bottle:
First Authorization: 24th May, 1997.
Renewal: 30th April, 2012.

10. DATE OF REVISION OF THE TEXT:
May, 2016.