SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product

1.1 Product name

Tagera Forte

1.2 Strength

Secnidazole 1 g

1.3 Pharmaceutical Dosage form

Tablet

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

Each film coated tablet contains:
Secnidazole.....1g

For a full list of excipients, see section 6.1.

3. Pharmaceutical Form

Film coated tablets.
White colored, capsule shaped, film coated with score mark on one side and plain on other side.

4. Clinical particulars

4.1 Therapeutic indications

Secnidazole is indicated for the treatment of intestinal and extra intestinal amoebiasis, trichomoniasis, giardiasis and bacterial vaginosis.

4.2 Posology and method of administration

Adult:
Intestinal amoebiasis - 2 g single dose
Amoebic liver abscess - 1.5 g per day for 5 days
Trichomoniasis and bacterial vaginosis for patient and partner – 2 g single dose
Giardiasis – 2 g single dose

Children:
Intestinal amoebiasis and giardiasis - 30 mg / kg body weight as single or divided doses.
Method of administration: Via the oral route.

4.3 Contraindications

As in the case of all imidazole derivatives, Secnidazole should not be administered during the first trimester of pregnancy or during lactation or in individuals having hypersensitivity to imidazole derivatives. Avoid alcohol and disulfiram during treatment. Avoid use in patients with past history of blood disorders.

4.4 Precautions for use

Adult:
Intestinal amoebiasis - 2 g single dose
Amoebic liver abscess - 1.5 g per day for 5 days
Trichomoniasis and bacterial vaginosis for patient and partner – 2 g single dose
Giardiasis – 2 g single dose

Children:
Intestinal amoebiasis and giardiasis - 30 mg / kg body weight as single or divided doses.
Method of administration: Via the oral route

4.5 Interaction with other medicinal products and other forms of interactions

Secnidazole may potentiate the anticoagulant effect of warfarin thereby increasing the risk of haemorrhage. Alcoholic beverages should be avoided during the Secnidazole therapy and at least one day afterwards because antabuse effect may occur. Similarly consumption of Secnidazole with disulfiram should not be allowed in order to avoid occurrence of delirious bouts and confusion.

4.6 Undesirable effects

Secnidazole is well tolerated. Majority of side effects are of mild and transient nature. They include nausea, vomiting, gastralgia, metallic taste, glossitis, stomatitis and urticaria. Vertigo, dizziness, headache and neurological disturbances occur very rarely.

4.7 Overdose and special antidotes

To the best of our knowledge, no instances of deliberate or accidental overdose with Secnidazole have been reported so far. In the event of overdosage, supportive and symptomatic therapy is indicated.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Secnidazole and other 5-nitroimidazoles enter micro-organisms by passive diffusion and undergo activation by reduction of the 5-nitro group, in anaerobic micro-organisms such as Trichomonas, Giardia and Entamoeba spp. This intracellular reduction enhances transport of the parent drug into the cell.

DNA is the intracellular target of the 5-nitroimidazoles. Drug induced DNA damage results in strand breakage, loss of helical structure and impaired template function. The lethal effect of 5-, nitroimidazoles on susceptible micro-organisms is attributed to a short lived reduction product, nitro radical anion.

Overview of Antibacterial activity:

The 5-nitroimidazoles are characterised by their selective toxicity against anaerobic microorganisms. The spectrum of in vitro antimicrobial activity of secnidazole includes protozoa like Entamoeba histolytica, Giardia lamblia, Trichomonas vaginalis and bacteria like Bacteroides fragilis, Gardnerella vaginalis. MIC (mg/L) values of secnidazole against the susceptible microorganisms are quite low. These are 6 mg/L against Entamoeba histolytica, 0.7 mg/L against Trichomonas vaginalis, 0.48 mg/L against Bacteroides fragilis. Against Giardia lamblia, ID 50 (drug concentration required to obtain a 50% reduction in growth of treated cells compared to treated controls) of secnidazole is 0.15 mg/L

5.2 Pharmacokinetic Properties

Secnidazole is rapidly and completely absorbed after oral administration. Following oral administration of Secnidazole, the maximum serum level is obtained after 3 hours. Plasma drug concentration are linear over the therapeutic dose range of 0.5 to 2 grams. The plasma elimination half life time is about 20-25 hours. Secnidazole crosses the placental barrier and can be found in maternal milk. Most of the absorbed drug is excreted via urine.

6. Pharmaceutical Particulars

6.1 List of excipients

Microcrystalline Cellulose, Starch, Gelatine, Sodium Starch Glycollate, Colloidal Anhydrous Silica, Magnesium Stearate, Hydroxypropyl methylcellulose, Polyethylene Glycol, Titanium dioxide, Ethanol, Dichloromethane.

6.2 Incompatibilities

None

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30ºC.

6.5 Nature and contents of container

Each outer carton contains 10 inner cartons containing one blister of 2 tablets each along with pack insert.

7.0 Marketing Authorization Holder

Unichem Laboratories Limited
Unichem Bhavan, Prabhat Estate,
S.V. Road, Jogeshwari (West)
Mumbai – 400102, INDIA

8.0 Marketing Authorization Number

TAN 22 HM 0027

9.0 Date of first authorization/renewal of the authorization

10/01/2022

10.0 Date of revision of the text