SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SECNILYM 1g TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Secnidazole ….. 1 g

For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Film Coated Tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indication(s)

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: Oral.

4.3 Contraindications

Hypersensitivity to Secnidazole or to any excipients in this formulation.

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 Special warnings and precautions for use

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.

4.5 Interaction with other medicinal products and other forms of interaction

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 Pregnancy and lactation

Pregnancy

Animal studies have not demonstrated any teratogenic effects, therefore no Malformative effect is expected in humans. This is because, to date, substances that cause Malformations in man have been shown to be teratogenic in animals during controlled studies in two species.

There are currently not enough relevant clinical data to evaluate possible teratogenic or fetotoxic effects of Secnidazole when administered during pregnancy.
Therefore, as a precautionary measure, Secnidazole should preferably not be used during Pregnancy.

Lactation

No data are available concerning excretion of the medicinal product in breast milk.
However, excretion in breast milk has been documented with other imidazole derivatives, and cases of oral and anal candidiasis and diarrhoea have been described in breast-fed infants whose mothers were treated with other imidazole derivatives.
Therefore, clinical monitoring of the neonate or even discontinuation of breast-feeding is required during treatment.

4.7 Effects on ability to drive and use machines

Rare cases of dizziness have been reported following administration of imidazole derivatives

4.8 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.

4.9 Overdose

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

Pharmacotherapeutic Group: :Antiprotozoal.

ATC Code: P01AB07

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.

5.3 Preclinical safety data

None stated

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose, Starch, Gelatin, Sodium starch Glycollate, Colloidal silicon dioxide, Magnesium stearate, Hydroxypropyl methylcellulose, Polyethylene glycol, Titanium dioxide, Industrial Methylated Spirit, Methylene chloride

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months from the date of manufacture.

6.4 Special precautions for storage

Store below 30°C. Protect from light & moisture.

Keep all medicines out of reach of children.

6.5 Nature and contents of containers

A Blister of 2 tablets packed in inner carton along with pack insert. Such 10 inner cartons are further packed in printed outer carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESS

Lymens Medical Supplies Ltd
P.O. BOX DS 1776
Dansoman
Accra

The Madras Pharmaceuticals
Chennai, 600 017,
Tamil Nadu, India

8. MARKETING AUTHORISATION NUMBER

FDA/SD.243-040647

9. DATE OF FIRST AUTHORISATION OR RENEWAL

April 2024

10. DATE OF REVISION OF THE TEXT

April 2024