SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
SECNEFIL

2. QUALITY AND QUANTITATIVE COMPOSITION

Each Film Coated Tablet Contains:
Secnidazole..... 1 g

For the full list of excipients, please see section 6.1

3.PHARMACEUTICAL FORM
Yellow coloured, capsule shaped, film coated tablet with break line on one side.

4.CLINICAL PARTICULARS

4.1 Therapeutic indications
Secnefil is indicated in the treatment of intestinal amoebiasis, hepatic amoebiasis, trichomoniasis, giardiasis and bacterial vaginosis.

4.2 Posology and method of administration
Intestinal amebiasis and giardiasis:

Children over 2 years: single dose of 30 mg/kg/day, with a maximum of 2000 mg. Adults: Single dose of 2000 mg. (ie., 2 tablets at a time)

Observations:
For asymptomatic amoebiasis (called cystic form) should prolong treatment for 3 days.

In giardia lamblia infestation, it is recommended treat all cohabitants with the patients, to avoid reproducing the disease.

Hepatic Amoebiasis*:*
Children over 2 years: 30 mg/kg/day with a maximum of 2000 mg for 5-7 days. Adults: 500 mg (½ tablet)3 times daily for 5 to 7 days.
Urethral or vaginal trichomoniasis:

Adults: 2000 mg as single dose.

Route of Administration: Oral administration

4.3 Contraindications
History of hypersensitivity to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives.

4.4 Special warnings and precautions for use

Vulvo-vaginal candidiasis may develop with Secnefil and require treatment with an antifungal agent.

Potential Risk for Carcinogenicity: Carcinogenicity has been seen in mice and rats treated chronically with nitroimidazole derivatives, which are structurally related to secnidazole. It is unclear if the positive tumor findings in lifetime rodent studies indicate a risk to patients taking a single dose of Secnefil to treat bacterial vaginosis. Avoid chronic use.

4.5 Interaction with other medicinal products and other forms of interaction

Secnidazole enhances the effects of anticoagulants (warfarin, acenocoumarol), so the concurrent administration with these drugs may increase the risk of bleeding.

- Simultaneous administration with phenobarbital reduces the effects of Secnidazole and increases its elimination speed.
- Simultaneous administration with lithium derivatives increases the risk of toxicity due to antidepressant.
- It should not be administered simultaneously secnidazole and disulfiram(medicine used in alcohol detoxification), as it may cause neurological symptoms such as confusion and delirium.

There are published reports of psychotic reactions in patients who have taken secnidazole together with disulfiram (see below Use with food and beverages).

Simultaneous administration with cimetidine decreases its elimination and increases the risk of overdose.

Laboratory tests:

Secnidazole can interfere with liver function tests, masking the results of those tests, giving lower values of the real. This substance can also interfere with the determination of blood glucose obtained by hexokinase procedure.

Consult your doctor or pharmacist before taking any medicine.

Remember that your doctor has prescribed this medicine only for you. Never give it to someone else.

Use with food and beverages

Secnidazol absorption is not influenced by food intake; can be administered before, after or while meals.

Secnidazole should not be administered with drugs whose composition includes ethyl alcohol neither with alcoholic beverages since may occur aches, malaise, severe hypotension, tachycardia, flushing and vomiting, which is known as disulfiram effect.

For this reason, drinking alcoholic beverages should be avoided during treatment including up to 4 days after completion.

Secnidazole should not be given to patients who have taken disulfiram in the past two weeks.

4.6 Fertility, pregnancy and lactation

Secnidazole should not be administered during pregnancy, especially during the first trimester. Secnidazole reaches in breast milk similar concentration to that of maternal blood, so it must not be administered to nursing mothers.

4.7 Effects on ability to drive and use machines

No adverse effects have been observed. However, in the event that appears dizziness or other adverse effects that could prevent you to carry out these activities, avoid driving and the use of potentially hazardous machinery.

4.8 Undesirable effects

This medicune usually does not cause severe adverse reactions, although have been reported occasionally adverse effects as decreased appetite,headache, discomfort, heartburn and gastric pain, nausea, vomiting,diarrhea o constipation, dry mouth and bad taste (metallic) and vertigo. These effects are transient and do not require discontinuation of treatment.They may reduce gastrointestinal symptoms by administering a single dose at night, compared with reactions that occur when administered in the morning.

Other adverse reactions:

Hematological side effects:

Decrease in white blood cells, particularly neutrophils (leukopenia, neutropenia)) and platelets (thrombocytopenia), both transients.

Dermatological side effects:

Urticaria, rash and pruritus (itching).

Neurological side effects:

Seizures, peripheral neuropathy, vertigo, motor incoordination conabnormal gait (ataxia), confusional state, irritability, depression, weaknessand sleep disturbance.

Cardiovascular side effects:

Alterations in the ECG: QT prolongation. Genitourinary side effects:

Cystitis, polyuria, dysuria, urinary incontinence and dark urine, vaginal candidiasis, dyspareunia, decreased libido.

Other disorders:

Abdominal distension, glositis, proctitis, fever, hot flushes, nasal congestionand dry mucous membranes (oral, vaginal).

This list not includes all adverse reactions associated with the use of secnidazole, both well established as those that are under consideration or confirmation. In case you feel unwell, should immediately consult with the doctor who prescribed this medicine.

4.9 Overdose

There is no specific antidote for the treatment of overdosage. Treatment is symptomatic and supportive. Gastric lavage may be useful.

5.PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Secnidazole is the first nitroimidazole to offer a 3 day antiprotozoal activity from one single dose. With its prolonged half life, Secnidazole offers an effective treatment and thus ensures improved patient compliance because of the short duration of treatment with excellent therapeutic efficacy.

Secnidazole exhibits activity against anaerobic protozoa Entamoeba histolytica, Giardia lamblia and Trichomonas vaginalis. Secnidazole is rapidly absorbed following oral administration. The maximum serum level is obtained after 3 hours following oral administration of 2 gm secnidazole.

The plasma elimination half-life is about 20 hours. The majority of Secnidazole is eliminated via urine (50% of the ingested dose is excreted within 120 hours). The pharmacokinetic profile of Secnidazole gives it the longest half-life of all the second generation nitroimidazoles, ensuring 72-hour therapeutic blood levels from a 2-gm single dose.

Mechanisms of Action:

Secnidazole is a 5-nitroimidazole antimicrobial. 5-nitroimidazoles enter the bacterial cell as an inactive prodrug where the nitro group is reduced by bacterial enzymes to radical anions. It is believed that these radical anions interfere with bacterial DNA synthesis of susceptible isolates.

Resistance

The development of resistance to secnidazole by bacteria associated with bacterial vaginosis was not examined. Bacterial isolates exhibiting reduced in vitro susceptibility to metronidazole also show reduced susceptibility to secnidazole. The clinical significance of such an effect is unknown.

Antibacterial Activity

Culture and sensitivity testing of bacteria are not routinely performed to establish the diagnosis of bacterial vaginosis; standard methodology for the susceptibility testing of potential bacterial pathogens, Gardnerella vaginalis or Mobiluncus spp. has not been defined. The following in vitro data are available but their clinical significance is unknown.

Secnidazole is active in vitro against most isolates of the following organisms reported to be associated with bacterial vaginosis:

5.2 Pharmacokinetic properties

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5.3 Preclinical safety data

Nitroimidazoles, which have similar chemical structures to secnidazole, have been associated with tumors affecting the liver, lungs, mammary, and lymphatic tissues in animals after lifetime exposures. It is unclear if these positive tumor findings in lifetime rodent studies of these nitroimidazoles indicate a risk to patients taking a single dose of secnidazole to treat bacterial vaginosis.

Secnidazole was positive in the Bacterial Reverse Mutation Assay, but was negative for the rat micronucleus test and mouse lymphoma test.

In a rat fertility study, females were dosed for two weeks prior to mating until Day 7 of gestation with males that were dosed for a minimum of 28 days before cohabitation. No parental toxicity

6.PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Polacrilin Potassium,
Pregelatinized starch,
Purified Talc, Povidone,
Colloidal silicon dioxide,
Magnesium Stearate,
Hypromellose,
Macrogol 6000,
Propylene Glycol,
Polysorbate 80,
Titanium Dioxide &
Lake Quinoline yellow.

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 Months

6.4 Special Precautions for storage

Store below 30°C in a dry place. Protect from light.

6.5 Nature and contents of container

Nature: Blister pack of clear PVC and printed aluminium foil.

Contents of container: 1x 2's pack

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDERAND MANUFACTURING SITE ADDRESSES

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8.MARKETING AUTHORIZATION NUMBER

H2006/659

9.DATE OF FIRST REGISTRATION / RENEWAL OF THE REGISTRATION

April, 2026

10. DATE OF REVISION OF THE TEXT

April, 2026