SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SECNOL 2 g, granules in sachet-dose

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Secnidazole ..... 2.000 g per sachet
Excipient with known effect: sucrose
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Granules.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

SECNOL 2 g, granules in sachet-dose, is indicated for the treatment of the following infections (see sections 4.4 and 5.1):

- **Urethritis and vaginitis due to *Trichomonas vaginalis*,**
- **Bacterial vaginosis (see section 4.4 "Bacterial vaginosis"),**
- **Intestinal amoebiasis,**
- **Hepatic amoebiasis,**
- **Giardiasis.**

Official recommendations regarding the appropriate use of antibacterial agents should be taken into account.

4.2 Posology and method of administration

Posology

This formulation containing 2 g per sachet is not suitable for all recommended dosages. If necessary, other presentations should be used, particularly in children.
Urethritis and vaginitis due to *Trichomonas vaginalis*, bacterial vaginosis:

- **Adults: 2 g in a single dose; taken on a single day.**
  In cases of urethritis and vaginitis, the partner should be treated simultaneously.

Intestinal amoebiasis:

- **Acute symptomatic amoebiasis (*histolytica* form):**
  - **Adults: 2 g in a single dose; taken on a single day**
  - **Children: 30 mg/kg/day in a single dose; taken on a single day**
- **Asymptomatic amoebiasis (minuta and cystic forms):**
  Same daily dose for 3 days.

Hepatic amoebiasis:

- **Adults: 1.5 g per day, in one or several doses, for 5 days**
- **Children: 30 mg/kg/day, in one or several doses, for 5 days**

Note: In the suppurative phase of hepatic amoebiasis, treatment with secnidazole must be combined with drainage of pus or abscesses.

Giardiasis:

- **Children: 30 mg/kg/day in a single dose; taken on a single day.**

Method of administration

Oral use.
This medicinal product should be taken at the beginning of a meal.

4.3 Contraindications

Hypersensitivity to secnidazole, to the imidazole class, or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Bacterial vaginosis

The level of evidence is based on a single study comparing a single dose of secnidazole with metronidazole administered for seven days. In relation to pharmacokinetic parameters (see section 5.2), the single-dose regimen of secnidazole may be insufficient in some patients, and local vaginal treatment may be required.

Hypersensitivity
Allergic reactions may occur and may be severe (see section 4.8). In such cases, secnidazole must be discontinued and appropriate medical treatment should be initiated.

Blood disorders
Avoid administering secnidazole in patients with a history of blood dyscrasia.

Excipient with known effect
This medicinal product contains sucrose. Its use is not recommended in patients with fructose intolerance, glucose-galactose malabsorption syndrome, or sucrase/isomaltase deficiency.

Drug interactions
Concomitant use of secnidazole and alcohol is not recommended (see section 4.5).

4.5 Interaction with other medicinal products and other forms of interaction

Disulfiram-like reaction
Many medicinal products produce a disulfiram-like reaction with alcohol, and their combination with alcohol is not recommended.

Combinations not recommended
+ Alcohol (beverage or excipient)
Disulfiram-like effect (flushing, heat, vomiting, tachycardia). Avoid consuming alcoholic beverages and medicinal products containing alcohol. Consider the complete elimination of medicinal products (according to their half-life) before resuming alcohol consumption or taking medicinal products containing alcohol.

4.6 Fertility, pregnancy and lactation

Pregnancy
Animal studies have not shown teratogenic effects.
During the first trimester of pregnancy, clinical data are limited. As a precaution, secnidazole should preferably not be used during the first trimester. Beyond the first trimester, based on clinical experience, use of secnidazole can be considered.

Breast-feeding
No data are available on the passage of secnidazole into breast milk. However, transfer into breast milk has been documented for other imidazole derivatives, and cases of oro-anal candidiasis and diarrhoea have been reported in breastfed infants whose mothers received these medicinal products.
Therefore, it is preferable to avoid administering this medicinal product during breastfeeding or to interrupt breastfeeding for 24 hours if a single dose is taken.

4.7 Effects on ability to drive and use machines

Patients should be informed of the potential risk of dizziness and advised not to drive or operate machinery if such symptoms occur.

4.8 Undesirable effects

Adverse reactions are listed in decreasing order of frequency using the following convention:
very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000), frequency not known (cannot be estimated from available data).

Gastrointestinal disorders
Common: nausea, vomiting, epigastric pain, dysgeusia (metallic taste), glossitis, stomatitis
Blood and lymphatic system disorders
Frequency not known: leukopenia (reversible upon discontinuation)

Nervous system disorders
Rare: headache, dizziness, incoordination, ataxia, paraesthesia, sensory-motor polyneuritis

Immune system disorders
Rare: immediate hypersensitivity reaction (fever, erythema, urticaria, angioedema)

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after marketing authorisation is important. It allows continuous monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals should report any suspected adverse reactions via the national reporting system:
Agence nationale de sécurité du médicament et des produits de santé (ANSM) and the network of Regional Pharmacovigilance Centres – Website:
https://signalement.social-sante.gouv.fr/

4.9 Overdose
In case of overdose, an increase in adverse effects related to secnidazole administration should be expected, particularly neurological disorders as reported with other imidazoles.
Treatment is symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic class: ANTIPROTOZOAL AGENTS – NITROIMIDAZOLE DERIVATIVES,
ATC code: P01AB07
Secnidazole is a synthetic derivative of the 5-nitroimidazole family.

Mechanism of action
Secnidazole has amoebicidal and antiprotozoal activity.
From a bacteriological standpoint, although the species usually involved in bacterial vaginosis are resistant to 5-nitroimidazoles, including secnidazole, available data have shown activity of secnidazole in this condition, although the mechanism has not been elucidated.

Breakpoints
Breakpoints distinguish susceptible strains from those with intermediate susceptibility, and these in turn from resistant strains.
Recommendations of the Antibiogram Committee of the French Society for Microbiology (CA-SFM) (based on CA-SFM breakpoints established for metronidazole):
S ≤ 4 mg/L and R > 4 mg/L

Antimicrobial spectrum of activity
The prevalence of acquired resistance may vary geographically and over time for certain species. Therefore, it is useful to have information on local resistance prevalence, especially for the treatment of severe infections. If necessary, specialist advice should be sought, particularly when the usefulness of the medicinal product may be questioned due to the level of local resistance prevalence.

Classification of species according to susceptibility to the antimicrobial agent:

CLASSES

SPECIES USUALLY SUSCEPTIBLE
Anaérobies
Bacteroides fragilis
Bilophila wadsworthia
Clostridium spp. y compris Clostridium difficile et Clostridium perfringens
Fusobacterium
Peptostreptococcus
Porphyromonas
Prevotella
Veillonella

SPECIES WITH VARIABLE SUSCEPTIBILITY (ACQUIRED RESISTANCE ≥ 10%)"

Anaérobies
Bifidobacterium (+)
Eubacterium

NATURALLY RESISTANT SPECIES

Aérobies
Gardnerella vaginalis
Anaérobies
Atopobium
Actinomyces
Lactobacillus spp.
Mobiluncus
Propionibacterium acnes

(+) The prevalence of bacterial resistance is > 50% in France.

Antiparasitic activity
Susceptible species
Entamoeba histolytica
Giardia intestinalis
Trichomonas vaginalis

5.2 Pharmacokinetic properties
After oral administration of a single 2 g dose of secnidazole, the maximum serum concentration is reached at 5.3 ± 1.3 hours. The plasma half-life is 17.5 ± 4.3 hours on average. Elimination, mainly urinary, is slow; approximately 15% of the administered dose is recovered in urine collected up to 168 hours after administration.
In a Phase I study (IPR_CONCVAG_10) conducted in women (n = 14 evaluable) with bacterial vaginosis, considerable variability was observed with, in some cases, a marked decrease in pharmacokinetic parameters between 48 hours and 72 hours. Vaginal concentrations of secnidazole were 3.6 ± 2.8 mg/L and 1.74 ± 1.4 mg/L, respectively 48 hours and 72 hours after oral administration of a single 2 g dose.
As with other imidazole derivatives, secnidazole can cross the placenta and pass into breast milk.

5.3 Preclinical safety data
Non-clinical data from conventional studies of safety pharmacology, repeated-dose toxicity, genotoxicity, carcinogenicity, and reproductive and developmental toxicity revealed no special hazard for humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Neutral microgranules*, povidone, macrogol 4000, methacrylic acid ester copolymers (Eudragit NE30D), talc, colloidal anhydrous silica (Aerosil 200).
***Composition of neutral microgranules: sucrose – starch**

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
3 years.

6.4 Special precautions for storage
This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container
4.224 g in sachet. Box of 1 or 3 sachets (Paper/Aluminium/Polyethylene).

6.6 Special precautions for disposal and handling
No special requirements.

7. MARKETING AUTHORISATION HOLDER

SUBSTIPHARM
24 RUE ERLANGER
75016 PARIS
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

- **34009 333 707 1 8: 4.224 g sachet (Paper/Aluminium/Polyethylene).**
- **34009 333 708 8 6: 4.224 g sachet (Paper/Aluminium/Polyethylene), box of 3.**

9. DATE OF REVISION OF THE TEXT

March 2026

10. DOSIMETRY

Not applicable.

11. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

PRESCRIPTION AND DISPENSING CONDITIONS

List I