*For the use of a Registered Medical Practitioner only*

**1. GENERIC NAME AND BRAND NAME**

Secnidazole Tablets I.P. 1gm

**Secnil® Forte**

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each film coated tablet contains:
Secnidazole I.P: 1 gm.
Colours: Titanium Dioxide I.P. & Tartrazine Lake

**DOSAGE FORM AND STRENGTH**

Refer section 1 & 2

**4. CLINICAL PARTICULARS**

**4.1 THERAPEUTIC INDICATION**

Treatment of intestinal amoebiasis, amoebic hepatitis, trichomonial vaginitis, bacterial vaginitis, and giardiasis.

**4.2 POSOLOGY AND METHOD OF ADMINISTRATION**

Oral
Severe invasive amoebiasis
Adult: 1.5 g daily as single or in divided doses for 5 days.
Child: 30 mg/kg daily for 5 days.

Oral
Trichomoniasis
Adult: 2 g as a single dose.
Child: 30 mg/kg as a single dose.

Oral
Amoebiasis
Adult: 2 g as a single dose.
Child: 30 mg/kg as a single dose.

Oral
Giardiasis
Adult: 2 g as a single dose.
Child: 30 mg/kg as a single dose.

**Note**

Secnidazole is rapidly and completely absorbed after oral administration and has a longer terminal elimination half-life (approximately 17 to 29 hours) than commonly used drugs in this class. in patients with intestinal amoebiasis or giardiasis, clinical or parasitological cure rates of 80 to 100% are achieved after treatment with a single dose of secnidazole 2g (30 mg/kg in

children), similar to the response rates achieved with multiple dosage regimens of metronidazole or tinidazole.
Patients with hepatic amoebiasis appear to respond well to 5- to 7-day therapy with secnidazole, but the efficacy of this drug regimen requires further evaluation in larger numbers of patients.
After administration of a single dose of secnidazole, parasitological eradication was achieved in approximately 92 to 100% of patients with urogenital trichomoniasis.
Patients with bacteria vaginosis respond to a single dose of secnidazoleas well as to single-dose tinidazole, or single- or 7-day treatment with metronidazole; clinical improvement and/or microbiological evidence of cure was observed in approximately 59 to 96% of patients.

**4.3 CONTRAINDICATIONS**

Secnidazole is contraindicated in patients with hypersensitivity to any component of product.
Secnidazole is contraindicated in pregnancy & lactation.

**4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE**

- Secnidazole is not recommended in patients consuming alcohol and disulfiram.
- Secnidazole is not recommended in patients with history of blood disorders.

**4.5 DRUG INTERACTIONS**

| No | Drug | Drug interaction | Remark |
|---|---|---|---|
| 1 | Disulfiram | Concurrent disulfiram admin may cause psychotic reactions. Disulfiram-like reactions with alcohol. | Administration of secnidazole with disulfiram is not recommended<br><br>Confusional state & paranoid reaction may occur. |
| 2 | Oral anticoagulants | Increased effect of oral anticoagulants and of the hemorrhagic risk is likely | Use of secnidazole simultaneously with warfarin requires close monitoring: |
| 3 | Lithium | Plasma lithium levels may increase resulting in lithium toxicity | Monitor serum lithium levels |
| 4 | Cimetidine | Prolongs the half-life of Secnidazole | |
| 5 | Alcohol | Disulfiram-like reactions with alcohol | Ask the patient to avoid alcohol when taking secnidazole |

**4.6 USE IN SPECIAL POPULATIONS (SUCH AS PREGNANT WOMEN, LACTATING WOMEN, PAEDIATRIC PATIENTS, GERIATRIC PATIENTS ETC.)**

**Pregnancy**

Limited available data with secnidazole use in pregnant women are insufficient to inform a drug associated risk of adverse developmental outcomes. In animal reproduction studies, there were no adverse developmental outcomes when secnidazole was administered orally to pregnant rats and rabbits during organogenesis at doses up to 4 times the clinical dose

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriages in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

**Lactation**

Breastfeeding is not recommended. Discontinue breastfeeding for 96 hours after administration of secnidazole .

There is no information on the presence of secnidazole in human milk, the effects on the breastfed child, or the effects on milk production. Other nitroimidazole derivatives are present in human milk. Because of the potential for serious adverse reactions, including tumorigenicity, advise patients that breastfeeding is not recommended during treatment with secnidazole and for 96 hours (based on half-life) after administration of secnidazole

**Pediatric Use**

The safety and effectiveness of secnidazole in pediatric patients below the age of 18 years have not been established.

**Geriatric Use**

Clinical studies with secnidazole did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

## 4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Do not drive or operate heavy machinery after taking secnidazole as it may cause side effects such as vertigo.

## 4.8 UNDESIRABLE EFFECTS

Secnidazole is very well tolerated. Majority of side effects are of mild and transient in nature

**Gastrointestinal :**nausea, vomiting , epigastric , pain, metallic taste, glossitis, and stomatitis, altered taste

**Nervous system:**Headache, dizziness, vertigo, ataxia and motor incoordination, paresthesia, and peripheral neuropathy

**Skin :**Urticaria

**Blood :** moderate leukopenia which is reversible on treatment discontinuation.

**Others:** A disulfiram like reaction is observed if alcohol is taken by thepatient treated with secnidazole

## 4.8 OVERDOSE

An overdose of secnidazole is unlikely to occur.

## 5. PHARMACOLOGICAL PROPERTIES
## 5.1 MECHANISM OF ACTION

Secnidazole is a 5-nitroimidazole antimicrobial. The drug enters the cell by diffusion . The Nitro group of the drug is reduced by redox proteins present in anerobes to reactive nitro radical . This results in a cytotoxic action by damaging DNA and other critical biomolecules, DNA helix destabilization and breakage occurs.

## 5.2 PHARMACODYNAMIC PROPERTIES

Secnidazole is antiprotozoal, and a derivative of 5-nitromidazole closely related to metronidazole. Secnidazole is used in the treatment of amoebiasis, giardiasis, and trichomoniasis.

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:

*Bacteroides* spp.

*Gardnerella vaginalis*

*Prevotella* spp.

*Mobiluncus* spp.

*Megasphaera*-like type I/II

## 5.2 PHARMACOKINETIC PROPERTIES

| **Parameters** | **Secnidazole** |
|---|---|
| Absorption | Secnidazole is rapidly and completely absorbed after oral administration. Plasma drug concentrations are linear over the therapeutic dose range of 0.5 to 2g.<br><br>The mean peak blood levels were equal to 40.5 +/- 9.4 micrograms ml-1 at 2 h in blood. |
| Distribution | Protein binding accounts for only about 15% of total plasma drug concentration and the volume of distribution is low (49.2L). |

| | |
|---|---|
| Metabolism | Secnidazole undergoes oxidation in the liver. |
| Excretion | Secnidazole and a hydroxymethyl metabolite are detected in urine as glucuronide conjugates. |
| Half life | The terminal elimination half-life (t1/2β) of secnidazole ranged from about 17 to 29 hours. |

## 6. NONCLINICAL PROPERTIES

### 6.1 ANIMAL TOXICOLOGY OR PHARMACOLOGY

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

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 or adverse effects on mating performance, estrous cycles, fertility or conception was observed at doses of up to the maximum tolerated dose (300 mg/kg/day, approximately 1.4 times the recommended dose based on AUC comparisons).

## 7. DESCRIPTION

SECNIL FORTE is supplied for oral administration, as a film coated tablet of Secnidazole. Each film coated tablet of SECNIL FORTE contains Secnidazole 1 gm.

## 8. PHARMACEUTICAL PARTICULARS

### 8.1 INCOMPATIBILITIES

Not applicable

### 8.2 SHELF-LIFE

Refer Pack

### 8.3 PACKAGING INFORMATION

Refer Pack

### 8.4 STORAGE CONDITION AND HANDLING INSTRUCTIONS

Refer Pack

## 9. PATIENT COUNSELLING INFORMATION

Advise the patient that secnidazole may be taken without regard to the timing of meals.
Advise women not to breastfeed during treatment with secnidazole and to discontinue breastfeeding for 96 hours following the administration of secnidazole.

Also, advise a nursing mother that she may choose to pump and discard her milk for 96 hours after administration of secnidazole and feed her infant stored human milk or formula

Vulvo-Vaginal Candidiasis Advise the patient that use of secnidazole may result in vulvo-vaginal candidiasis that may require treatment with an antifungal agent.

Patients should be counseled that antibacterial drugs including secnidazole should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold).

When secnidazole is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by secnidazole or other antibacterial drugs in the future.

## 10. DETAILS OF MANUFACTURER

Refer Pack for manufacturer details.

Marketed By
**Abbott Healthcare Pvt. Ltd.**
Angel Space, Bldg. D-4, Gala No. 1 to 3 &
11 to 13 Ground Floor, 101 to 106 &
111 to 116 First Floor, 201 to 206 & 211 to 216
2nd Floor, Pimplas, Dist. Thane, Bhiwandi - 421 302,
Maharashtra, India.

## 11. DETAILS OF PERMISSION OR LICENCE NUMBER

Refer Pack for Permission/License details

## 12. DATE OF REVISION

Version 4.0 Dated 09th May 2025

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For Product Complaints/Adverse events or Queries please write to
**webmasterindia@abbott.com**