

## 1.0 Summary Product Characteristics (SPC)

### 1. Name of the medicinal product

#### 1.1 Name of the Medicinal Product

VITASEC FORTE

Secnidazole Tablets 1000 mg

#### 1.2 Strength

1000 mg

#### 1.3 Pharmaceutical Form

Tablet, Oral dosage form

## 2. Qualitative and Quantitative Composition

Each film coated tablet contains:

Secnidazole 1000 mg

Excipient qs

Colour: Titanium Dioxide & Quinoline yellow

## 3. Pharmaceutical Form

Tablet

## 4. Clinical particulars

### 4.1 Therapeutic indications

Secnidazole is primarily indicated in conditions like amoebiasis, giardiasis, trichomoniasis and Bacterial vaginosis.

### 4.2 Posology and method of administration

One day treatment: Secnidazole is given 2 gm as a single dose after food.

#### Method for administration

For oral administration.

### 4.3 Contraindications

The severe or irreversible adverse effects include Leucopenia.

The symptomatic adverse reactions produced by Secnidazole are more or less tolerable and if

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they become severe, they can be treated symptomatically, these include Dizziness, Abdominapain, Urticaria, Glossitis, Stomatitis X, Taste disturbances, Paresthesias

#### 4.4 Special warnings and precautions for use

The severe or irreversible adverse effects include Leucopenia.

The symptomatic adverse reactions produced by Secnidazole are more or less tolerable and ifthey become severe, they can be treated symptomatically, these include Dizziness, Abdominapain, Urticaria, Glossitis, Stomatitis X, Taste disturbances, Paresthesias

#### 4.6 Fertility, pregnancy and lactation

No Data Available

#### 4.7 Effects on ability to drive and use machines

There is no evidence to suggest that secnidazole may have an effect: on a patient's ability to drive or operate machinery. Visual impairment and vision blurred may have an effect on a patient's ability to drive or operate machinery (section 4.8).

#### 4.8 Undesirable effects

The severe or irreversible adverse effects include Leucopenia.

The symptomatic adverse reactions produced by Secnidazole are more or less tolerable and ifthey become severe, they can be treated symptomatically, these include Dizziness, Abdominalpain, Urticaria, Glossitis, Stomatitis Taste disturbances, Paresthesias

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

#### 4.9 Overdose

The severe or irreversible adverse effects include Leucopenia.

The symptomatic adverse reactions produced by Secnidazole are more or less tolerable and ifthey become severe, they can be treated symptomatically, these include Dizziness, Abdominalpain, Urticaria, Glossitis, Stomatitis X, Taste disturbances, Paresthesias

### 5. Pharmacological properties

#### 5.1 Pharmacodynamic properties

General properties

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Pharmacotherapeutic group: antibacterials for systemic use; macrolids; secnidazole, ATC code: J Plasma half life is 20 hr.

- Renal Excretion accounts for 50 %
- Is rapidly and completely absorbed after oral administration
- Has a longer terminal elimination half-life (approximately 17 to 29 hours) than commonly used drugs in this class. Secnidazole have a much longer half-life than Metronidazole, allowing single-dose or once daily administration

#### 5.3 Preclinical safety data

Plasma half life is 20 hr.

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#### 6. Pharmaceutical Particulars

##### 6.1. List of Excipients

Maize Starch, Lactose, Microcrystalline cellulose, Sodium benzoate, Purified Talc, Magnesium Stearate, Sodium Starch Glycolate Colloidal Silicon Dioxide, Isopropyl alcohol, Methylene Dichloride & Titanium Dioxide & Quinoline Yellow

##### 6.2. Incompatibilities

None

##### 6.3. Shelf life

36 Months.

##### 6.4 Special precautions for storage

Store below 30 °C.

Protect from light & moisture.

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**6.5. Nature and contents of container**

Aluminium–PVC Blister Pack

2 Tablets are blister packed with Aluminum - PVC foil; such 1 blister is packed in one carton pack.

Pack size: 1 x2 Tablets (i.e. 2 Tablets) in one carton box along with packing leaflet.

**6.6. Special precautions for disposal and other handling**

There are no special storage precautions. Any unused product or waste material should be disposed of in accordance with local requirements.

**7.0 Registrant**

Eastleigh Pharmaceuticals Co. Ltd

P.O Box 167-00610 Nairobi, Kenya

**8.0 Manufacturer**

MARS REMEDIES PVT LTD

Address: 635, GIDC Estate, Waghodia-391760, Vadodara, Gujarat India

**9.0 Date of Publication or Revision**

Last revised on 10-July-2020

**10. DOSIMETRY (IF APPLICABLE)**

Not Applicable

**11. Instructions for Preparation of Radiopharmaceuticals (If Applicable):**

Not Applicable