1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1- Name of the Medicinal Product:

1.1 Product Name

Generic Name or International Non-Proprietary Name (INN)

SECNIDAZOLE TABLETS 500 mg

Brand Name

BACTROSEC

1.2 Dosage Strength

Each film coated tablet contains:

Secnidazole……500 mg

Excipients…….... q.s.

Colour: Titanium Dioxide

1.3 Dosage Form

Film coated tablets

2- Quality and Quantitative Composition:

2.1 Qualitative Declaration

Each film coated tablet contains:

Secnidazole……500 mg

Excipients…….... q.s.

Colour: Titanium Dioxide

2.2 Quantitative Declaration

Sr. No:	Ingredients	Specification	Mg/Tab	Overages %	Qty./ Batch (kg)	Uses
DRY MIXING						
1.	Secnidazole	IHS	500.00	---	50.00	Active
2.	Maize Starch	BP	109.34	---	10.934	Diluent
3.	Microcrystalline cellulose (Plain)	BP	50.00	---	5.00	Diluent
4.	Sodium Starch Glycolate	BP	15.00	---	1.50	Disintegrant
PAST PREPARATION						
5.	Maize Starch	BP	35.00	---	3.50	Binder
6.	Methyl Paraben	BP	0.600	---	0.060	Preservative
7.	Propyl Paraben	BP	0.060	---	0.006	Preservative
8.	Purified Water *	BP	QS	---	QS	Binder solvent
LUBRICATION						
9.	Colloidal Anhydrous Silica	BP	8.00	---	0.800	Glidant
10.	Sodium Starch Glycolate	BP	15.00	---	1.500	Disintegrant
11.	Magnesium Stearate	BP	10.00	---	1.00	Lubricant
12.	Purified Talc	BP	7.00	---	0.700	Lubricant
Average Weight of uncoated tablet			**750.00**	**750.00±5.00**		
COATING						
13.	Hypromellose (H.P.M.C E 15)	BP	10.00	---	1.00	Film forming Agent
14.	Purified Talc	BP	2.00	---	0.200	Lubricant
15.	Titanium Dioxide	BP	2.00	---	0.200	Coating Colour
16.	Isopropyl alcohol*	BP	140.00	---	14.00	Solvent
17.	Methylene Chloride DCM*	BP	196.00	---	19.60	Solvent
Average Weight of coated tablet			**764.00**	**764.00±5.00**		

Note: Active material was calculated on assay or Potency Basis.
BP = British Pharmacopoeia
IHS= In- House specification
*Does not found in finished product

3- Pharmaceutical Form:

White colour Caplet shaped Film coated Tablets having one side break line and other side Plain.

4- Clinical Particulars:

4.1 Therapeutic indications

Treatment of the following infections:

1. Eradication of Helicobacter pylori associated with duodenal ulcers, in the presence of antibiotic and acid suppressant therapy .
2. Anaerobic infections such as:
   Intraperitoneal infections: peritonitis, abscess.
   Gynaecological infections: endometritis, endomyometritis, tube-ovarian abscess.
   Bacterial septicaemia.
   Post-operative wound infections.
   Skin and soft tissue infections.
   Upper and lower respiratory tract infections: pneumonia, empyema, lung abscess.
3. Non-specific vaginitis.
4. Acute ulcerative gingivitis.
5. Urogenital trichomoniasis in both male and female patients.
6. Giardiasis.
7. Intestinal amoebiasis.
8. Amoebic involvement of the liver.
9. Prophylaxis: The prevention of post-operative infections caused by anaerobic bacteria, especially those associated with colonic, gastro-intestinal and gynaecological surgery.

4.2 Posology and method of administration

Route: Oral administration during or after a meal.

Posology

Eradication of H. pylori associated with duodenal ulcers:

Adults: The usual dose of is 500mg twice daily coadministred with omeprazole 20mg twice daily and clarithromycin 250mg twice daily for 7 days.

Clinical studies using this 7 day regimen have shown similar H. pylori eradication rates when omeprazole 20mg once daily was used. For further information on the dosage for omeprazole see Astra data sheet.

Anaerobic infections:

Adults: An initial dose of 2g the first day followed by 1g daily given as a single dose or as 500mg twice daily. Treatment for 5 to 6 days will generally be adequate but clinical judgement must be used in determining the duration of therapy, particularly when eradication of infection from certain sites may be difficult. Routine clinical and laboratory observation is recommended if it is considered necessary to continue therapy for more than 7 days.

Children: < 12 years – there is no data available.

Non-specific vaginitis:

Adults: Non-specific vaginitis has been successfully treated with a single oral dose of 2g. Higher cure rates have been achieved with 2g single doses on 2 consecutive days (total dose 4g).

Acute Ulcerative Gingivitis:

Adults: A single oral dose of 2g.

Urogenital trichomoniasis:

(when infection with Trichomonas vaginalis is confirmed, simultaneous treatment of the consort is recommended).

Adults: A single dose of 2g.

Children: A single dose of 50 to 75mg/kg of body weight. It may be necessary to repeat this dose.

Giardiasis:

Adults: A single dose of 2g.

Children: A single dose of 50 to 75mg/kg of body weight. It may be necessary to repeat this dose.

Intestinal Amoebiasis:

Adults: A single daily dose of 2g for 2 to 3 days.

Children: A single daily dose of 50 to 60mg/kg of body weight on each of 3 successive days.

Amoebic involvement in the liver:

Adults: Total dosage varies from 4.5 to 12g, depending on the virulence of the Entamoebahistolytica.

For amoebic involvement of the liver, the aspiration of pus may be required in addition to therapy with Fasigyn.

Initiate treatment with 1.5 to 2g as a single oral daily dose for three days. Occasionally when a three day course is ineffective, treatment may be continued for up to six days.

Children: A single dose of 50 to 60 mg/kg of body weight per day for five successive days.

Use in Renal impairment

Dosage adjustments in patients with impaired renal function are generally not necessary. However, because tinidazole is easily removed by haemodialysis, patients may require additional doses of tinidazole to compensate.

Prevention of post-operative infection:

Adults: A single dose of 2g approximately 12 hours before surgery.

Children: < 12 years – there is no data available.

It is recommended that tinidazole be taken during or after a meal.

Use in the elderly: there are no special recommendations for this age group.

Method of administration

Oral administration. Swallow tablets whole with a glass of water during or after a meal

4.3 Contraindications

Secnidazole is contraindicated for those patients who are hypersensitive toimidazole derivatives.

Patients should be advised not to take alcohol during treatment withsecnidazole (because of possibility of antabuse effect). Administration ofsecnidazole should be avoided to patients with a history of blood dyscrasia

4.4 Special warning and precautions for use

Alcoholic drinks and alcohol containing medicines should be avoided during Secnidazole, treatment. Do not administer to subjects with a history of blood dyscrasia.

4.5 Interaction with other medicinal products and other forms of interaction

Contraindications of concomitant use

Administration of Secnidazole with disulfiram is not recommended: confusional state & paranoid reaction may occur. Use of Secnidazole simultaneously with warfarin

requires close monitoring: increased effect oforal anticoagulants and of the haemorrhagic risk is likelySecnidazole is known to interact with other drugs like

- Cimetidine (HCl)
- Fluorouracil
- Lithium
- Phenobarbitone
- Phenytoin
- Warfarin

These interactions are sometimes beneficial and sometimes may pose threats to life.

4.6 Fertility, Pregnancy and lactation

Secnidazole may be prescribed in pregnancy after the first trimester. As withother similar drugs, secnidazole should not be administered during the firsttrimester of pregnancy or during lactation because secnidazole is found inplacenta and breast milk

4.7 Effects on ability to drive and use machine

No special precautions should be necessary. However, drugs of similar chemical structure, including BACTROSEC have been associated with various neurological disturbances such as dizziness, vertigo, ataxia, peripheral neuropathy (paraesthesia, sensory disturbances, hypoaesthesia) and rarely convulsions. If any abnormal neurological signs develop during Fasigyn therapy, the drug should be discontinued.

4.8 Undesirable effects

During treatment initiation, the most common adverse reactions are nausea, vomiting, diarrhoea, abdominal pain and loss of appetite which resolve spontaneously in most cases. To prevent them, it is recommended to take Metformin in 2 or 3 daily doses and to increase slowly the doses.

The following adverse reactions may occur under treatment with Metformin.

Metabolism and nutrition disorders:

Very rare: Lactic acidosis.

Decrease of vitamin B12 absorption with decrease of serum levels during long-term use of Metformin. Consideration of such aetiology is recommended if a patient presents with megaloblasticanaemia.

Nervous system disorders:

Common: Taste disturbance

Gastrointestinal disorders:

Very common: Gastrointestinal disorders such as nausea, vomiting, diarrhoea, abdominal pain and loss of appetite. These undesirable effects occur most frequently during initiation of therapy and resolve spontaneously in most cases. To prevent them, it is recommended that Metformin be taken in 2 or 3 daily doses during or after meals. A slow increase of the dose may also improve gastrointestinal tolerability.

Hepatobiliary disorders:

Skin and subcutaneous tissue disorders:

Very rare: Skin reactions such as erythema, pruritus, urticaria

Paediatric population

In published and post marketing data and in controlled clinical studies in a limited paediatric population aged 10-16 years treated during 1 year, adverse event reporting was similar in nature and severity to that reported in adults

4.9 Overdose and treatment

Features:

Nausea, vomiting, diarrhoea, anorexia, metallic taste, headache, dizziness and occasionally insomnia and drowsiness. Transiently increased liver enzyme activities have been reported rarely.

Transient epileptiform seizures have been reported following intensive or prolonged therapy. Other adverse effects occurring in these circumstances include peripheral motor neuropathy, blood dyscrasias and liver damage.

The combination of alcohol and metronidazole has been said to cause disulfiram type reactions in about 10% of individuals with sudden onset of excitement, giddiness, flushing, nausea, headache, hypotension and dyspnoea. However the mechanism of this reaction has been questioned.

Treatment:

Unlikely to be required.

Disulfiram type reactions should be treated with intravenous fluids and plasma expanders if necessary. Symptomatic and supportive.

In more serious cases:

1. Single brief convulsions do not require treatment. If frequent or prolonged control with intravenous diazepam (10-20mg in adults; 0.1-0.3mg/kg body weight) or

lorazepam (4mg in an adult and 0.05mg/kg in a child). Give oxygen and correct acid base and metabolic disturbances as required.

2. Other measures as indicated by the patient's clinical condition

5- Pharmacological Properties:

5.1 Pharmacodynamics Properties

General properties

Pharmacotherapeutic group: Antiprotozoal

ATC code: P01AB07

Mode of action:

Secnidazole enters the bacterial cell as a prodrug without an antimicrobial activity. The drug is converted to an active form via reduction of nitro groups to radical anions by bacterial enzymes. The radical anions are thought to interfere with bacterial DNA synthesis of susceptible isolates.

Pharmacotherapeutic group: Nitroimidazolederivativeshasantiprotozoan and antibacterial effects. It is effects against Trichomonasvaginalis, Gardnerellavaginalis and other protazoa including Entamoebahistolytica, Gardialamblia and anaerobic bacteria.

5.2 Pharmacokinetic Properties

Absorption

Secnidazole is rapidly and completely absorbed after oral administration [1]. Following a single oral dose of 2 g in healthy adult female subjects, the mean (SD) secnidazole peak plasma concentration (Cmax) of 45.4 (7.64) mcg/mL and mean (SD) systemic exposure (AUC0-inf) of 1331.6 (230.16) mcg x hr/mL was reached. Median (range) time to peak concentration (Tmax) was 4.0 (3.0-4.0) hours.

Volume of Distribution

The apparent volume of distribution of secnidazole is approximately 42-49 L.

Protein Binding

The plasma protein binding of secnidazole is < 5-15%.

Metabolism

According to *in vitro* studies, secnidazole is metabolized via oxidation by human hepatic CYP450 enzyme system with ≤ 1% conversion to metabolites

Excretion

The predominant route of elimination is renal elimination. Following a single oral dose of 2g secnidazole, approximately 15% of the drug is excreted as unchanged compoung in the urine.

5.3 Preclinical safety Data: None

6- Pharmaceutical Particulars

6.1 List of excipients

Excipients
Maize Starch
Microcrystalline Cellulose (Plain)
Sodium Starch Glycolate
Methyl Paraben
Propyl Paraben
Purified Water*
Colloidal Anhydrous Silica
Magnesium Stearate
Purified Talc
Hypromellose (H.P.M.C E 15)
Titanium Dioxide
Isopropyl Alcohol*
Methylene Chloride DCM*

6.2 Incompatibilities

None known

6.3 Shelf life

36 months from the date of manufacture.

6.4 Special precautions for storage

Store below 30°C, Protect from light and Moisture.

6.5 Nature and contents of container

10 or 4 tablet packed in one Alu-PVC blister. Such 1Alu-PVC blister packed in unit printed duplex board carton along with its package insert. Such cartons packed in export worthy shipper.

Note: All pack style may not be marketed.

7- Marketing Authorization Holder:

Name : REGLOB PHARMACEUTICALS LIMITED.

Address : PLOT 1, ALHAJI JUNAID DOSHUNMU, CBD, ALAUSA, IKEJA, LAGOS, NIGERIA

8- Marketing Authorization Number(s): G/25/1749

Product license / registration Number (s)

9- Manufacturer Name:

-Name : **GLOBELA PHARMA PVT. LTD.**

- Address : Plot No. 357-358, Unit-I
G.I.D.C., Sachin,
Surat – 394 230,
Gujarat,
India.

- Phone : +91– 261–6158000

- E-mail : info@globelapharma.com

10- Date of first authorization/renewal of the Authorization: 13/10/2016

11- Date of revision of the text: