SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Secwid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains secnidazole 500mg.

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL form

Film coated tablet.

White to off white caplet shaped tablets with one side engraved with “SECWID” along the center of the major axis and other side with “MBN” along the center of the major axis and break line along the center of the minor axis

4. Clinical particulars

4.1 Therapeutic indications

Secwid (secnidazole) is specifically indicated for the oral treatment of:

- Urogenital trichomoniasis in both male and female patients. When infections with Trichomonas vaginalis are confirmed, simultaneous treatment of the consort (spouse or sexual partner) is recommended.
- Giardiasis
- Intestinal amobiasis and ameobic involvement of the liver.

4.2 Posology and method of administration

Route: Oral administration during or after a meal.

Posology

A. 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 30mg/kg of body weight. It may be necessary to repeat this dose.

B. Giardiasis:

- Adults: a single dose of 2g.
- Children: a single dose of 30mg/kg of body weight. It may be necessary to repeat this dose.

C. Bacterial vaginosis

- Adults: 2g orally as a single start dose

- Children 30mg/kg of body mass given as a single dose. It may be necessary to repeat this dose in some cases.

D. Intestinal Amoebiasis:

Acute, symptomatic amoebiasis

- Adults: a single daily dose of 2g (4 tablets) at the beginning of a meal.
- Children: a single daily dose of 30mg/kg of body weight at the beginning of a meal.

Asymptomatic amoebiasis

- Adults: 2g orally as a single daily dose for 3 days.

E. Amoebic involvement in the liver:

- Adults: total dosage varies from 4.5 to 12g, depending on the virulence of the *Entamoeba histolytica*. 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 30mg/kg of body weight per day for five successive days. For amoebic involvement of the liver, the aspiration of pus may be required in addition to therapy with Secwid (Secnidazole).

F. 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 secwid be taken during or after a meal.
- Use in the elderly**:** there are no special recommendations for this age group.

G. 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 judgment 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

H. Acute Ulcerative Gingivitis:

- Adults: a single oral dose of 2g.

I. Use in PID:

- Adults: a single oral dose of 2g in combination with single dose of Azithromycin and Fluconazole or the recommended dose of secwid for anaerobic cover in combination with other anti-infective agents to which the causative organism is sensitive to.

J. Eradication of Helicobacter pylori:

- Adults: 2g on alternate days for 1 week. (In combination with appropriate antibiotics and proton pump inhibitor).

Paediatric population

The safety and effectiveness of secnidazole in paediatric patients below the age of 12 years in the prophylaxis and treatment of anaerobic infections have not yet been established.

Method of administration

Oral administration

4.3 Contraindications

Secwid (Secnidazole) is contraindicated in patients who have shown hypersensitivity to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives. Secwid (Secnidazole) is contraindicated in patients having, or with a history of, blood dyscrasia, although no persistent haematological abnormalities have been noted in clinical or animal studies. Secwid (secnidazole) should be avoided in patients with organic neurological disorders. Use of Secwid is contraindicated during the first trimester of pregnancy and used with caution in nursing mothers.

4.4 Special warnings and precautions for use

As with related compounds, alcoholic beverages should be avoided during treatment because of the possibility of a disulfiram-like reaction (flushing, abdominal cramps, vomiting, tachycardia). Alcohol should be avoided until 72 hours after discontinuing Secwid.
Drugs of similar chemical structure have also produced various neurological disturbances such as dizziness, vertigo, incoordination and ataxia. If during therapy with Secwid abnormal neurological signs develop, therapy should be discontinued.

4.5 Interaction with other medicinal products and other forms of interaction

Alcohol: Concurrent use of Secnidazole and alcohol may produce a disulfiram-like reaction and should be avoided, (see section 4.4, Special warnings and precautions for use).
Anticoagulants: Drugs of similar chemical structure have been shown to potentiate the effects of oral anticoagulants. Prothrombin time should be closely monitored and adjustments to the dose of the anticoagulants should be made as necessary.

4.6 Pregnancy and lactation

Pregnancy

Secnidazole crosses the placental barrier. Since the effects of compounds of this class on foetal development are unknown, the use of secnidazole during the first trimester is contraindicated. There is no evidence that Secwid is harmful during the latter stages of pregnancy, but its use during the second and third trimesters requires that the potential benefits be weighed against possible hazards to mother or foetus.

Breastfeeding

Secnidazole is excreted in breast milk. Secnidazole may continue to appear in breast milk for more than 72 hours after administration. Women should not nurse until at least 3 days after having discontinued taking Secwid.

4.7 Effects on ability to drive and use machines

No special precautions should be necessary. However, drugs of similar chemical structure, including Secwid, 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 Secwid therapy, the drug should be discontinued.

4.8 Undesirable effects

Reported side effects have generally been infrequent, mild and self-limiting.

The reported undesirable effects are listed below according to MedDRA system organ class classification and frequency. Within each frequency category, the ADRs are presented in the order of clinical importance. Frequency categories are expressed as: 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); not known (the frequency cannot be estimated from the available data).

System Organ Class	*Common*	*Not known*
Blood and the lymphatic system disorders		Leukopenia
Immune system disorders		Drug hypersensitivity
Metabolism and nutrition disorders	Decreased appetite	
Nervous system disorders	Headache	Convulsions Neuropathy peripheral Paraesthesia Hypoaesthesia Sensory disturbances Ataxia Dizziness Dysgeusia
Ear and labyrinth disorders	Vertigo	
Vascular disorders		Flushing
Gastrointestinal disorders	Vomiting Diarrhoea Nausea Abdominal pain	Glossitis Stomatitus Tongue discolouration
Skin and subcutaneous tissue disorders	Dermatitis allergic Pruritis	Angioedema Urticaria
Renal and urinary disorders		Chromaturia
General disorders and administration site conditions		Pyrexia Fatigue

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. Healthcare professionals are asked to report any suspected adverse reactions.

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4.9 Overdose

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In acute animal studies with mice and rats, the LD_{50} for mice was >3600mg/kg and >2300mg/kg for oral and intraperitoneal administration respectively. For rats, the LD_{50} was >2000mg/kg for both oral and intraperitoneal administration.

Signs and symptoms of overdosage: There are no reported overdoses in humans with Secwid.

Treatment for overdosage: There is no specific antidote for treatment of overdosage with secnidazole. Treatment is symptomatic and supportive. Gastric lavage may be useful. Secnidazole is easily dialysable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiinfectives for systemic use.
ATC code: P01AB07
Secwid is active against both protozoa and obligate anaerobic bacteria. The activity against protozoa involves *Trichomonas vaginalis*, *Entamoeba histolytica* and *Giardia lamblia.*
The mode of action of Secwid against anaerobic bacteria and protozoa involves penetration of the drug into the cell of the micro-organism and subsequent damage of DNA strands or inhibition of their synthesis.
Secwid is active against *Helicobacter pylori*, *Gardnerella vaginalis* and most anaerobic bacteria including *Bacteroides fragilis*, *Bacteroides melaninogenicus*, Bacteroides spp., Clostridium spp., Eubacterium spp., Fusobacterium spp., Peptococcus spp., Peptostreptococcus spp. and Veillonella spp.
Helicobacter pylori (H.pylori) is associated with acid peptic disease including duodenal ulcer and gastric ulcer in which about 95% and 80% of patients respectively are infected with this agent. *H.pylori* is also implicated as a major contributing factor in the development of gastritis and ulcer recurrence in such patients. Evidence suggests a causative link between *H.pylori* and gastric carcinoma.
Various different *H.pylori* eradication regimens have shown that eradication of *H.pylori* heals duodenal ulcers and reduces the risk of ulcer recurrence.

5.2 Pharmacokinetic properties

Secwid is rapidly and completely absorbed following oral administration. In studies with healthy volunteers receiving 2g secnidazole orally, peak serum levels of 40-51 micrograms/ml were achieved within two hours and decreased to between 11-19 micrograms/ml at 24 hours. Healthy volunteers who received 800mg and 1.6g secnidazole IV over 10-15 minutes achieved peak plasma concentrations that ranged from 14 to 21mcg/ml for the 800mg dose and averaged 32mcg/ml for the 1.6g dose. At 24 hours postinfusion, plasma levels of secnidazole decreased to 4-5mcg/ml and 8.6mcg/ml respectively, justifying once daily dosing. Plasma levels decline slowly and secnidazole can be detected in plasma at concentrations of up to 1 microgram/ml at 72 hours after oral administration. The plasma elimination half-life for secnidazole is between 12-14 hours.
Secnidazole is widely distributed in all body tissues and also crosses the blood brain barrier, obtaining clinically effective concentrations in all tissues. The apparent volume of distribution is about 50 litres. About 12% of plasma secnidazole is bound to plasma protein.
Secnidazole is excreted by the liver and kidneys. Studies in healthy patients have shown that over 5 days, 60-65% of an administered dose is excreted by the kidneys with 20-25% of the administered dose excreted as unchanged secnidazole. Up to 5% of the administered dose is excreted in the faeces.

5.3 Preclinical safety data

Secnidazole has been shown to be mutagenic in some bacterial strains tested *in vitro* (with and without metabolic activation). Secnidazole was negative for mutagenicity in a mammalian cell culture system utilising Chinese hamster lung V79 cells (HGPRT test system) and negative for

genotoxicity in the Chinese hamster ovary (CHO) sister chromatid exchange assay. Secnidazole was positive for *in vivo* genotoxicity in the mouse micronucleus assay.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core:

Microcrystalline cellulose (Avicel PH 101)

Methyl hydroxybenzoate

Maize starch

Magnesium stearate

Colloidal silica (aerosil 200)

Sodium starch glycollate

Film Coating:

Hydroxypropyl methyl cellulose

Polythene glycol

Titanium dioxide

Povidone K30

Isopropyl alcohol

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 25°C in the original pack to protect from light and moisture

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Printed aluminium foil backed blister packs of 4 tablets, 1 blister in a pack and 100 packs in a carton. 4 tablets per pack.

6.6 Special precautions for disposal <and other handling>

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

7. <APPLICANT/SUPPLIER>

May & Baker Nigeria Plc.
1 May & Baker Avenue, Off Idiroko, Opposite covenant
University, Ota, Ogun State

8. WHO PREQUALIFICATION REFERENCE NUMBER

9. DATE OF <PREQUALIFICATION> / <RENEWAL OF PREQUALIFICATION>

10. DATE OF REVISION OF THE TEXT

07/10/2019