SUMMARY OF PRODUCT CHARACTERISTICS

1. PRODUCT NAME
ORNICARE – Ornidazole, 500 mg, film coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:
Ornidazole 500 mg

3. PHARMACEUTICAL FORM
A white-coloured oblong shaped biconvex film coated tablet bisected on one side

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
ORNICARE -ORNIDAZOLE is an antimicrobial agent for the treatment of infections due to trichomonads, amoebae, Giardia lamblia and anaerobic bacteria.

1. Bacterial vaginosis (non-specific vaginitis).
2. Trichomoniasis. Genitourinary infections in women and men due to *Trichomonas vaginalis.*
3. Amoebiasis. All intestinal infections due to *Entamoeba histolytica,* including amoebic dysentery. All extraintestinal forms of amoebiasis, especially amoebic liver abscess.
4. Giardiasis (lambliasis).
5. Infections due to anaerobic bacteria. Treatment of infections such as septicaemia, meningitis, peritonitis, postoperative wound infections, puerperal sepsis, septic abortion, and endometritis, with demonstrated or suspected involvement of susceptible bacteria (see section 5.1 Pharmacodynamic properties).
6. Prophylaxis during surgical interventions, particularly those involving the colon, and in gynaecological operations.

4.2 Dose and method of administration
Dose Trichomoniasis

Adults

There are two possible therapeutic regimens:
(a) Single-dose therapy (for acute trichomoniasis)
(b) Five-day therapy (for chronic forms of trichomoniasis)

Type of Treatment	Daily Dosage (500 mg tablets)
(a) Single dose therapy	3 tablets in the evening
(b) Five-day therapy	2 tablets (1 tablet mornings and evenings)

In all cases, the sexual partner should also be treated using the same oral dosage so as to avoid reinfection. *Children*
The dosage for children is 25 mg per kg bodyweight per day, given in a single dose.Version 1.0 2

Amoebiasis

(a) Three-day treatment of patients with amoebic dysentery

(b) Five-to-ten-day treatment for all forms of amoebiasis

Duration of Treatment	Daily Dosage	
	Adults and children over 35 kg	**Children up to 35 kg**
a) Three days	3 tablets in one evening dose Over 60 kg bodyweight: 4 tablets (2 tablets mornings and evenings)	125 mg per 3 kg body weight in one dose (equivalent to 40 mg per kg)
b) Five to ten days	2 tablets (1 tablet mornings and evenings)	125 mg per 5 kg body weight in one dose (equivalent to 25 mg per kg)

Giardiasis (lambliasis)

Duration of Treatment	Daily Dosage	
	Adults and children over 35 kg	**Children up to 35 kg**
One to two days	3 tablets in the evening in one dose	125 mg per 3 kg body weight in one dose (equivalent to 40 mg per kg)

Anaerobic Infections

Prophylaxis: 1500 mg orally, 12 hours before surgery then 500 mg 12-hourly for 3 to 5 days postoperatively.

Method of administration

The tablets must always be taken after meals. ORNICARE – Ornidazole does not have the strengths or dose forms available to deliver the smaller doses required for some paediatric patients therefore other pharmaceutical forms/strengths may be more appropriate for administration to this population.

4.3 Contraindications

ORNICARE -ORNIDAZOLE is contraindicated in patients with known hypersensitivity to the medicine or to other nitroimidazole derivatives.

4.4 Special warnings and precautions for use

Ornidazole must be used with caution in patients with diseases of the CNS (e.g., epilepsy or multiple sclerosis) and liver disease.
The effect of other medicines can be intensified or impaired.

4.5 Interaction with other medicines and other forms of interaction

Alcohol must not be ingested when taking ornidazole or for at least 3 days after discontinuing the medicine.
Ornidazole potentiates the effect of coumarin type oral anticoagulants. The dosage of the anticoagulant has to be adjusted accordingly.

Caution must be exercised when taking ORNICARE -ORNIDAZOLE together with lithium, cimetidine and antiepileptic medicines such as phenytoin and phenobarbital. Ornidazole prolongs the muscle relaxant effect of vecuronium bromide.

Fertility, pregnancy and lactation Use in pregnancy

There is no clinical data available for ornidazole exposure in pregnancy. Studies conducted on animals do not demonstrate direct or indirect harmful effects on pregnancy/embryonic/foetal development/birth or post-natal development. The effect of ornidazole on women of childbearing potential or birth control methods is unknown. Extensive studies in various species have revealed no sign of any teratogenic or foetotoxic action of ornidazole. However, no controlled studies have been carried out in pregnant women. As a matter of principle, ORNICARE -ORNIDAZOLE should not be prescribed in early pregnancy or to nursing mothers except when absolutely necessary. **Use in lactation**

It is not known whether ornidazole is excreted in human milk. The excretion of ornidazole via milk in animals has not been researched. In making the decision whether or not to discontinue breastfeeding or whether or not ornidazole treatment should be discontinued/avoided, the benefit of breastfeeding to the infant and the benefit of ornidazole treatment for the nursing mother must be considered.

Fertility

When ornidazole is administered at a high dosage of 400mg/kg/day, it produces infertility in male rats by inhibiting epididymal sperm motility in terms of decreased sperm velocity. No data has been obtained from research involving humans.

4.7 Effects on ability to drive and use machines

Somnolence, dizziness, tremor, rigidity, poor coordination, seizures, vertigo or temporary loss of consciousness may occur in patients receiving ORNICARE -ORNIDAZOLE. If they occur, such effects may affect tasks requiring alertness including the patient's ability to drive and operate machinery.

4.8 Undesirable effects

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* (cannot be estimated from the available data)

Diseases of the vascular and lymph system

Rare: Leukopenia

Nervous system disorders

Very rare: Somnolence, headache, dizziness, tremor, rigidity, coordination impairments, seizures, fatigue, vertigo, temporary loss of consciousness and sensory or mixed peripheral neuropathy.

Gastrointestinal disorders
Uncommon: Nausea, vomiting, diarrhoea, epigastric discomfort, dry mouth, loss of appetite.
Rare: Impairment of the sense of taste
Hepatobiliary diseases
Unknown: Jaundice, abnormal liver function tests
Skin and subcutaneous tissue diseases
Rare: Pruritus and skin reactions

Reporting of suspected adverse reactions:
Healthcare professionals are requested to report any suspected adverse reactions via the national Pharmacovigilance Electronic Reporting Systems to the respective national regulatory authorities.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiprotozoals, Nitroimidazole derivatives;
ATC code: P01AB03
Chemical name: a-(chloromethyl)-2-methyl-5-nitroimidazole-1-ethanol
ORNICARE -ORNIDAZOLE is effective against *Trichomonas vaginalis, Entamoeba histolytica* and *Giardia lamblia (Giardia intestinalis),* and also against certain anaerobic bacteria such as *Bacteroides* and *Clostridium* spp., *Fusobacterium* spp., and anaerobic cocci.

5.2 Pharmacokinetic properties

Absorption
Following oral administration ornidazole is rapidly absorbed. Mean absorption is 90%. Peak plasma concentrations are reached within three hours.
Distribution
The mean volume of distribution after i.v. administration is 1 litre per kg. Plasma protein binding of ornidazole is about 13%. The active ingredient of ORNICARE -ORNIDAZOLE penetrates the cerebrospinal fluid, the body fluids and the tissues very effectively. Plasma concentrations are within the range considered to be optimal for the various indications (6 to 36 mg/l).
After repeated administration of 500 mg or 1000 mg every twelve hours to healthy volunteers, an accumulation factor of 1.5-2.5 was calculated.

Metabolism
Ornidazole is mainly metabolised to 2-hydroxymethyl and a-hydroxymethyl metabolites in the liver.
Both main metabolites are less active against *Trichomonas vaginalis* and anaerobic bacteria than the unchanged ornidazole.

Elimination

The half-life is about thirteen hours. 85% of a single dose is eliminated within the first five days, most of this being metabolised. 4% of the dose is excreted as unaltered substance in the urine.

Special Populations Patients with hepatic impairment
In patients with liver cirrhosis the elimination half-life is longer (22 versus 14 hours) and clearance lower (35 versus 51 ml/min) than in healthy subjects. The dosing interval should be doubled in patients with severe hepatic impairment.

The pharmacokinetics of ornidazole are unaltered in renal impairment. Dose adjustment is therefore unnecessary in patients with impaired renal function. Ornidazole is removed by haemodialysis. An additional dose of 500 mg of ornidazole should be administered if the daily dose is 2 g/day, or an additional dose of 250 mg ornidazole if the daily dose is 1 g/day, should therefore be administered before the start of haemodialysis.

Neonates and children
The pharmacokinetics or ornidazole in neonates and young children are similar to those in adults.

5.3 Preclinical safety data
None.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Maize starch
Microcrystalline cellulose
Hydroxypropylmethylcellulose
Magnesium stearate
Talc
Titanium dioxide

6.2
Incompatibilities
Not applicable.

6.3 Shelf life
60 months

6.4 Special precautions for storage
Store at or below 30°C. Protect from light.

6.5 Nature and contents of container
PVC/Aluminium foil blister packs. Pack size of 10 tablets.
Not all pack types or pack sizes may be marketed.

6.6 Special precautions for disposal
No special requirements for disposal.

7. Marketing Authorization Holder
Krishna Chemists Limited
Industrial area, Lusaka road, 3rd floor
Metrix Hardware, P.O Box:3328-00506, Nairobi Kenya

8. Marketing Authorization Number
H2024/CTD9320/15572

9. Date of registration/renewal
28 February 2024

10. Date of revision of the text
28 February 2024