SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT.

ORNIDA [Ornidazole Tablets 500 mg]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION :

Each film-coated tablet contains:

Ornidazole 500 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

TABLET.

Red coloured, capsule shaped biconvex, film-coated tablets with breakline on one side & plain on the other side.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

Ornidazole is effective in the treatment of anaerobic infections of trichomoniasis, amoebiasis, giardiasis and nonspecific vaginitis and in surgical antibiotic prophylaxis.

4.2 Posology and method of administration:

Standard Dosage:

The tablets must always be taken after meals.

Trichomoniasis:

There are two possible therapeutic regimens: Single-dose therapy (for acute trichomoniasis); five-day therapy (for chronic forms of trichomoniasis). The tablets should be taken after meals.

(a) Single dose therapy.

(b) Five day therapy.

4.2 Posology and method of administration:[CONTD]

In all cases, the sexual partner should also be treated using the same oral dosage so as to avoid reinfection.

The dosage for children is 25 mg per kg body weight per day, given in a single dose.

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 (1/4 tablet) per 3 kg bodyweight in one dose. (equivalent to 40 mg per kg)
b) Five to ten days	2 tablets (1 tablet mornings and evenings)	125 mg (1/4 tablet) per 5 kg bodyweight 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 (1/4 tablet) 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.

4.3 Contraindications:

Ornidazole is contraindicated in person with hypersensitivity associated with the use of Ornidazole and any other member of nitroimidazole group of antimicrobial agents.

4.4 Special warnings and special precautions for use:

Caution should be exercised in patients with diseases of the CNS, e.g., epilepsy or multiple sclerosis. A health risk exists, among others, in patients with liver disease, in alcoholics, epileptics, in patients with brain damage, in pregnant and nursing women, and children, if the special dosage for children is exceeded. The effect of other medicines can be intensified or impaired.

PRECAUTIONS :

Special precautions are required in case of ataxia, vertigo, epilepsy, peripheral neuropathy, mental confusion and patients with neurological diseases.

Blood disorders: Leukocyte counts should be checked before and after start of therapy (especially in repeat therapy), in patient with history of blood disorders.

CNS: Severe diseases of central and peripheral nervous system may get aggravated on Ornidazole therapy. Treatment should be discontinued in case of onset of peripheral neuropathy, ataxia, vertigo or confusion.

Candidiasis: Ornidazole therapy may aggravate existing candidiasis. Necessary precautions should be taken.

In special population:

Renal & Hepatic impairment & Geriatrics: Precautions are needed to be exercised while administering Ornidazole & Ofloxacin combination in patients with renal & hepatic insufficiency & in elderly patients.

4.5 Interaction with other FPPs and other forms of interaction:

Ornidazole potentiates effect of coumarin-type oral anticoagulants. Ornidazole prolongs the muscle-relaxant effect of vecuronium bromide.

Alcohol intolerance: Unlike other nitro-imidazoles, Ornidazole does not inhibit enzyme aldehyde dehydrogenase. No disulfiram like reaction has been reported on consumption of alcohol. However, as is the case with all imidazoles, this drug should be avoided in concomittance with alcohol usage.

No clinically relevant interactions were seen with food and no interaction was found between Ofloxacin and theophylline.

4.6 Pregnancy and lactation:

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, Ornidazole should not be prescribed in early pregnancy or to nursing mothers except when absolutely necessary.

4.7 Effects on Ability to drive & Use Machines:

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

4.8 ADVERSE REACTIONS:

Dermatological effects: Pruritus has been reported during Ornidazole therapy.

Gastrointestinal system: Bitter or metallic taste, dose related nausea, diarrhea, epigastric distress, dry mouth & anorexia.The incidence of GI complications has varied in studies, but has usually been 10% or less. Adverse GI effect may be less frequent than metronidazole.

Hematological effects: Leucopenia has been described occasionally with Ornidazole therapy.

Neurological effects: Headache, dizziness, somnolence, fatigue & weakness.

4.9 OVERDOSAGE AND TREATMENT OF OVERDOSAGE:

In cases of overdosage, the symptoms such as somnolence, headache and gastrointestinal disturbances such as nausea and vomiting may occur in a more severe form. No specific antidote is known. The administration of diazepam is recommended if cramps occur.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacotherapeutic group: ANTI -BACTERIAL

ATC code: G01AF06

Mechanism of action:

Ornidazole is a 5-nitroimidazole derivative active against protozoa and anaerobic bacteria. After passive absorption into bacterium cell, the nitro group of Ornidazole is reduced to amine group by ferrodoxin type redox system. The formation of redox intermediate intracellular metabolite is believed to be the key component of microorganism killing for Ornidazole.

Antimicrobial Spectrum: Ornidazole has demonstrated invitro and invivo activity against Bacteroides fragilis and other Bacteroides spp, Clostridium spp, Peptostreptococcus spp, Peptococcus spp, and Fusobacterium spp. In vivo activity against aerobic organisms Enterobacteriaceae, Pseudomonas aeruginosa, enterococci has also been reported in the presence of anaerobes mixed aerobic-anaerobic infections.

The antiprotozoal activity of Ornidazole includes Trichomonas vaginalis, Trichomonas foetus, Giardia intestinalis (formerly Giardia lamblia), and Entamoeba histolytica .

5.2 Pharmacokinetic properties:

Absorption: Following oral administration Ornidazole is rapidly absorbed.

Mean absorption is 90%.Peak plasma concentration are reached within 2hrs.

Distribution: Ornidazole gets widely distributed in various body tissues & fluids. Plasma protein binding of Ornidazole is about 13%. The active ingredients of Ornidazole penetrates the cerebrospinal fluid(CSF),the body fluids & the tissue very effectively. The volume of distribution of Ornidazole is 0.9L/Kg

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

Excretion: Most of the dose of Ornidazole is excreted in urine as free & conjugated metabolites,with less than 4% of a dose appearing as unchanged

drug. Renal clearance of Ornidazole is 45-50ml/min upto 22% of metabolites are excreted through feces. Elimination half life of Ornidazole is 11-14hrs.

Pharmacokinetics in Special Populations:

In renal impairment: Dose adjustments of Ornidazole are not required in patients with renal impairment.

In hepatic impairment: Dosage interval of Ornidazole should be doubled in the presence of marked hepatic impairment to avoid accumulation.

5.3 Preclinical safety data:

Not applicable

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients: Microcrystalline Cellulose, Croscarmellose Sodium, Hydroxypropyl Cellulose , Magnesium Stearate , Instacoat Aqua IC-A-472 & Purified Water.

6.2 Incompatibilities:

Not applicable.

6.3 Shelf life: 36 MONTHS.

6.4 Special precautions for storage:

Store at a temperature not exceeding 30 °C.

KEEP OUT OF REACH OF CHILDREN.

PROTECT FROM MOISTURE AND LIGHT.

6.5 Nature and contents of container:

Alu/PVC Blister with VMCH coating, blister of 10 tablets . Packed in printed & BOPP lamination carton. Secondary pack: 3 x 10's & 10 x 10's.

6.6 Instructions for use and handling:

No special requirements. Any unused product or waste material should be disposed off in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER:

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8. MA number issued by Ethiopian FDA:

06774/08058/REN/2021

9. Date of first authorization/renewal of the authorization:

4/11/2021

10. DATE OF REVISION OF THE TEXT:

05-07-2023