TINIZOL 500 TABLETS

(Tinidazole Tablets 500 mg)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

TINIZOL-500 Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr. No	Name	Quantity per Tablet (mg)
1	Tinidazole BP	500.0
2	Calcium Hydrogen Phosphate BP (DCP)	60.000
3	Microcrystalline Cellulose BP	60.000
4	Maize Starch BP	101.00
5	Gelatin BP	7.500
6	Methyl Hydroxy benzoate BP (Methylparaben)	0.415
7	Propyl Hydroxy benzoate BP (Propylparaben)	0.085
8	Colloidal Anhydrous Silica BP (Aerosil)	5.000
9	Purified Talc BP	11.61
10	Magnesium Stearate BP	5.000
11	Hypromellose E-5 BP	13.80
12	Macrogol 6000 BP (Polyethylene glycol 6000)	2.250
13	Titanium Dioxide BP	2.230
14	Colour Sunset Yellow Supra IH	0.080

Note: BP: British Pharmacopoeia

IH: In-House Specification

3. PHARMACEUTICAL FORM

Tablets (Solid Oral)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Tinizol-500 is indicated for urogenital trichomoniasis, Non-specific vaginitis, Lambliasis (giardiasis), Amoebiasis & prevention of anaerobic infections in certain surgical operations.

4.2 Posology and method of administration

Route of Administration: Oral

Dosage:

Do not exceed the prescribed dose.

In the treatment of Urogenital trichomoniasis & Non-specific vaginitis-Adults: 4 coated tablets (500mg) each taken as single dose.

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In the treatment of Lambliasis (giardiasis)-Adults: 4 coated tablets (500mg) each taken as single dose.
Children: 50 to 70 mg /kg of body weight in a single daily dose up to 2gms.
In the treatment of Amoebiasis- Adults: 12 to 15 coated tablets (500mg) each administered over the period of 4-5 days, taken as a single daily dose.
In the prevention of post-operative anaerobic infections- 2gms as a single dose 4-8 hours before surgery.

Route of Administration: Tablets (Oral)

4.3 Contraindications

Tinizol-500 is contraindicated in individuals with hypersensitivity to Tinidazole or more generally to Imidazole.

4.4 Special warnings and precautions for use

Precautions: If urticarial or nervous disorders occur, the treatment should be discontinued and treating physician should be informed. Avoid alcoholic beverages during the treatment course. In the treatment of urogenital trichomoniasis & Non-specific vaginitis, sexual partner should also be treated.

Paediatric: Other than for use in the treatment of Lambliasis (giardiasis) & Amoebiasis in Paediatric patients older than three year of age, safety and effectiveness of Tinidazole in Paediatric patients have not been established.

Geriatric: No data over 65 years of age. In general, dose selection for an elderly patient should be cautions, reflecting greater frequency of decreased hepatic, renal and cardiac function, and of the concomitant disease or other drug therapy.

Renal Impairment: Because of the pharmacokinetics of Tinidazole in the patients with severe renal impairment (CrCL less than 22 ml/min) are not significantly different from those in healthy subjects, no dose adjustment are necessary in these patients.

Patients undergoing hemodialysis: If Tinidazole is administered on same day as and prior to hemodialysis, it is recommended that an additional dose of Tinidazole equivalent to one-half of the recommended dose be administered after the end of hemodialysis.

Hepatic failure: Since there is no data on hepatic impairment, usual recommended doses of Tinidazole should be administered cautiously in the patient with hepatic dysfunction.

4.5 Interaction with other medicinal products and other forms of interaction

An interaction with alcohol may produce a disulfiram-like reaction.

4.6 Pregnancy and lactation

Use in Pregnancy: Category C Drug, **Tinizol-500** should not be given during first trimester of pregnancy since its effect on foetal development are unknown.

Use in Nursing Mothers: It was considered that breast-feeding should not be initiated until 3 days after such prophylactic treatment.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Adverse reactions are rare, moderate and limited. The following have been reported:

Metallic taste in the mouth, digestive disorder (nausea and gastric pain), hypersensitivity reactions with skin rash, pruitis, urticarial, headache, tiredness, vertigo, dark urine.

4.9 Overdose

There are no reported overdoses with Tinidazole in humans.

Treatment of Overdosage: There is no specific antidote for the treatment overdosage with Tinidazole; therefore, treatment should be symptomatic and supportive. Gastric lavage may be helpful. Hemodialysis can be considered because approximately 43% of the amount present in the body is eliminated during 6 hours hemodialysis session.

5. PHARMACOLOGICAL PROPERTIES

ATC Code: J01XD02

5.1 Pharmacodynamic properties

Tinizol-500 is a 5-nitroimidazole derivative. It has antimicrobial actions of metronidazole and is used similarly in the treatment of susceptible protozoal infections and in the treatment and prophylaxis of anaerobic bacterial infections.

5.2 Pharmacokinetic properties

The pharmacokinetics of **Tinizol-500** resemble those of metronidazole although the half-life is longer. **Tinizol 500** is almost completely absorbed following administration by mouth and, typically, a peak plasma concentration of about 40 µg per ml is achieved 2 hours after a single 2 gms dose, falling to about 10 µg per ml at 24 hours and 2.5 µg per ml at 48 hours; concentrations above 8 µg per ml are maintained by daily maintenance doses of 1gm. Comparable concentrations are achieved with equivalent intravenous doses. The plasma elimination half-life of **Tinizol-500** is 12-14 hours. Tinizol-500 is widely distributed and concentrations similar to those in plasma have been achieved in bile, breast milk, cerebrospinal fluid, saliva and variety of body tissues; it crosses the placenta readily. Only 12% is reported to be bound to plasma proteins. An active hydroxy metabolite has been identified. Unchanged drug and metabolites are excreted in the urine and to a lesser extent, in the faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch BP, Microcrystalline Cellulose BP, Calcium Hydrogen Phosphate BP, Gelatin BP, Methyl Hydroxybenzoate BP, Propyl Hydroxybenzoate BP, Magnesium Stearate BP, Colloidal Anhydrous Silica BP, Purified Talc BP, Hypromellose BP, Macrogol 6000 BP, Titanium Dioxide BP.

6.2 Incompatibilities

None.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

6.5 Nature and contents of container

Aluminium / PVC film blister.

Tinizol-500 is available in a blister pack of 4 tablets. 1 such filled blister is packed in a printed inner carton along with one leaflet.

6.6 Special precautions for disposal and other handling

None.

7. MARKETING AUTHORISATION HOLDER

SHALINA HEALTHCARE DMCC

30th Floor, Almas Towers,

Jumeirah Lakes Towers Dubai-UAE.

8. MARKETING AUTHORISATION IN OTHER COUNTRIES

Registered in Democratic Republic of Congo, Central African Republic, Kenya.