Summary of Product Characteristics
TINIZEN 500
(Tinidazole Tablets 500 mg)

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1. Name of the medicinal product

TINIZEN 500

Tinidazole Tablets 500 mg

2. Qualitative and quantitative composition

Each film-coated tablet contains 500 mg of tinidazole.

Excipients with known effect
Each tablet contains 20 mg of lactose monohydrate and the azo colouring agent tartrazine (E102).

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Film-coated tablet.

Yellow, round, biconvex film-coated tablets, plain on both sides.

4. Clinical particulars

4.1 Therapeutic indications

TINIZEN 500 is indicated for the oral treatment of:

- Trichomonas vaginalis infections of the genito-urinary tract in both female and male patients. Where infection with Trichomonas vaginalis has been confirmed or is suspected, simultaneous treatment of the sexual partner is recommended.
- Intestinal and hepatic amoebiasis caused by Entamoeba histolytica, and giardiasis caused by Giardia lamblia.
- Bacterial vaginosis (non-specific vaginitis) associated with Gardnerella vaginalis.
- Infections caused by susceptible anaerobic bacteria, including Bacteroides fragilis and other Bacteroides species, Fusobacterium species, Peptococcus species, Peptostreptococcus species, Clostridium species, Eubacterium species and Veillonella species — for example in septicaemia, peritonitis, post-operative anaerobic infections, lung abscess and osteomyelitis caused by these organisms.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Posology

Tinidazole should be administered orally during or after a meal.

Urogenital trichomoniasis
Adults: a single oral dose of 2 g (4 × 500 mg tablets). Children: a single dose of 50 to 75 mg/kg body weight, which may need to be repeated.

Amoebiasis
Acute intestinal amoebiasis – Adults: 2 g orally as a single daily dose for two to three days; where a three-day course is ineffective, treatment may be continued for up to six days. Children: 50 to 60 mg/kg body weight as a single daily dose for three successive days.

Amoebic liver abscess – Adults: total dosage 4.5 to 12 g depending on the virulence of the organism; initiate with 1.5 to 2 g as a single daily dose for three days, extended to up to six days if needed. Children: 50 to 60 mg/kg body weight as a single daily dose for five successive days. Aspiration of pus may be required in addition to tinidazole in hepatic amoebiasis.

Giardiasis
Adults: a single oral dose of 2 g. Children: a single dose of 50 to 75 mg/kg body weight, which may need to be repeated.

Bacterial vaginosis (non-specific vaginitis)
Adults: a single oral dose of 2 g; higher cure rates have been achieved with 2 g once daily on two consecutive days (total 4 g).

Anaerobic infections
Adults: an initial dose of 2 g on the first day followed by 1 g daily, given as a single dose or as 500 mg twice daily. A course of 5 to 6 days is generally adequate, although the duration should be guided by clinical judgement. The maximum adult dose should not be exceeded in children.

Special populations

Paediatric population
There are no data to support dosage recommendations for the prophylaxis of anaerobic infections in children below 12 years of age.

Renal impairment
Dose adjustment is generally not necessary in patients with renal impairment. As tinidazole is readily removed by haemodialysis, an additional dose may be required to compensate following dialysis.

Method of administration
For oral use.

4.3 Contraindications

- Hypersensitivity to tinidazole, to other 5-nitroimidazole derivatives, or to any of the excipients listed in section 6.1.
- Blood dyscrasia, or a history of blood dyscrasia.

- Organic neurological disorders (active organic disease of the central nervous system).
- History of acute porphyria.
- First trimester of pregnancy (see section 4.6).
- Breast-feeding, during treatment and for 3 days after the last dose (see section 4.6).

4.4 Special warnings and precautions for use

Use restricted to approved indications

Carcinogenicity has been observed in some animal species with nitroimidazole compounds structurally related to tinidazole; although no carcinogenic effect has been established in humans, use should be restricted to the approved indications and unnecessary or chronic use avoided.

Neurological effects

Neurological disturbances such as dizziness, vertigo, incoordination, ataxia, peripheral neuropathy and, rarely, convulsive seizures may occur. If abnormal neurological signs develop during treatment, tinidazole should be discontinued promptly.

Alcohol

Concomitant use of alcohol should be avoided during tinidazole treatment and for at least 3 days after discontinuation, owing to the possibility of a disulfiram-like reaction (flushing, abdominal cramps, vomiting and tachycardia).

Hepatic impairment and blood dyscrasias

Tinidazole should be used with caution in patients with hepatic impairment and in those with a history of blood dyscrasia. If treatment is required for longer than usual, clinical and laboratory monitoring is advised.

Superinfection

As with other nitroimidazoles, treatment may result in superinfection with Candida albicans, which may require appropriate treatment.

Excipients

This medicinal product contains tartrazine (E102), which may cause allergic reactions. It also contains lactose; patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

4.5 Interaction with other medicinal products and other forms of interaction

Combinations that are not recommended

- Disulfiram: concomitant use may cause confusion and psychotic reactions; use with tinidazole (or within the preceding 2 weeks) should be avoided.

- Alcohol and products containing propylene glycol: may provoke a disulfiram-like reaction; should be avoided during treatment and for at least 3 days (72 hours) afterwards.

Combinations requiring precautions

- Oral anticoagulants (e.g. warfarin): tinidazole may potentiate their effect; prothrombin time/INR should be monitored and the anticoagulant dose adjusted as necessary.
- Enzyme inducers (phenobarbital, phenytoin, rifampicin): may increase the elimination of tinidazole and reduce its plasma concentration.
- Lithium, ciclosporin and tacrolimus: plasma concentrations may be increased; monitoring is advised.
- Fluorouracil: tinidazole may reduce its clearance and increase the risk of toxicity.
- Cholestyramine: may reduce the oral bioavailability of tinidazole; administration should be separated.
- Live typhoid (Ty21a) vaccine: antibacterials may reduce its efficacy.

4.6 Fertility, pregnancy and lactation

Pregnancy

Tinidazole is contraindicated during the first trimester of pregnancy. There is no evidence of harm during the later stages of pregnancy, but its use during the second and third trimesters requires that the potential benefit be weighed against possible hazard to the mother and foetus.

Breast-feeding

Tinidazole is excreted in breast milk and may continue to appear in milk for more than 72 hours after administration. Women should not breast-feed during treatment and for at least 3 days after the last dose.

Fertility

There are no data on the effect of tinidazole on human fertility.

4.7 Effects on ability to drive and use machines

The effect of tinidazole on the ability to drive or operate machinery has not been studied. Drivers and operators of machinery should be aware of the potential for dizziness and vertigo.

4.8 Undesirable effects

Summary of the safety profile

The most frequently reported adverse reactions are gastrointestinal disturbances (including nausea, vomiting and a metallic taste). Neurological effects, hypersensitivity reactions and, rarely, convulsions and transient leucopenia may also occur.

Tabulated list of adverse reactions

The adverse reactions reported with tinidazole are derived largely from clinical experience and spontaneous reporting; their frequency cannot be reliably estimated from the available data and is therefore classified as not known (cannot be estimated from the available data).

System Organ Class	Adverse reactions (frequency not known)
Infections and infestations	Superinfection with Candida albicans
Blood and lymphatic system disorders	Transient leucopenia
Immune system disorders	Hypersensitivity reactions (skin rash, pruritus, urticaria, angioedema; occasionally severe)
Nervous system disorders	Headache, dizziness, vertigo, ataxia, incoordination, peripheral neuropathy, paraesthesia, hypoaesthesia, sensory disturbances and, rarely, convulsions
Gastrointestinal disorders	Nausea, vomiting, anorexia, abdominal pain, diarrhoea, metallic taste, furry tongue, glossitis, stomatitis
Skin and subcutaneous tissue disorders	Skin rash, pruritus, urticaria, angioneurotic oedema
Renal and urinary disorders	Dark-coloured urine
General disorders and administration site conditions	Fever, tiredness, flushing
Investigations	Modification of laboratory (biological) test values

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 to the National Regulatory Authority.

4.9 Overdose

Symptoms

There are no reports of overdose with tinidazole in humans.

Management

There is no specific antidote. Treatment is symptomatic and supportive; gastric lavage may be useful. Tinidazole is readily removed by haemodialysis.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antiinfectives for systemic use; other antibacterials; nitroimidazole derivatives. ATC code: J01XD02.

Mechanism of action

Tinidazole is a 5-nitroimidazole derivative. Its action against anaerobic bacteria and protozoa involves penetration of the drug into the micro-organism, followed

by reduction of the nitro group to a reactive intermediate that causes damage to, and inhibition of the synthesis of, DNA strands, leading to cell death.

Spectrum of activity

Tinidazole is active against Trichomonas vaginalis, Entamoeba histolytica and Giardia lamblia, and against anaerobic bacteria including Bacteroides fragilis and other Bacteroides species, Fusobacterium species, Peptococcus and Peptostreptococcus species, Clostridium species, Eubacterium species and Veillonella species. It is active in vitro against Gardnerella vaginalis but is inactive against Candida albicans.

5.2 Pharmacokinetic properties

Absorption

Tinidazole is rapidly and completely absorbed after oral administration. Following a single 2 g oral dose, peak serum concentrations of approximately 41 micrograms/mL are reached at about 1 to 2 hours, declining slowly so that tinidazole remains detectable in serum at 48 hours.

Distribution

Tinidazole is widely distributed into body tissues and crosses the blood-brain barrier, achieving clinically effective concentrations in tissues. Plasma protein binding is approximately 12%.

Biotransformation and elimination

Tinidazole is eliminated by hepatic metabolism and renal and biliary excretion. Over 5 days, approximately 60 to 65% of a dose is excreted by the kidneys, of which 20 to 25% is unchanged tinidazole and about 12% metabolites; up to about 5% is excreted in the faeces. The plasma elimination half-life is approximately 12 to 14 hours. Pharmacokinetic parameters are not significantly altered in patients with renal impairment.

5.3 Preclinical safety data

Tinidazole has shown mutagenic activity in some bacterial in vitro test systems, an effect common to the nitroimidazole class. Carcinogenicity has been reported with structurally related nitroimidazoles (e.g. metronidazole) following chronic high-dose administration in mice and rats; corresponding lifetime studies with tinidazole are limited, and the relevance of these findings to the short-course human use of tinidazole is uncertain. As a precaution, use should be restricted to the approved indications and chronic use avoided.

6. Pharmaceutical particulars

6.1 List of excipients

- Lactose monohydrate
- Maize starch
- Microcrystalline cellulose
- Povidone (PVP K30)

- Croscarmellose sodium
- Sodium lauryl sulphate
- Colloidal anhydrous silica
- Purified talc
- Magnesium stearate
- Hypromellose (HPMC)
- Titanium dioxide
- Tartrazine (E102)
- Propylene glycol
- Isopropyl alcohol
- 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. Protect from light and moisture. Keep out of the reach of children.

6.5 Nature and contents of container

4 tablets in an Alu-PVC blister; one blister packed in a printed carton together with a package insert.

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. Marketing Authorisation Holder

ZAIN PHARMA LTD

Plot No. 209/13741, Colchester Park, Go-Down No. 1, 2, 3, Off Mombasa Road, P.O. Box 100167-00101, Nairobi, Kenya.

8. Marketing Authorisation Number

CTD12846

9. Date of first authorisation / renewal of the authorisation

03.07.2026

10. Date of revision of the text

02.07.2026