

TORTHROCIN

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for TORTHROCIN [Azithromycin 250 mg tablets]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: The mechanism of action of azithromycin is based upon the suppression of bacterial protein synthesis by means of binding to the ribosomal 50S sub-unit and inhibition of peptide translocation.

INDICATIONS: It is indicated for the treatment of uncomplicated multidrug resistant enteric fever only

DOSAGE AND ADMINISTRATION: Azithromycin should be given as a single daily dose. The total dose is 1500 mg, administered as 500 mg once daily for 3 days. Alternatively, the same total dose (1500 mg) can be administered in a period of 5 days, 500 mg on the first day and 250 mg on day 2 to 5. In the case of uncomplicated Chlamydia trachomatis urethritis and cervicitis, the dosage is 1000 mg as a single oral dose. For patients who are allergic to penicillin and/or cephalosporins, prescribers should consult local treatment guidelines. Azithromycin tablets are not suitable for patients under 45 kg body weight. Other dosage forms are available for this group of patients. For elderly patients the same dose as for adults can be applied.

CONTRAINDICATION: Hypersensitivity to azithromycin, erythromycin, any macrolide or ketolide antibiotic, or to any of the excipient listed.

WARNINGS & PRECAUTIONS: Allergic reactions including angioneurotic oedema and anaphylaxis (rarely fatal), dermatologic reactions including acute generalised exanthematous pustulosis (AGEP), Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) (rarely fatal) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported. Since the liver is the principal route of elimination for azithromycin, the use of azithromycin should be undertaken with caution in patients with significant hepatic disease. In case of signs and symptoms of liver dysfunction, such as rapid developing asthenia associated with jaundice, dark urine, bleeding tendency or hepatic encephalopathy, liver function tests/ investigations should be performed immediately. In patients receiving ergot derivatives, ergotism has been precipitated by coadministration of some macrolide antibiotics.

DRUG INTERACTIONS: Antacids, Cetirizine, Didanosine (Dideoxyinosine), Digoxin and colchicine, Zidovudine, Ergot derivatives, Atorvastatin, Carbamazepine, Cimetidine, Coumarin-Type Oral Anticoagulants, Ciclosporin, Efavirenz, Fluconazole, Indinavir, Methylprednisolone, Midazolam, Nelfinavir, Rifabutin, Sildenafil, Terfenadine, Theophylline, Triazolam, Trimethoprim/sulfamethoxazole, Hydroxychloroquine and chloroquine,

ADVERSE REACTIONS: Candidiasis, oral candidiasis, vaginal infection, Pseudomembranous colitis, Leukopenia, neutropenia, Thrombocytopenia, haemolytic anaemia, Angioedema, hypersensitivity, Anaphylactic reaction, Anorexia, Nervousness, Agitation, Aggression anxiety, Dizziness, headache, paraesthesia, dysgeusia, Hypoaesthesia somnolence, insomnia, Syncope, convulsion, psychomotor hyperactivity, anosmia, ageusia, parosmia, Visual impairment, Deafness, Hearing impaired, tinnitus, Vertigo, Palpitations, Torsades de pointes arrhythmia including ventricular tachycardia, Diarrhoea, abdominal pain, nausea, flatulence, Vomiting, dyspepsia, Gastritis, constipation, Pancreatitis, tongue discoloration, Hepatitis, Hepatic function abnormal, Hepatic failure (which has rarely resulted in death), hepatitis fulminant, hepatic necrosis, jaundice cholestatic, Rash, pruritus, Stevens-Johnson syndrome, photosensitivity reaction, urticaria, Acute generalised exanthematous pustulosis (AGEP) *§ , DRESS (Drug reaction with eosinophilia and systemic symptoms), Toxic epidermal necrolysis, erythema multiforme, Arthralgia, Renal failure acute, nephritis interstitial, Fatigue, Chest pain, oedema, malaise, asthenia, Lymphocyte count decreased, eosinophil count increased, blood bicarbonate decreased, Aspartate aminotransferase increased, alanine aminotransferase increased, blood bilirubin increased, blood urea increased, blood creatinine increased, blood potassium abnormal, Electrocardiogram QT prolonged.

MARKETED BY:



Torrent Pharmaceuticals Limited.

IN/TORTHROCIN 250,500/Apr-22/01/ABPI

(Additional information is available on request)