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BACTIFLOX™-250/500/750 LACTAB™
ACINO SWITZERLAND

Composition:
Bactiflox™-250/500/750 Lactab™ active ingredient is ciprofloxacin.

Each film-coated tablet contains contains 250 mg ciprofloxacin (Bactiflox™-250 Lactab™), 500 mg ciprofloxacin (Bactiflox™-500 Lactab™) or 750 mg ciprofloxacin (Bactiflox™-750 Lactab™).

Indications and dosage:
Bactiflox™-250/500/750 Lactab™ is an antibacterial agent (a fluoroquinolone), it blocks bacterial DNA replication, transcription, repair and recombination.

Bactiflox™-250/500/750 Lactab™ is indicated in adults: for

(1) lower respiratory tract infection (RTI) due to Gram-negative bacteria (as in exacerbations of chronic obstructive pulmonary disease, broncho-pulmonary infection in cystic fibrosis or in bronchiectasis, pneumonia)
(2) upper RTI (chronic suppurative otitis media, acute exacerbation of chronic sinusitis, malignant external otitis)
(3) urinary tract infection (UTI)
(4) genital tract infection including gonorrhoeae
(5) gastro-intestinal tract infection
(6) intra-abdominal infection
(7) Gram-negative bacterial infection of skin and soft tissue
(8) bones and joint infection
(9) infection and infection prophylaxis in neutropenia
(10) prophylaxis of invasive Neisseria meningitidis infection
(11) inhalation anthrax;

In children and adolescents: for

(1) broncho-pulmonary Pseudomonas aeruginosa infection in cystic fibrosis
(2) complicated UTI and pyelonephritis
(3) inhalation anthrax.

Bactiflox™-250/500/750 Lactab™ should be given in adults at doses of:

lower RTI, 2 x 500-700 mg/day for 7-14 days; upper RTI, 2 x 500-750 mg/day for 7-14 days or 28 days-3 months (malignant external otitis); UTI, 2 x 250-500 mg/day for 3-7 days or 2 x 500-750 mg/day for 7-21 days (complicated pyelonephritis, prostatitis) or up to 6 weeks (chronic prostate infection); UTI, 1 x 500 mg (gonococcal urethritis/cervicitis) or 2 x 500-750 mg/day for ≥14 days; GI infection, 2 x 500 mg/day for 1 day (Shigella), 5 days (Shigella dysenteriae type 1), 3 days (Vibrio cholera), 7 days (Typhoid fever) or 5-14 days (intra-abdominal Gram-negative); 2 x 500-750 mg/day for 7-14 days (skin and soft tissue infection), up to 3 months (bone and joint infection), or as long as indication present (neutropenia + infection treatment/prophylaxis); prophylaxis of Neisseria meningitides, 1 x 500 mg; 2 x 500 mg/day for 60 days (inhalation anthrax prophylaxis/treatment);

Should be given in children and adolescents at doses of:

cystic fibrosis, 2 x 20 mg/kg, maximally 750 mg/dose for 10-14 days; complicated UTI, pyelonephritis, 2 x 10-20 mg/kg, maximally 750 mg/dose for 10-21 days; inhalation anthrax prophylaxis/treatment, 2 x 10-15 mg/kg, maximally 500 mg/dose for 60 days; other severe infections, 2 x 20 mg/kg, maximally 750 mg/dose for variable periods depending on infection type; in geriatrics: dose depends on infection severity and creatinine clearance;

in cases of impaired renal function:

If respective values for creatinine clearance (ml/min/1.73 m²) and serum creatinine (μmol/L) are >60 and <124, dose=usual; if 30 - 60 and 124-168, dose=250 - 500 mg/12 h; if <30 and >169, dose=250 - 500 mg/24 h; in cases of haemodialysis/peritoneal dialysis and serum creatinine >169, dose=250 - 500 mg/24 h (after haemodialysis).

Contraindications:
Hypersensitivity to ciprofloxacin/other quinolones/any excipients; concomitant tizanidine.

Precautions:

(i) no or limited efficacy in: severe/mixed infection with Gram-positive or anaerobic pathogens; streptococcal infection; genital tract, ciprofloxacin-resistant Neisseria gonorrhoea infection; post-surgical intra-abdominal infection; travellers' diarrhoea with ciprofloxacin-resistant pathogens; possibly ciprofloxacin-resistant bone and joint infection;

(ii) risk of anaphylactic/anaphylactoid/photosensitivity reactions in: antibiotic-associated colitis, crystalluria, hepatic necrolysis/life-threatening hepatic failure; ciprofloxacin-resistant infection during prolonged treatment;

(iii) in children and adolescents: risk of cartilage damage;

(iv) caution in: cases of tendinitis history; myasthenia gravis; CNS disorders; neuropathy; QT-prolongation risk; impaired renal function; glucose-6-phosphate-dehydrogenase deficiency;

(v) only use when other treatments are not possible or effective (because of limited data or experience) in: inhalational anthrax; broncho-pulmonary infection in cystic fibrosis cases aged 1 - 5 years; complicated UTI; pyelonephritis; other severe infection;

(vi) risk of false-negative in: *in-vitro* testing of ciprofloxacin on Mycobacterium tuberculosis;

(vii) ability to drive and use machines may be impaired;

(viii) overdose: symptomatic treatment, ECG monitoring.

Pregnancy / lactation:

It is recommended to avoid using Bactiflox™-250/500/750 Lactab™ during pregnancy and during breast-feeding. Undesirable effects: nausea and diarrhoea are the most commonly reported adverse events (AEs) with ciprofloxacin (oral/intravenous).

Less commonly reported AEs include mycotic superinfection, eosinophilia, anorexia, psychomotor hyperactivity/agitation, vomiting, gastrointestinal and abdominal pains, increased blood levels of transaminases/bilirubin/alkaline phosphatise, dyspepsia, flatulence, rash, pruritus, urticaria, musculoskeletal pain, arthralgia, renal impairment, asthenia, fever.

Interactions:

Bactiflox™-250/500/750 Lactab™ should not be given concomitantly with tizanidine, and caution is needed with concomitant treatment with:

(i) agents with QT-interval prolongation risk

(ii) agents containing calcium, magnesium, aluminium or iron

(iii) glibenclamide

(iv) duloxetine

(v) ropinirole

(vi) lidocaine

(vii) clozapine

(viii) sildenafil.

Presentation:

Packs of 10 film-coated tablets in PVC/PVDC/Aluminium blisters.

Since indications, dosage forms and strengths may vary from country to country, please consult your local prescribing information. Full prescribing information, details and literature references are available on request.

Latest update of information: July 2011.