

COMPOSITION

VIPROLOX 250 TABLETS contains Ciprofloxacin HCl equivalent to ciprofloxacin 250mg.

VIPROLOX 500 TABLETS contains Ciprofloxacin HCl equivalent to ciprofloxacin 500mg.

VIPROLOX 750 TABLETS contains Ciprofloxacin HCl equivalent to ciprofloxacin 750mg.

INDICATIONS: VIPROLOX is indicated for the treatment of infections of the upper and lower respiratory tract, eye, urinary tract, skin/soft tissue, bone and joint, intra-abdominal, biliary tract, gastro-intestinal, pelvic, for severe systemic infections (e.g. septicaemia) and gonorrhoea. Also, for prophylaxis against infection in elective upper gastro-intestinal tract surgery and endoscopic procedures.

VIPROLOX use in adolescents and children is generally not recommended, only in paediatric cystic fibrosis patients (5-17yrs) with acute pulmonary exacerbations associated with *P. aeruginosa* infection. For any other indications it may be used if the benefit is considered to outweigh the potential risks.

DOSAGE: General dosage is 500-750mg b.d.

Gonorrhoea: 250mg single dose

Acute, uncomplicated cystitis in women: 100mg b.d

Upper and lower urinary tract infections: 250-500mg bi.d.

Upper and lower respiratory tract infections: 250-750mg b.d.

Pneumococcal pneumonia (second-line): 750mg b.d.

Cystic fibrosis patients with pseudomonal lower RTI: 750mg b.d.

(dosage alteration if the child has low body-weight)

Severe infections, (due to *Pseudomonas*, staphylococci and streptococci): 750mg b.d.

Prophylaxis in elective upper gastro-intestinal surgical and endoscopic procedures: 750mg single dose 60-90min prior to the procedure. If gastro-oesophageal obstructive lesions are suspected use with an antibiotic against anaerobes

Severe renal impairment (creatinine clearance < 20ml/min): $\frac{1}{2}$ the total daily adult dose

Elderly: No adjustment of dosage is necessary.

Adolescents and children: Cystic fibrosis patients (5-17yrs): 20mg/kg orally twice daily (maximum daily dose 1500mg).

For other indications (if the benefit outweighs the potential risks): 5-15mg/kg orally twice daily

Duration of Treatment: Usual treatment period is 5-10 days.

For acute pulmonary exacerbations of cystic fibrosis in paediatric patients (5-17yrs) → 10-14 days

PHARMACODYNAMIC PROPERTIES:

Ciprofloxacin is a synthetic 4-quinolone derivative, with bactericidal activity. It acts via inhibition of bacterial DNA gyrase, ultimately resulting in interference with DNA function. Ciprofloxacin is highly active against a wide range of Gram-positive and Gram-negative organisms and has shown activity against some anaerobes, *Chlamydia* spp. and *Mycoplasma* spp. Ciprofloxacin is also suitable for use in combination with penicillins, cephalosporins, aminoglycosides and tetracyclines where additive behaviour is usually observed.

PHARMACOKINETIC PROPERTIES:

Absorption of ciprofloxacin occurs rapidly, mainly from the small intestine ($\text{Abs.T}_{1/2} = 2-15\text{min}$). Plasma levels are dose-related and peak 0.5-2.0hrs after dosing. The AUC also increases dose proportionately after administration of both single and repeated oral doses. The oral bioavailability is approximately 70-80%. Distribution of ciprofloxacin within tissues is wide and the volume of distribution high, though slightly lower in the elderly. Protein binding is low (between 19-40%).

Elimination of ciprofloxacin and its metabolites occurs rapidly, primarily by the kidney. After single dose of ciprofloxacin, 55% are eliminated by the kidney and 39% in the faeces within 5 days. The elimination half-life of unchanged ciprofloxacin over a period of 24-48hrs post-

dose is 3.1-5.1hrs.

Even though, studies with severely renally impaired patients (creatinine clearance <20ml/minute) do not give clear indications, it is recommended to reduce by half the total daily dose.

Results of studies in paediatric cystic fibrosis patients have shown dosages of 20mg/kg orally twice daily is recommended to achieve plasma concentration/time profiles comparable to those achieved in the adult population at the currently recommended dosage regimen.

CONTRAINDICATIONS:

- In patients who have shown hypersensitivity to ciprofloxacin or other quinolones.
- In children/adolescents except in cases of cystic fibrosis associated (5-17yrs)
- Pregnancy and lactation.

WARNINGS:

Viprolox should be used with caution in patients suffering from epilepsy and CNS disorders.

Crystalluria related to the use of ciprofloxacin has been reported.

Patients with a family history of or actual defects in glucose-6-phosphate dehydrogenase activity are prone to haemolytic reactions with quinolones. Older patients and those treated concurrently with corticosteroids might experience tendon inflammation and rupture. At the first sign of pain or inflammation, patients should discontinue ciprofloxacin and rest the affected limbs.

Patients should avoid prolonged exposure to strong sunlight or UV radiation during treatment.

Viprolox could result in impairment of the patient's ability to drive or operate machinery, particularly in conjunction with alcohol.

Particular caution is advised in patients who

need to concurrently take: antacids, any other preparations containing aluminium, calcium, magnesium or iron, anticoagulants (such as warfarin), medicines used to relieve pain and inflammation (e.g. fenbufen) except aspirin, *glibenclamide, probenecid or metoclopramide*, cyclosporin, phenytoin.

PREGNANCY AND LACTATION: Viprolox during pregnancy is not recommended. Studies have indicated that ciprofloxacin is secreted in breast milk. Administration to nursing mothers is thus not recommended.

SIDE EFFECTS: Usual side effects are diarrhoea, nausea and skin rashes.

Rare side effects reported include: Allergic reactions (e.g. angioedema), CNS reaction (e.g. headache, dizziness, tremor, depression), hyperglycaemia, gastrointestinal reactions (e.g. vomit, indigestion, anorexia, pseudomembranous colitis), skin sensitivity to the sun, haematological disturbances (e.g. anaemia, eosinophilia), musculoskeletal reactions (e.g. arthralgia, myalgia), hepatitis, yellow jaundice, crystalluria, or visual disturbances.

OVERDOSE: Routine emergency measures and to monitor renal function, including urinary pH and acidify, if required, to prevent crystalluria. Patients must be kept well hydrated and, in the case of renal damage resulting in prolonged oliguria, dialysis should be initiated. Calcium or magnesium antacids may be administered as soon as possible after ingestion of Ciprofloxacin tablets in order to reduce the absorption of ciprofloxacin. Serum levels of ciprofloxacin are reduced by dialysis.

STORAGE: Store below 25°C in a dry place protected from light.

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