CODAL-SYNTO

Successful infection control

Floxasynt®

Levofloxacin

FLOXASYNT® 250mg film coated tablets • **FLOXASYNT**® 500mg film coated tablets

Summary of SPC for Floxasynt®

Name of the Medicinal Product:	Floxasynt®.
Qualitative and Quantitative Composition:	Each tablet contains 250/500 mg levofloxacin corresponding to 256.23/ 512.46 mg of levofloxacin hemihydrate.
Pharmaceutical Form:	Film coated tablet.
Therapeutic Indications:	Acute bacterial sinusitis; Acute bacterial exacerbations of chronic bronchitis; Community-acquired pneumonia; Uncomplicated urinary tract infections; Complicated urinary tract infections including pyelonephritis; Chronic bacterial prostatitis; Skin and soft tissue infections.
Posology and Method of Administration:	Floxasynt is administered once or twice daily. The dosage depends on the type and severity of the infection and the sensitivity of the presumed causative pathogen. The duration of treatment varies according to the course of the disease. The tablets should be swallowed without crushing and with sufficient amount of liquid. They may be divided at the score line to adapt the dosage. The tablets may be taken during meals or between meals. Floxasynt should be taken at least two hours before or after iron salts, antacids and sucralfate administration since reduction of absorption can occur.
Contraindications:	Hypersensitivity; Epilepsy; History of tendon disorders related to fluoroquinolone administration; Children or growing adolescents; Pregnancy; Breast-feeding women.
Special Warnings and Precautions for Use:	Severe cases of pneumococcal pneumonia; Nosocomial infections due to P. aeruginosa; Tendinitis and tendon rupture; Clostridium difficile-associated disease; Patients predisposed to seizures; Patients with G-6- phosphate dehydrogenase deficiency; Renal impairment; Hypersensitivity reactions; Hypoglycemia; Prevention of photosensitisation; Patients treated with Vitamin K antagonists; Psychotic reactions; Cardiac disorders, patients with known risk factors for prolongation of the QT interval; Peripheral neuropathy; Opiates; Hepatobiliary disorders; Vision disorders.
Interactions with other Medicaments and other forms of Interaction:	Iron salts, magnesium- or aluminium-containing antacids; Sucralfate; Theophylline, fenbufen or similar NSAIDs; Probenecid and cimetidine; Ciclosporin; Vitamin K antagonists; Drugs known to prolong QT interval.
Pregnancy and Lactation:	Must not be used.
Undesirable Effects:	Fungal infection; Leukopenia, eosinophilia, thrombocytopenia, neutropenia, agranulocytosis, pancytopenia, haemolytic anaemia; Anaphylactic shock, hypersensitivity; Anorexia, hypoglycemia; Insomnia, nervousness, psychotic disorder, depression, confusional state, agitation, anxiety, psychotic reactions with self-endangering behaviour, hallucination; Dizziness, headache, somnolence, convulsion, tremor, paraesthesia, sensory or sensorimotor peripheral neuropathy, dysgeusia including ageusia, parosmia including anosmia; Visual disturbance; Vertigo, hearing impaired, tinnitus; Tachycardia, ventricular arrhythmia and torsades de pointes, ECG QT prolonged; Hypotension; Bronchospasm, dyspnoea, pneumonitis allergic; Diarrhoea, nausea, vomiting, abdominal pain, dyspepsia, flatulence, constipation; Hepatic enzyme increased, blood bilirubin increased, hepatitis, jaundice and severe liver injury, acute liver failure; Rash, pruritus, urticaria, angioneurotic oedema, photosensitivity reaction, toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme, hyperhidrosis, mucocutaneous reactions; Tendon disorder, arthralgia, myalgia, tendon rupture, rhabdomyolysis; Blood creatinine increased, renal failure acute; Asthenia, pyrexia, pain; Extrapyramidal symptoms and other disorders of muscular coordination, hypersensitivity vasculitis, attacks of porphyria in patients with porphyria.
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