

- ✓ function. Patients should be advised to stop treatment and contact their doctor if signs and symptoms of hepatic disease develop, such as anorexia, jaundice, dark urine, pruritus, or tender abdomen.
- ✓ Caution should also be exercised when administering clarithromycin to patients with moderate to severe renal impairment.
- ✓ Caution is advised in patients with severe renal insufficiency.
- ✓ Long-term use may, as with other antibiotics, result in colonization with increased numbers of non-susceptible bacteria and fungi. If superinfections occur, appropriate therapy should be instituted.
- ✓ Attention should also be paid to the possibility of cross resistance between clarithromycin and other macrolide drugs, as well as lincosyn and clindamycin. Therefore caution is required when prescribing clarithromycin for such patients.
- ✓ Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. Therefore, discontinuation of clarithromycin therapy should be considered regardless of the indication. Microbial testing should be performed and adequate treatment initiated.
- ✓ Caution is advised regarding concomitant administration of clarithromycin with other ototoxic drugs, especially with aminoglycosides. Monitoring of vestibular and auditory function should be carried out during and after treatment.

Pregnancy

The safety of clarithromycin for use during pregnancy has not been established. Based on variable results obtained from studies in mice, rats, rabbits and monkeys, the possibility of adverse effects on embryo foetal development cannot be excluded. Therefore, use during pregnancy is not advised without carefully weighing the benefits against risk.

Breast-feeding

The safety of clarithromycin for using during breast-feeding of infants has not been established. Clarithromycin is excreted into human breast milk.

SIDE EFFECTS

Infections and infestations

Uncommon: candidiasis, vaginal infection
Not known: Pseudomembranous colitis, erysipelas

Blood and the lymphatic system disorders

Uncommon: Leukopenia, neutropenia, eosinophilia
Not known: Agranulocytosis, thrombocytopenia

Immune system disorders

Uncommon: hypersensitivity
Not known: Anaphylactic reaction, angioedema

Metabolism and nutrition disorders

Uncommon: Anorexia, decreased appetite

Psychiatric disorders

Common: Insomnia
Uncommon: Anxiety
Not known: Psychotic disorder, confusional state, depersonalization, depression, disorientation, hallucination, abnormal dreams

Nervous system disorders

Common: Dysgeusia, headache, taste perversion
Uncommon: Dizziness, somnolence, tremor
Not known: Convulsion, ageusia, parosmia, anosmia, paraesthesia

Ear and labyrinth disorders

Uncommon: Vertigo, impaired hearing, tinnitus

Not known: deafness

Cardiac disorders

Uncommon: electrocardiogram QT prolonged.
Not known: Torsade de Pointes, ventricular tachycardia, ventricular fibrillation.

Vascular disorders

Not known: Hemorrhage
Gastrointestinal disorders
Common: Diarrhea, vomiting, abdominal pain, nausea, dyspepsia,
Uncommon: Gastritis, stomatitis, glossitis, abdominal distension, constipation, dry mouth, eructation, flatulence,

Not known: Pancreatitis, tongue discoloration, tooth discoloration

Hepato-biliary disorders

Common: Liver function test abnormal
Uncommon: Cholestasis, hepatitis, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyltransferase increased
Not known: Hepatic failure, jaundice hepatocellular

Skin and subcutaneous tissue disorders

Common: Rash, hyperhidrosis
Uncommon: pruritus, urticaria

General disorders and administration site conditions

Uncommon: Malaise, asthenia, chest pain, chills, fatigue

DRUG INTERACTIONS

- ✓ Elevated cisapride levels have been reported in patients receiving clarithromycin and cisapride concomitantly. This may result in QT prolongation and cardiac arrhythmias.
- ✓ Macrolides have been reported to alter the metabolism of terfenadine resulting in increased levels of terfenadine which has occasionally been associated with cardiac arrhythmias such as QT prolongation, ventricular tachycardia, and ventricular fibrillation and torsades de pointes. Similar effects have been observed with concomitant administration of astemizole and other macrolides.
- ✓ Co-administration of clarithromycin with ergotamine or dihydroergotamine associated with acute ergot toxicity characterized by vasospasm, and ischemia of the extremities and other tissues including the central nervous system.
- ✓ Concomitant administration of rifabutin and clarithromycin resulted in an increase in rifabutin, and decrease in clarithromycin serum levels together with an increased risk of uveitis.

OVERDOSE

Reports indicate that the ingestion of large amounts of clarithromycin can be expected to produce gastrointestinal symptoms. Symptoms of overdose may differ correspond to the profile of adverse reactions. One patient who had a history of bipolar disorder ingested 8 grams of clarithromycin and showed altered mental status, paranoid behaviour, hypokalaemia and hypoxemia. There is no specific antidote on overdose. Serum levels of clarithromycin cannot be reduced by haemodialysis or peritoneal dialysis.

CONTRAINDICATIONS

- ✓ Hypersensitivity to macrolide antibiotic drugs or to any of its excipients.
- ✓ Concomitant administration of Clarithromycin and ergot alkaloids (ergotamine or dihydroergotamine) is contraindicated, as this may result in ergot toxicity.
- ✓ Concomitant administration of clarithromycin and oral midazolam is

contraindicated.

- ✓ Concomitant administration of clarithromycin and any of the following drugs is contraindicated: astemizole, cisapride, pimozide, terfenadine as this may result in QT prolongation and cardiac arrhythmias including ventricular tachycardia, ventricular fibrillation and torsades de pointe.
- ✓ Concomitant administration with ticagrelor or ranolazine is contraindicated.
- ✓ Clarithromycin should not be given to patients with hypokalaemia (risk of prolongation of QT-time).
- ✓ Clarithromycin should not be used concomitantly with HMG-CoA reductase inhibitors (statins) that are extensively metabolized by CYP3A4 (lovastatin or simvastatin) or atorvastatin, due to the increased risk of myopathy, including rhabdomyolysis.
- ✓ As with other strong CYP3A4 inhibitors, Clarithromycin should not be used in patients taking colchicine.
- ✓ Clarithromycin should not be used in patients who suffer from severe hepatic failure in combination with renal impairment.

STORAGE & INSTRUCTIONS

Store between 15-25°C. Protect from sunlight, heat and moisture. Do not freeze. Keep away from reach of children. To be sold on the prescription of a medical practitioner only.

HOW SUPPLIED

Selclar Suspension 125mg/5ml
60ml Bottle

Selclar Suspension 250mg/5ml
60ml Bottle

Selclar Tablet 250mg
10 Tablets

Selclar Tablet 500mg
10 Tablets

خوراک و طریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔

دھوپ، گرمی، نمی سے محفوظ اور بچوں کی پہنچ سے دور رکھیں۔

صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

Manufactured by:

**PHARMASOL
PRIVATE LIMITED**

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