# VEGACLAR TABLETS

(Clarithromycin 250 mg)

## COMPOSITION

Each tablet contains Clarithromycin 250 mg. Excipients: as per approved formulation.

## DESCRIPTION & PHARMACOLOGY

Clarithromycin is a semisynthetic macrolide antibiotic. It binds to the bacterial 50S ribosomal subunit and inhibits protein synthesis. Its active 14-hydroxy metabolite also contributes to antimicrobial activity.

## INDICATIONS

For infections caused by susceptible organisms, including acute bacterial exacerbations of chronic bronchitis, acute maxillary sinusitis, community-acquired pneumonia, pharyngitis/tonsillitis and uncomplicated skin and soft-tissue infections, subject to local approval.

Clarithromycin is also used in selected combination regimens for Helicobacter pylori eradication and for certain mycobacterial infections. These require specific regimens and susceptibility assessment.

## DOSAGE & ADMINISTRATION

Oral use. Adults: usually 250 mg every 12 hours for 7-14 days; some infections require 500 mg every 12 hours. Dose and duration depend on indication, severity, susceptibility and renal function. Tablets may be taken with or without food.

## ADDITIONAL DOSAGE GUIDANCE

For H. pylori eradication, clarithromycin is used only as part of an appropriate combination regimen; 250 mg tablets alone do not constitute an eradication regimen. Follow current local resistance guidance.

In severe renal impairment (creatinine clearance below 30 mL/min), dose reduction is generally required. Further adjustments may be needed with certain interacting antiretroviral medicines.

## PAEDIATRIC USE

Children generally require weight-based dosing (commonly 7.5 mg/kg every 12 hours, up to the adult maximum) using a suitable formulation. The 250 mg tablet is not appropriate for all paediatric doses.

## ELDERLY PATIENTS

Assess renal function and concomitant medicines, particularly those affecting cardiac rhythm or metabolised by CYP3A.

## CONTRAINDICATIONS

Hypersensitivity to clarithromycin or other macrolides; previous clarithromycin-associated cholestatic jaundice or hepatic dysfunction; concomitant cisapride, pimozide, ergotamine/dihydroergotamine, lovastatin, simvastatin, lomitapide or lurasidone; and colchicine in patients with renal or hepatic impairment.

Review the complete prescribing information for additional contraindications and interaction-specific restrictions.

## WARNINGS & PRECAUTIONS

QT prolongation and serious arrhythmias, including torsades de pointes, may occur. Avoid use in patients with known QT prolongation, significant bradycardia, uncorrected low potassium/magnesium or relevant antiarrhythmic treatment.

Severe allergic or skin reactions, liver injury and Clostridioides difficile-associated diarrhoea have been reported. Stop treatment and seek urgent care for jaundice, severe rash, breathing difficulty or persistent severe diarrhoea.

Clarithromycin may worsen myasthenia gravis. In patients with coronary artery disease, weigh potential longer-term cardiovascular risk against treatment benefit.

## PREGNANCY & LACTATION

Avoid in pregnancy unless no appropriate alternative is available and the benefit outweighs potential risk. Clarithromycin is excreted into breast milk; consider infant monitoring and clinical benefit-risk assessment.

## DRUG INTERACTIONS

Clarithromycin inhibits CYP3A and P-glycoprotein and can raise concentrations of many medicines. Important interactions include statins, colchicine, calcium-channel blockers, anticoagulants, digoxin, carbamazepine, certain benzodiazepines and QT-prolonging agents.

A full medication review is required before prescribing.

## ADVERSE REACTIONS

Common: nausea, diarrhoea, abdominal pain, vomiting, altered taste and headache. Less common or serious: liver injury, severe skin reactions, hearing disturbance, hypoglycaemia with interacting medicines, arrhythmias and antibiotic-associated colitis.

## OVERDOSAGE

Overdose may cause gastrointestinal symptoms and other adverse effects. Seek urgent medical care. Management is supportive; haemodialysis is not expected to substantially remove clarithromycin.

## STORAGE CONDITIONS

Store according to the approved product specifications, protected from excessive heat and moisture. Keep out of reach of children. Do not use after expiry.

## PRESENTATION

Vegaclar Tablets 250 mg: pack of 10 tablets.

## PATIENT ADVICE

Take only as prescribed and complete the prescribed course. Do not use for viral infections. Inform the prescriber about all medicines, heart-rhythm disorders, liver disease and kidney problems. Seek medical attention for severe diarrhoea, rash, palpitations or jaundice.

## MANUFACTURED BY

**Vega Pharmaceuticals (Pvt.) Ltd.**