

For the use of only Registered Medical Practitioners or a Hospital.

## CLARYL

### Clarithromycin Tablets USP

#### COMPOSITION:

##### CLARYL-250

Each filmcoated tablet contains:

Clarithromycin USP . . . 250 mg

Excipients . . . . . q.s.

Colour: Aluminium lake of Quinoline yellow.

Excipients: AC-DI-SOL, Colloidal silicon dioxide, Isopropyl alcohol, Magnesium stearate, Methylene chloride, Microcrystalline cellulose, P.V.P.K.30, Sodium starch glycolate, Starch, Talcum, Wincoat WT-AQ-1001 White, Colour yellow quinoline lake, Stearic acid.

##### CLARYL-500

Each filmcoated tablet contains:

Clarithromycin USP . . . 500 mg

Excipients . . . . . q.s.

Colour: Aluminium lake of Quinoline yellow.

Excipients: Colloidal silicon dioxide, Magnesium stearate, Isopropyl alcohol, Methylene chloride, P.V.P.K. 30, AC-DI-SOL, Microcrystalline cellulose, Sodium starch glycolate, Starch, Talcum, Wincoat WT-1125 Yellow, Stearic acid.

#### DESCRIPTION:

Clarithromycin is a macrolide antibiotic effective against a wide spectrum of gram-positive and gram-negative bacteria; used in the treatment of respiratory tract, skin and soft tissue infections and of *Helicobacter pylori* associated duodenal ulcer.

#### PHARMACODYNAMIC PROPERTIES:

Clarithromycin is a semi-synthetic derivative of Erythromycin. It exerts its antibacterial action by binding to the 50s ribosomal subunit of susceptible bacteria and suppresses protein synthesis. It is highly potent against a wide variety of aerobic and anaerobic gram-positive and gram-negative organisms. The Minimum Inhibitory Concentrations (MICs) of Clarithromycin are generally two-fold lower than the MICs of Erythromycin.

The 14-hydroxy metabolite of Clarithromycin also has antimicrobial activity. The MICs of this metabolite are equal or two-fold higher than the MICs of the parent compound, except for *H. influenzae* where the 14-hydroxy metabolite is two-fold more active than the parent compound.

#### PHARMACOKINETIC PROPERTIES:

It is a new macrolide antimicrobial drug. It has broad spectrum of activity and is better absorbed than Erythromycin is well tolerated and is to be administered less frequently. It is the most effective macrolide against *Haemophilus influenzae*, *Chlamydia trachomatis* and *Chlamydia pneumoniae*. After oral administration it is absorbed rapidly & is metabolised significantly in liver which leads to reduced bioavailability. The 14-hydroxy metabolite has antimicrobial activity.

#### INDICATIONS:

Upper respiratory tract infection (Pharyngitis, Sinusitis), Lower Respiratory tract infection (Bronchitis, Pneumonia), Skin and soft tissue infection (Cellulitis, Folliculitis), Discominot or localised mycobacterial infections, Legionella and Chlamydial infections & Eradication of *Helicobacter pylori*.

#### POSOLGY AND METHOD OF ADMINISTRATION:

**Adults:** The usual recommended dosage of Clarithromycin in adults is one 250 mg tablet twice daily. In more severe infections, the dosage can be increased to 500 mg twice daily. The usual duration of therapy is 6 to 14 days.

**Children under 12 years:** The use of Clarithromycin tablets has not been studied in children under 12 years. Clinical trials have been conducted using Clarithromycin paediatric suspension in children 6 months to 12 years of age. Therefore, children under 12 years of age should use Clarithromycin paediatric suspension (granules for oral suspension).

**Children over 12 years:** As for Adults.

In patients with renal impairment with creatinine clearance less than 30 ml/min, the dosage of Clarithromycin should be reduced by one-half.

#### CONTRAINDICATIONS:

Clarithromycin is contraindicated in patients with known hypersensitivity to macrolide antibiotic drugs or any of its excipients.

Colchicine is contraindicated in patients with renal or hepatic impairment (risk of prolongation of QT-time).

Clarithromycin should not be given to patients with hypokalaemia (risk of prolongation of QT-time).

#### WARNINGS AND PRECAUTIONS :

The physician should not prescribe Clarithromycin to pregnant women without carefully weighing the benefits against risk, particularly during the first three months of pregnancy.

Caution is advised in patients with severe renal insufficiency.

Hepatic dysfunction, including increased liver enzymes and hepatocellular and/or cholestatic hepatitis, with or without jaundice, has been reported with Clarithromycin. This hepatic dysfunction may be severe and is usually reversible.

Clarithromycin should be used with caution when administered concurrently with medications that induce the cytochrome CYP3A4 enzyme.

Attention should also be paid to the possibility of cross resistance between Clarithromycin and other macrolide drugs, as well as Lincomycin and Clindamycin. Caution is advised in patients with severe renal insufficiency.

#### DRUG INTERACTIONS:

**Terfenadine:** Concomitant use may cause cardiac arrhythmia.

**Carbamazepine & Theophylline:** Concurrent use causes increase in serum levels of these drugs.

**Zidovudine:** In HIV infected patients study states Zidovudine levels decreased.

**Increased efficacy of the following drugs which are metabolised by the cytochrome P450 system:**

Digoxin, Warfarin, Ergot Alkaloids, Triazolam, Midazolam and Cyclosporine.

#### UNDESIRABLE EFFECTS:

##### Summary of the safety profile:

The most frequent and common adverse reactions related to Clarithromycin therapy for both adult and paediatric populations are abdominal pain, diarrhoea, nausea, vomiting and taste perversion.

There was no significant difference in the incidence of these gastrointestinal adverse reactions during clinical trials between the patient population with or without preexisting mycobacterial infections.

##### Description of selected adverse reactions:

There have been post-marketing reports of colchicine toxicity with concomitant use of Clarithromycin and Colchicine, especially in elderly and/or patients with renal insufficiency, some with a fatal outcome.

#### PREGNANCY AND LACTATION:

##### Pregnancy:

The safety of Clarithromycin for use in pregnancy has not been established. Therefore, use during pregnancy is not advised without carefully weighing the benefits against risk.

##### Lactation:

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

#### OVERDOSAGE:

Reports indicate that the ingestion of large amounts of Clarithromycin can be expected to produce gastrointestinal symptoms. One patient who had a history of bipolar disorder ingested eight grams of Clarithromycin and showed altered mental status, paranoid behaviour, hypokalaemia and hypoxaemia.

#### STORAGE:

Store below 30°C.

#### PRESENTATIONS:

Box of 1 Blisters of 10 Tablets,

Box of 5 Blisters of 10 Tablets,

Box of 10 Blisters of 10 Tablets.

Keep all the medicines away from reach of children.

For further information, please contact:

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