Rithrocid

Antibacterial Agent
Tablets

Composition
Each tablet contains:
Active ingredient: Clarithromycin 250mg or 500mg
Excipients: Cellulose, croscarmellose, povidone, polysorbate, starch, magnesium stearate, talc, stearic acid, and aerosil.

Properties
Clarithromycin, the active ingredient of **Rithrocid**, is an antibiotic included in the family of macrolides. Clarithromycin exerts its antibacterial activity by means of inhibition of protein synthesis, linking to 50S ribosomal subunit.
Rithrocid is active *in vitro* against the following microorganisms:
Staphylococcus aureus, Streptococcus agalactiae, Streptococcus pyogenes, Streptococcus viridans, Streptococcus pneumoniae, Haemophilus influenzae, Haemophilus parainfluenzae, Helicobacter pylori, Campylobacter jejuni, Listeria monocytogenes, Legionella pneumophila, Mycoplasma pneumoniae, Chlamydia trachomatis, Branhamella catarrhalis, Ureaplasma urealyticum, Neisseria gonorrheae, Bordetella pertussis, Propionibacterium acnes, Mycobacterium avium, Mycobacterium chelonae, Mycobacterium leprae, Bacteroid spp., and anaerobic Gram-positive cocci.

Indications
Rithrocid is indicated for the treatment of the following infections when caused by susceptible organisms:
- Infections of upper respiratory tract: sinusitis and pharyngitis.
- Infections of lower respiratory tract: bronchitis, bacterial pneumonia, and atypical pneumonia.
- Infections of skin and soft tissues: impetigo, erysipelas, folliculitis, furunculosis, and septic wounds.

Rithrocid is also indicated as an adjunct therapy in the treatment of duodenal ulcers for the eradication of *Helicobacter pylori*.

Dosage
Adults and children above 12 years:
- Respiratory tract and skin infections:
  One 250mg tablet every 12 hours for 7 days. In cases of severe infections, dosage can be increased up to 500mg every 12 hours for up to 14 days.
- Eradication of *Helicobacter pylori*:

One-week triple therapy regimens:
- **Rithrocid** 250mg and metronidazole 400mg, both given twice daily, in addition to omeprazole 20mg twice daily (or 40mg once daily).
- **Rithrocid** 500mg and amoxicillin 1g, both given twice daily, in addition to omeprazole 20mg twice daily (or 40mg once daily).
- **Rithrocid** 250mg, amoxicillin 1g (or metronidazole 400mg), and lansoprazole 30mg, all given twice daily.

Two-week dual therapy regimen:
- **Rithrocid** 250mg 4 times daily and ranitidine bismuth citrate 400mg twice daily.

Note: Triple therapy regimens have higher eradication rates than with the dual therapy regimen.
In patients with renal impairment with creatinine clearance less than 30mL/min, the dosage may need to be halved to 250mg once daily, or 250mg twice daily in severe infections. Dosage should not be continued beyond 14 days in these patients.

If you miss a dose
- Take the medicine as soon as you remember.
- If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose.
- Do not take two doses at one time.

Contraindications
Clarithromycin is contraindicated in patients hypersensitive to macrolides.

Precautions
Clarithromycin, being mainly metabolised and excreted by the liver, particular caution should be taken when given to patients with impaired liver function.
Dosage should be reduced in patients with renal impairment.
Caution should be taken in patients with porphyria.
It is necessary to take care to the possibility of cross-over resistance between clarithromycin and other macrolides, lincomycin, and clindamycin.
Pregnancy and Lactation: Clarithromycin in general, is not known to be harmful during pregnancy as well as during lactation as only trace amounts are reported to be excreted in breast milk. Clarithromycin should be used only when the potential benefits outweigh the possible risks.

Side Effects
Headache and gastrointestinal disturbances such as nausea, vomiting, abdominal discomfort, diarrhoea, antibiotic-associated colitis, taste disturbances, stomatitis, and glossitis have been reported in some patients receiving clarithromycin.
Urticaria, rashes, and other allergic reactions may occur less frequently.
Rarely, side effects such as cholestatic jaundice, Stevens-Johnson syndrome, cardiac effects (including chest pain and arrhythmias), and hepatitis may occur.
Very rarely, reversible hearing loss have been reported after large doses of clarithromycin.

Overdosage
In case high doses of clarithromycin have been ingested, gastrointestinal disturbances can occur. A systemic reaction can also follow, to be readily treated by means of gastric lavage and supportive measures.
Provided that clarithromycin can not be removed by haemodialysis or peritoneal dialysis, a rapid action is needed aimed to eliminate the amount of drug not yet absorbed, applying at the same time a suitable symptomatic therapy.

Drug Interactions
- Upon concurrent administration, clarithromycin may increase plasma concentrations of some drugs, thereby enhancing their effects. These drugs include disopyramide (antiarrhythmic) as risk of toxicity may possibly be increased; bromocriptine and cabergoline (dopaminergics); tacrolimus; atorvastatin (lipid-regulating agent). In addition, clarithromycin may possibly increase rifabutin (antibacterial) plasma concentration and thereby increase the risk of uveitis; rifabutin dose should be reduced.
- Clarithromycin may inhibit the metabolism of some drugs upon concurrent administration, thereby increasing their plasma concentration. These drugs include carbamazepine and phenytoin (antiepileptics); cyclosporin; midazolam (anxiolytic) as it results in profound sedation; theophylline.
- Upon concurrent administration, clarithromycin may possibly enhance the effect of digoxin and oral anticoagulants (e.g., warfarin and acenocoumarol).
- Upon concurrent administration of clarithromycin with some antiviral agents, the following interactions have been reported:
  - Increased plasma concentration of clarithromycin with ritonavir; reduction of clarithromycin dose in patients with renal impairment is recommended.
  - Increased risk of rash with efavirenz.
  - Reduction in the absorption of zidovudine, which has been reported as a reduction in steady-state zidovudine levels upon simultaneous oral administration of clarithromycin and zidovudine to HIV-infected adults.
- Concomitant administration of clarithromycin with some medications should be avoided, these include:
  - Reboxetine (antidepressant).
  - Tolterodine (antimuscarinic).
  - Pimozide (antipsychotic) due to the risk of arrhythmias.
  - Simvastatin (lipid-regulating agent) due to increased risk of myopathy.
  - Terfenadine and mizolastine (antihistaminics) due to inhibition of their metabolism. Increased risk of hazardous arrhythmia with terfenadine.
  - Ergotamine due to risk of ergotism.

Presentations
Rithrocid 250mg tablets: Pack of 14 tablets.
Rithrocid 500mg tablets: Pack of 14 tablets.

** Store at a temperature of 15 - 25°C.*

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.

Any information ? Call Our Toll Free No. **(971) 800-4994**

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