**KLARICID**

(Chlorthromycin)

**Granules**

**Precautions for Use**

- **Contraindications**
  - Hypersensitivity to macrolide antibiotic drugs or any of its excipients.
  - **Drug Interactions**

**Indications**

- Clarithromycin is indicated for treatment of infections due to susceptible organisms in adults and children 12 years and older (adult only formulations, e.g. tablets, IV, adult granules) / in children 6 months to 12 years (pediatric oral suspension).

**Dosage and Administration**

- Clarithromycin Granules for Oral Suspension

**Preparation for Use**

- See Special precautions for disposal and other handling.

**Packaging and Storage**

- Packaged in blister packs of 150 mg tablets or 300 mg tablets.

**Manufacured by:**

Abbott Laboratories (Pakistan) Ltd.

Lendi, Karachi.

Abbott

01-066820

SOLID: 1003297883 UT 10 FEB 2017

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**Leaflet Klaricid Granules**

Size: 146 x 278mm

Date: 15-03-2017

Ammara Commercial Printers (Pvt.) Ltd.
The use of the following drugs is strictly contraindicated due to the potential for severe drug interaction effects:

- *Pravastatin* should be considered.
- *Disopyramide* is also contraindicated.

Signs and symptoms of myopathy.

Reports of rhabdomyolysis have been reported in patients taking these drugs concomitantly. Patients should be monitored for creatine kinase (CK) increases.

**Effect of Clarithromycin on Other Medicinal Products**

**Contraindications**

- There have been post-marketing reports of severe intolerance to concomitant use of clarithromycin and oral hypoglycemic agents (e.g., sulfonylureas, insulin). In one study involving 299 patients with type 2 diabetes, 48% had at least one hypoglycemic episode while on clarithromycin. Careful monitoring of glucose levels is recommended in patients at risk for hypoglycemia.

**Drug Interactions**

The concomitant use of clarithromycin and oral hypoglycemic agents and/or insulin can result in significant hypoglycemia. Careful monitoring of glucose levels is recommended in patients at risk for hypoglycemia.

- *Caution is advised regarding concomitant administration of clarithromycin and drugs with a narrow therapeutic index, such as triazolobenzodiazepines, including triazolam and midazolam (see CONTRAINDICATIONS).*

**Contraindications**

- *Concomitant administration of clarithromycin with astemizole, cisapride, pimozide and terfenadine is contraindicated.*

**Effect of Clarithromycin on Other Medicinal Products**

- There have been post-marketing reports of hypoglycemia with the concomitant administration of clarithromycin and oral hypoglycemic agents (e.g., sulfonylureas, insulin). In one study involving 299 patients with type 2 diabetes, 48% had at least one hypoglycemic episode while on clarithromycin. Careful monitoring of glucose levels is recommended in patients at risk for hypoglycemia.

**Drug Interactions**

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- *Caution is advised regarding concomitant administration of clarithromycin and drugs with a narrow therapeutic index, such as triazolobenzodiazepines, including triazolam and midazolam (see CONTRAINDICATIONS).*
Both clarithromycin and saquinavir are substrates and inhibitors of CYP3A, and there is evidence of a bi-directional drug interaction. When saquinavir is co-administered with clarithromycin, the AUC of saquinavir increases by 177% and the Cmax increases by 187%. The mean 24-hour gastric pH value is 5.2 when omeprazole was administered alone and 3.7 when omeprazole was co-administered with clarithromycin. The interaction results in decreased esophageal pH and increased esophageal acid exposure time.

There have been post-marketing reports of drug interactions and central nervous system (CNS) effects (e.g., somnolence and headache) in patients taking clarithromycin with agents that may interfere with the absorption of clarithromycin, such as calcium channel blockers.

Tolterodine is a side effect of both clarithromycin and saquinavir. There have been no significant differences in the incidence of gastrointestinal adverse reactions between patients taking clarithromycin and those taking saquinavir.

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There have been spontaenous or published reports of interactions of CYP3A inhibitors, including clarithromycin with drugs such as digoxin, warfarin, oral anticoagulants, atypical antipsychotics, and antipsychotics (e.g., phenytoin and valproate). Serum level determinations are recommended for these drugs when co-administered with CYP3A inhibitors.

Both clarithromycin and atazanavir are substrates and inhibitors of CYP3A, and there is evidence of a bi-directional drug interaction. There have been post-marketing reports of drug interactions and central nervous system (CNS) effects (e.g., somnolence and headache) in patients taking clarithromycin with agents that may interfere with the absorption of clarithromycin, such as calcium channel blockers.

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Investigations
administration site
General disorders and
Musculoskeletal and
Tissue disorders
Skin and subcutaneous
Connective tissue disorders

1ADRs reported only for the Powder for Solution for Injection formulation

Listeria monocytogenes
Streptococcus pneumoniae
Staphylococcus aureus
Aerobic Gram-Positive microorganisms

Clarithromycin has been shown to be active against most strains of the following microorganisms both in vitro and in clinical
Enterobacteriaceae, pseudomonas species and other non-lactose fermenting Gram-negative bacilli are not susceptible to

Microbiology
Pharmacodynamic Properties

Clarithromycin is not expected to be appreciably affected by hemodialysis or peritoneal dialysis. In the case of overdosage, clarithromycin I.V.
prompt elimination of unabsorbed drug and supportive measures. As with other macrolides, clarithromycin serum levels are
paranoid behavior, hypokalemia, and hypoxemia. Adverse reactions accompanying overdosage should be treated by the

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

In these immunocompromised patients, evaluations of laboratory values were made by analyzing those values outside the
range for levels seen in immunocompetent patients. Elevations of liver enzymes were noted in a number of patients; however,
In adult patients, the most frequently reported adverse events by patients treated with total daily doses of 1000 mg of
a single dose of clarithromycin given by the I.V. route were diarrhea, headache, rash, nausea, vomiting, and abdominal pain. In
other patients who received 500 mg of clarithromycin daily, lactic acidosis was observed in both GEF and GSP, and

OVERDOSAGE

Pharmacologic Properties

Clarithromycin acts in a bacterial cell to inhibit the formation of the 50S ribosomal subunit of susceptible bacteria and
penicillins, cephalosporins, and other beta-lactams. The beta-lactamase produced by some strains of these organisms should have no effect on
clarithromycin activity.

Mycobacterium fortuitum
Mycobacterium kansasii
Mycobacterium leprae
Mycobacteria
Chlamydia pneumoniae (TWAR)
Mycoplasma pneumoniae
Other microorganisms

Methicillin-resistant Staphylococcus aureus (MRSA)
Methicillin-resistant Staphylococcus epidermidis
Methicillin-resistant Staphylococcus aureus (MRSA) consisting of all Methicillin-resistant
Methicillin-resistant Staphylococcus aureus (MRSA) consisting of all Methicillin-sensitive
Methicillin-sensitive Staphylococcus aureus
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WARNINGS AND PRECAUTIONS

Gastrointestinal Disorders

Non-steroidal anti-inflammatory drugs and other drugs which may cause ulceration should be avoided during treatment with clarithromycin.

Adequate and prolonged therapy should be given to patients with ulcers due to Helicobacter pylori to prevent recurrence, as brief treatment courses may not result in cure.

There have been post-marketing reports of colchicine toxicity with concomitant use of clarithromycin and colchicine,
There have been cases of clarithromycin overdose, with symptoms that suggest colchicine toxicity, especially in elderly and/or patients with renal insufficiency, some with a fatal outcome (see

DRUG INTERACTIONS

HIV Protease Inhibitors

Indinavir
Ritonavir

Acamprosate

Cardiac Decongestants (e.g. digoxin, quinidine, propafenone, amiodarone, sotalol)

Erythromycin

Cimetidine

Probenecid

Carcinogenesis, Mutagenesis, Impairment of Fertility

No evidence of carcinogenicity was seen in 2-year rat studies or 1-year mouse studies with the oral formulation of clarithromycin.

PREGNANCY

Safety in the third trimester

Animal reproduction studies have not been performed with clarithromycin granules for oral suspension.

PEDIATRIC USE

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