ERACID®

DESCRIPTION

ERACID is the trade name of Clarithromycin, a systemic macrolide antibiotic.
Each **ERACID 250** and **500** Tablet contains Clarithromycin USP 250mg and 500mg, respectively.

CHEMISTRY

Clarithromycin is: 6-*o*-methylerythromycin.

CLINICAL PHARMACOLOGY

ERACID has in vitro activity against many gram-positive and gram-negative aerobic and anaerobic organisms including methicillin-sensitive *Staphylococcus aureus* and most *Streptococcus* species. **ERACID** is bactericidal against *Streptococcus pyogenes* and *S. Pneumoniae*, and is active against *Haemophilus influenzae*. **ERACID** is active in vivo and in vitro against *Mycobacterium leprae* and displayed good clinical response with *M. chelonae*, but is inactive in vitro against *M. Tuberculosis*. ERACID has greater in vitro activity than erythromycin against *Mycobacterium avium* complex, *Legionella pneumophila, Moraxella (Branhamella) catarrhalis, Chlamydia trachomatis*, and *Ureaplasma urealyticum*. It is also active against *Neisseria gonorrhoeae*, anaerobic gram-positive cocci, *Bacteroides* species, and *Helicobacter pylori*.
ERACID inhibits protein synthesis in susceptible organisms by penetrating cell wall and binding to 50S ribosomal subunits, thereby inhibiting translocation of aminoacyl transfer-RNA and inhibiting polypeptide synthesis.
Clarithromycin is rapidly absorbed from the gastrointestinal tract. Its gastrointestinal absorption exceeds that of erythromycin. The bioavailability is approximately 55% due to first-pass metabolism, which converts Clarithromycin to its active metabolite, 14-hydroxyclarithromycin. Clarithromycin is widely distributed into tissues and fluids, and readily enters leukocytes and macrophages. It is primarily excreted by kidneys (20-30% as parent drug and 10-15% as active metabolite).

INDICATIONS

- **ERACID** is indicated for the treatment of bacterial exacerbations of bronchitis, acute otitis media, streptococcal pharyngitis, mycoplasmal pneumonia, streptococcal pneumonia, acute maxillary sinusitis, and skin and soft tissue infections (e.g., impetigo, cellulitis), when such disease states are caused by susceptible organisms (see Clinical Pharmacology).
- **ERACID** is indicated for use in combination with proton pump inhibitors for the treatment of *Helicobacter pylori* infection in patients with an active duodenal ulcer. ERACID also has been used orally in other multiple-drug regimens for the treatment of *H. pylori* infection associated with peptic ulcer disease.
- **ERACID** is indicated in the treatment of disseminated *Mycobacterium avium* complex, in combination with other antimycobacterials to prevent the development of resistance.
- **ERACID** is also used in the treatment of Legionnaires' disease caused by *Legionella pneumophila*.

DOSAGE

Usual adult dose

- Bacterial exacerbations of bronchitis due to *H. Influenzae*: 500mg every twelve hours for 7-14 days.
  Bacterial exacerbations of bronchitis due to other organisms: 250mg every twelve hours for 7-14 days.
- *Helicobacter pylori* infection in patients with an active duodenal ulcer: 500mg three times daily for 14 days.
- Disseminated *Mycobacterium avium* complex: 500mg every twelve hours.
- Streptococcal pharyngitis: 250mg every 12 hours for 10 days.
- Pneumonia due to *S. Pneumoniae* or *M. Pneumoniae*: 250mg every 12 hours for 7-14 days.
- Acute maxillary sinusitis: 500mg every 12 hours for 14 days.
- Skin and soft tissue infections: 250mg every 12 hours for 7-14 days.

Notes

- **ERACID** generally may be used without dosage adjustment in patients with hepatic impairment.
- In case of severe renal function impairment, with creatinine clearance below 30ml/minute, dosage is adjusted as follows:
  - In conditions requiring 500mg twice daily, the adjusted dose in severe renal impairment is 500mg as a loading dose, then 250mg twice daily.
  - In conditions requiring 250mg twice daily, the adjusted dosage is 250mg once daily.

Usual pediatric dose

- Acute otitis media, streptococcal pharyngitis, acute maxillary sinusitis, and skin and soft tissue infections in children 6 months of age and older: Clarithromycin 7.5mg per kg of body weight every 12 hours for 10 days.
- Disseminated *Mycobacterium avium* complex in children 6 months of age and older: Clarithromycin 7.5mg per kg of body weight, up to 500mg, every 12 hours for life if clinical and mycobacterial improvements are observed.
- Safety and efficacy of Clarithromycin has not been established in infants below 6 months of age.

ADVERSE EFFECTS

- Clarithromycin is well tolerated. No adverse effect has been reported to occur in more than 3% of patients treated with the drug.
- Less frequent effects: Abnormal taste, headache, and gastrointestinal disturbances (abdominal discomfort, pain, diarrhea, nausea and vomiting).
- Post-Marketing experience: Showed that as with other macrolides, clarithromycin has been associated with QT prolongation and ventricular arrhythmias, including Ventricular tachycardia and torsades de pointes.

USE IN PREGNANCY

There are no adequate and controlled studies to date in humans. In animals, Clarithromycin has been associated with adverse effects on pregnancy outcome and/or embryo fetal development at dosages that produced plasma drug concentrations 2-17 times those achieved with the maximum recommended human dosage. Even though the potential risk to fetus has not been clearly elucidated to date, Clarithromycin should be used during pregnancy only in infections for which safer drugs cannot be used or are ineffective. FDA Pregnancy Category C.

USE IN LACTATION

Clarithromycin and its active metabolite are distributed into human breast milk. Caution should be exercised when Clarithromycin is administered to nursing women.

INTERFERENCE WITH CLINICAL AND LABORATORY TESTS

The values of alanine and aspartate aminotransferases and blood urea nitrogen may rarely be elevated with Clarithromycin.

DRUG INTERACTIONS

- Clarithromycin may increase plasma concentrations of carbamazepine or digoxin. It is recommended that carbamazepine/digoxin serum levels be monitored upon concurrent use with Clarithromycin.
- Rifabutin and rifampin may decrease Clarithromycin serum concentration by more than 50%.
- Clarithromycin increases the area under the plasma concentration time curve (AUC) of theophylline by 17%. Theophylline serum levels monitoring is recommended in patients receiving high doses, or patients with theophylline serum levels in the upper therapeutic range.
- Clarithromycin potentiates the effects of warfarin. Prothrombin time should be closely monitored in patients receiving warfarin and Clarithromycin concurrently.
- Clarithromycin and zidovudine doses should be taken at least 4 hours apart because Clarithromycin may result in lower peak serum concentration, lower AUC, and delayed time to peak concentration of Zidovudine in HIV-infected patients.
- Clarithromycin and/or erythromycin inhibits hepatic metabolism of terfenadine, cisapride and pimozide resulting in cardiac arrhythmias (QT prolongation, ventricular tachycardia, ventricular fibrillation and torsades de pointes). Fatalities have been reported.

CONTRAINDICATIONS

- Clarithromycin is contraindicated in patients with known hypersensitivity to Clarithromycin, erythromycin, or to any other macrolide, due to cross-sensitivity.
- Concomitant administration of clarithromycin with cisapride, pimozide, or terfenadine is contraindicated, and is not recommended in patients receiving astemizole (see Drug Interactions).

WARNINGS

Risk-benefit should be considered in case of severe renal function impairment; because the elimination of Clarithromycin is reduced, especially in patients with a creatinine clearance below 30ml/min. Dose adjustment may be necessary (see Dosage).

OVERDOSE

Following large doses of Clarithromycin, gastrointestinal disturbances may occur, and may be accompanied by systemic manifestations. Treatment of overdose includes stomach evacuation by gastric lavage and rapid elimination of unabsorbed drug, followed by supportive and symptomatic measures.

PRECAUTIONS

Antibiotic-associated *Clostridium difficile* colitis has been rarely reported with the use of many anti-ineffective agents, including macrolides, and should be considered in patients developing severe or watery diarrhea during or after Clarithromycin therapy.

PRESENTATIONS

- Boxes containing 14 Film-Coated blistered tablets of **ERACID 250** Tablets.
- Boxes containing 14 Film-Coated blistered tablets of **ERACID 500** Tablets.
- Hospital packs of different presentations.

Store according to conditions specified on the package.
Do not use after the expiry date shown on the package.

THIS IS A MEDICAMENT

- A 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 dispensed the medicament.
- The doctor and the pharmacist are experts in medicine.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children

COUNCIL OF ARAB HEALTH MINISTERS
UNION OF ARAB PHARMACISTS

Prescribing Information Available Upon Request

THE JORDANIAN PHARMACEUTICAL MANUFACTURING CO. LTD.
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