Erythromycin Lactobionate for Injection, USP

INDICATIONS AND USAGE

Erythromycin has been associated with QT prolongation and ventricular arrhythmias, including ventricular tachycardia and torsades de pointes. (See WARNINGS.)

Erythromycin has been reported to significantly alter the metabolism of the nonsedating antihistamines, terfenadine and astemizole. (See PRECAUTIONS.)

Erythromycin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. It is only efficacious against strains of bacteria to which it is susceptible. In vitro susceptibility testing should be performed. (See CLINICAL PHARMACOLOGY.)

Erythromycin activity may be reduced by gastric pH. Antacids and other antacid-containing drugs, such as bismuth subsalicylate (Pepto-Bismol), which have an inhibitory effect on gastric pH, may significantly reduce the availability of erythromycin from the gastrointestinal tract, and may impair its antibacterial activity. (See CLINICAL PHARMACOLOGY.)

Dosage and Administration

- For slow continuous infusion: The final diluted solution of erythromycin lactobionate is prepared to give a concentration of 1 g per liter of 0.9% Sodium Chloride Injection, USP; Lactated Ringer's Injection, USP; Normosol™-R. Use only Sterile Water for Injection, USP, as other diluents may cause precipitation during reconstitution. Do not administer diluted solutions directly from vials. Do not administer undiluted. Do not administer refrigerated or frozen solutions. Reconstituted solutions are stable in the original container for 72 hours at room temperature or refrigerated for up to 7 days. Do not use solutions after 7 days.

- For rapid intravenous infusion: The final diluted solution of erythromycin lactobionate should be completely administered within 8 hours, since it is not suitable for storage. Do not administer undiluted. Do not administer refrigerated or frozen solutions. Reconstituted solutions are stable in the original container for 72 hours at room temperature or refrigerated for up to 7 days. Do not use solutions after 7 days.

- Use only a nonionic surfactant as a stabilizer. Acidic solutions of erythromycin lactobionate are unstable and lose their potency rapidly. A pH of at least 5.5 is necessary for storage. The final diluted solution of erythromycin lactobionate should be administered at a concentration of 500 or 1000 mcg/ml. The maximum concentration of 1000 mcg/ml may require a maximum of 30 minutes for administration. However, a dosage of 1 g may be administered in a total of 30 minutes. The maximum dosage should be administered in 30 minutes or less. A 10% solution of erythromycin lactobionate may be used, provided the maximum concentration of 1000 mcg/ml is not exceeded.

- The use of local anesthetics is contraindicated when erythromycin is used for the treatment of gonorrhea.

- The use of erythromycin should be reserved for treatment of mild to moderate respiratory infections, such as those caused by Mycoplasma pneumoniae, Streptococcus pneumoniae (Diplococcus pneumoniae), and gram-positive aerobic bacteria. Erythromycin is efficacious against Mycoplasma pneumoniae and Streptococcus pneumoniae. Erythromycin is not efficacious against infections caused by Haemophilus influenzae (Group D beta-hemolytic streptococci); Neisseria gonorrhoeae; Mycoplasma pneumoniae; and Pseudomonas aeruginosa.

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