Intravenous therapy effective in serious bacterial infections

Presentation
Erythromycin Lactobionate I.V. is a sterile presentation of erythromycin. It is not suitable for intramuscular use or intravenous bolus administration. It is available in vials of 1 g of erythromycin. Preparation of suitable solutions is detailed in the section on administration.

Uses
For the treatment of infections due to organisms susceptible to erythromycin in patients who cannot take oral medicine or in whom immediate high levels of erythromycin are important.

IT IS NOT FOR I.M. OR I.V. BOLUS USE. FOR I.V. INFUSION USE ONLY.

Microbiological Indications
Erythromycin has been shown to be active in vitro against the following organisms:
- Staphylococci, Streptococci, Haemophilus influenzae L-forms, Mycoplasma pneumoniae, Legionella pneumophila, Branhamella catarrhalis, Bordetella pertussis, Corynebacterium diphtheriae (as an adjunct to antistreptolysin), Neisseria, Treponema pallidum, Chlamydia trachomatis, Clostridia, Uracemella amyloplaca, Campylobacter.

Administration
The product must be reconstituted (step 1) and then further diluted (step 2) prior to administration.

Preparation of 1 g dose for intermittent infusion

STEP 1
Add 20 ml Water for Injections Ph.Eur to the 1 g vial. No other solvent apart from Water for Injections Ph.Eur should be used to prepare this initial solution.

STEP 2
Add 20 ml of Step 1 solution to 200-250 ml Sodium Chloride Intravenous Infusion B.P. (0.9% saline). The resulting diluted solution contains 5 mg/ml - 4 mg/ml (0.2% - 0.4%) of erythromycin. The recommended infusion time is 20-60 minutes. Therefore a longer period of infusion should be used in patients with risk factors or previous evidence of arthralgy. Rapid infusion is more likely to be associated with arthralgias or hypotension.

When administering the product by intermittent infusion do not use solution strengths greater than 5 mg/ml and do not use rapid infusion rates – failure to observe these precautions may result in pain along the vein. For detailed instructions on administration, see section 4.2.

For continuous infusion of 1 gram dose: Add 20 ml of Step 1 solution to 500 ml - 1,000 ml Sodium Chloride Intravenous Infusion B.P. (0.9% saline). The resulting diluted solution contains 2 mg/ml - 1 mg/ml (0.2% - 0.1%) of erythromycin.
2. BEFORE YOU ARE GIVEN ERYTHROMYCIN LACTOBIONATE I.V.

You should not receive Erythromycin Lactobionate I.V. if you:

- have had this medicine previously and it caused you problems;
- are allergic to any other macrolide antibiotics such as clarithromycin, azithromycin or dirithromycin;
- are allergic to any other antibiotic;
- have a history of anaphylactic reactions to any antibiotic;
- are allergic to any other medicine.

3. HOW YOU WILL BE GIVEN ERYTHROMYCIN LACTOBIONATE I.V.

Erythromycin Lactobionate I.V. is given either by intermittent infusion or intravenous bolus. It is available in vials of 1 g of erythromycin. Preparation of suitable diluents is necessary in order to use Erythromycin Lactobionate I.V.

- Ensure neutrality: Erythromycin Lactobionate I.V. contains no sodium.
- Diluents: The following diluents can be used:
  - 5% Glucose intravenous infusion B.P., or 0.18% Sodium Chloride and 4% Glucose intravenous infusion B.P.
  - Compound Sodium Lactate Intravenous infusion B.P. (Hartmann’s Solution).
  - Alternative Step 2 diluents:
    - 0.9% Sodium Chloride injection B.P.
    - 0.45% Sodium Chloride injection B.P.
    - 0.2% Dextrose and Water injection B.P.
    - 4% Glucose injection B.P.
    - 5% Glucose and Fructose intravenous infusion B.P.

4. POSSIBLE SIDE EFFECTS

The name of your medicine is Erythromycin Lactobionate 1 g Powder for Solution for Infusion. It will be referred to as Erythromycin Lactobionate I.V. for ease of use in this leaflet.

In this leaflet:
1. What Erythromycin Lactobionate I.V. is and what it is used for
2. Before you are given Erythromycin Lactobionate I.V.
3. How you will be given Erythromycin Lactobionate I.V.
4. Possible Side Effects
5. How to store Erythromycin Lactobionate I.V.
6. Further information

1. WHAT ERYTHROMYCIN LACTOBIONATE I.V. IS AND WHAT IT IS USED FOR

Erythromycin Lactobionate I.V. contains the active ingredient erythromycin which belongs to a group of medicines called macrolide antibiotics.

- Erythromycin Lactobionate I.V. is used when an intravenous antibiotic is required to treat serious infections, if you cannot swallow tablets or if you are at particular risk of developing an infection.
- Erythromycin Lactobionate I.V. is used to prevent and treat infections such as:
  - Throat and sinus infections;
  - Chest infections, such as bronchitis and pneumonitis;
  - Ear infections;
  - Mouth and dental infections;
  - Eye infections;
  - Skin and tissue infections, such as acne;
  - Stomach and intestinal infections;
  - Prevention of infection following burns, punctures or dental procedures;
  - Other infections, such as sexually transmitted diseases, bone infection or septic fever;
  - Septicaemia;
  - Endocarditis.

2. BEFORE YOU ARE GIVEN ERYTHROMYCIN LACTOBIONATE I.V.

You should not receive Erythromycin Lactobionate I.V. if you:

- have told your doctor you are allergic to erythromycin or other macrolide antibiotics such as clarithromycin or azithromycin;
- are taking other antibiotics or dihydroergotamine (used to treat migraine) while taking erythromycin as this may cause serious side effects;
- are taking midazolam or atropine or metoclopramide (widely taken for heartburn and ulcers), diphenhydramine (for nausea (feeling sick) and vomiting (feeling sick), cisapride (for stomach disorders) or pimozide or mirtazapine (for psychiatric conditions) while taking erythromycin, as combination of these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor before taking alternative medicines you can take instead;
- are pregnant or think you may be pregnant, or if you are breast-feeding;
- have previously experienced diarrhoea following the use of antibiotics;
- have previously experienced diarrhoea following the use of antibiotics;
- have recently been given or have been told that you may be pregnant; or if you are not sure, tell your doctor.

Take special care with Erythromycin Lactobionate I.V. if you:

- are taking quinidine (used for treatment of gout and arthritis), while taking erythromycin as this may cause serious side effects;
- have any liver problems or have been told that any drugs you are taking cause liver problems;
- have previously experienced diarrhoea following the use of antibiotics;
- have previously experienced diarrhoea following the use of antibiotics;
- have recently been given or have been told that you may be pregnant; or if you are not sure, tell your doctor.

If any of these apply to you, or if you are not sure, tell your doctor. Please tell your doctor if you are taking, or have recently taken any other remedies, including any medicines obtained without a prescription.

This is especially important if you are taking remedies from the following families:

- antacids, bismuth or magnesium (used to treat ulcers such as duodenal ulcers);
- diuretics (used to treat oedema (swelling)) and nitrates (used to treat angina);
- potassium or amiloride (used to treat heart problems);
- angiotensin converting enzyme (used to treat high blood pressure and heart problems);
- diuretics (used to treat heart failure);
- diuretics (used to treat liver disease) or cholestyramine or colestipol (used to treat high cholesterol levels or other lipid abnormalities);
- colestipol (used to treat high cholesterol levels or other lipid abnormalities);
- diuretics (used to treat liver disease) or cholestyramine or colestipol (used to treat high cholesterol levels or other lipid abnormalities);
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