

TECHNICAL LEAFLET
ON
Erythromycin Lactobionate 1g Powder for Solution for Infusion

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 antitoxin), *Neisseria, Treponema pallidum, Chlamydia trachomatis, Clostridia, Ureaplasma urealytica, 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



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.

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 (0.5% - 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 arrhythmias. Rapid infusion is more likely to be associated with arrhythmias 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.

Alternative Step 2 diluents:

Compound Sodium Lactate Intravenous infusion B.P. (Hartmann's Solution).

Solutions containing glucose may also be used but sodium bicarbonate must first be added as a buffer to ensure neutrality.

5 ml of sterile 8.4% w/v sodium bicarbonate solution will neutralise one litre of:

5% Glucose intravenous infusion B.P., or 0.18% Sodium Chloride and 4% Glucose intravenous infusion B.P.

The stability of solutions of Erythromycin Lactobionate is adversely affected below pH 5.5.

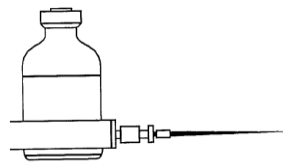
Once reconstituted, use immediately and discard any remainder of the contents.

Dosage

Adults: 2-4 g daily in divided doses,

Neonates (birth to 1 month): 10-15 mg/kg three times daily.

Children: 12.5 mg/kg four times daily (doses can be doubled in severe infections).



Prescribing Information

Erythromycin Lactobionate I.V.: 1.0 g erythromycin per vial.

Dose: Adults: mild to moderate infections 25 mg/kg/day; In divided doses. In cases of severe infections the dose may be increased up to 50 mg/kg/day. Neonates (birth to 1 month): 10-15 mg/kg three times daily. Children: 12.5 mg/kg four times daily (doses can be doubled in severe infections).

Contraindications: Sensitivity to erythromycin. Concurrent astemizole, terfenadine, cisapride or pimozone use.

Administration via I.M. or I.V. bolus

Side Effects: The following have been reported: diarrhoea, nausea, vomiting, abdominal pain, reversible hearing loss associated with doses usually greater than 4 g per day, mild allergic reactions, rarely anaphylaxis, symptoms of hepatitis, hepatic dysfunction and/or abnormal liver function test results may occur.

Precautions: Impaired liver function. Infrequently, hepatic dysfunction including increased liver enzymes and/or cholestatic hepatitis, with or without jaundice. May aggravate the weakness of patients with myasthenia gravis.

Rarely pseudomembranous colitis has been reported.

Rhabdomyolysis with or without renal impairment has been reported in seriously ill patients receiving erythromycin concomitantly with drugs known as 'statins'. If the patient has ever experienced diarrhoea following the use of antibiotics. Prolonged QTc interval and ventricular arrhythmias have rarely been reported in patients receiving erythromycin IV. Potentiation of drugs metabolised by the cytochrome P450 system.

Product Licence Number: 20072/0038

Further Information: Contains no sodium.

Legal Category POM

Marketed by

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Package leaflet: Information for the patient

Erythromycin Lactobionate 1g Powder for Solution for Infusion

erythromycin lactobionate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet . See section 4.

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

What is in this leaflet

1. What Erythromycin Lactobionate I.V. is and what is it used for
2. What you need to know 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. Contents of the pack and other information

1. What Erythromycin Lactobionate I.V. is and what is it 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 severe infections, if you cannot swallow erythromycin 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 pneumonia.
- Ear infections.
- Mouth and dental infections
- Eye infections
- Skin and tissue infections, such as acne.
- Stomach and intestinal infections.
- Prevention of infection following burns, operations or dental procedures.
- Other infections, such as sexually transmitted diseases, bone infection or scarlet fever.
- Septicaemia
- Endocarditis

2. What you need to know before you are given Erythromycin Lactobionate I.V.

You should not receive Erythromycin Lactobionate I.V. :

- if you are allergic to erythromycin or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to other macrolide antibiotics such as clarithromycin or azithromycin.
- if you are taking ergotamine or dihydroergotamine (used to treat migraines) while taking erythromycin as this may cause serious side effects.
- if you are taking terfenadine or astemizole or mizolastine (widely taken for hayfever and allergies), domperidone (for nausea (feeling sick) and vomiting (being sick)), cisapride (for stomach disorders) or pimozide or amisulpride (for psychiatric conditions) while receiving erythromycin, as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines you can take instead.
- if you using simvastatin (used to lower cholesterol and triglycerides (types of fat) in the blood).
- tolterodine (used for treating overactive bladder with symptoms of urinary frequency, urgency, and leakage).
- if you have abnormally low levels of potassium or magnesium in your blood (hypomagnesaemia or hypokalaemia).
- if you or someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia or torsades de pointes) or an abnormality of the electrocardiogram (electrical recording of the heart) called “long QT syndrome”.
- if you are taking lomitapide (used to lower increased blood fats such as cholesterol and triglycerides). Taking this medicine at the same time as erythromycin may lead to a rise in enzymes produced by liver cells (transaminases), which indicates that the liver is under stress and may lead to liver problems.

Warnings and precautions

Talk to your doctor or pharmacist before you are given Erythrocin I.V. Lactobionate:

- if you are taking colchicine (used for treatment of gout and arthritis) whilst taking erythromycin as this may cause serious side effects;
- if you have any liver problems or have been told that any drugs you are taking can cause liver problems;
- if you are taking other medicines which are known to cause serious disturbances in heart rhythm;
- if you have heart problems;
- if you have previously experienced diarrhoea following the use of antibiotics;
- if you are pregnant and have been told that you have a sexually transmitted disease called syphilis. In this case erythromycin may not be effective for preventing the transfer of this infection to your baby. Consult your doctor before receiving erythromycin. Alternatively if you were treated for early stages of syphilis during pregnancy, and your child is under 1 year and is prescribed erythromycin, consult your doctor before giving erythromycin to your child;
- if you are treating a young child with antibiotics and they are irritable or vomit when fed, you should contact your doctor immediately;
- if you suffer from a condition called myasthenia gravis, which causes muscle weakness, consult, your doctor before receiving erythromycin;

- if you are taking erythromycin with 'statins' such as simvastatin or lovastatin (used to lower cholesterol) as serious side effects can occur.

Children

If you are treating a young child with antibiotics and they are irritable or vomit when fed, you should contact your physician immediately.

Other medicines and Erythromycin Lactobionate I.V.

Tell your doctor if you are using, have recently used or might use any other medicines.

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

- astemizole, terfenadine or mizolastine (used to treat allergies such as hayfever);
- domperidone (used to treat nausea (feeling sick) and vomiting (being sick));
- pimozide or amisulpride (used to treat mental problems);
- ergotamine or dihydroergotamine (used to relieve migraine);
- cisapride (used to treat stomach disorders);
- statins (used to help lower cholesterol levels e.g. lovastatin and simvastatin);
- hydroxychloroquine or chloroquine (used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria). Taking these medicines at the same time as erythromycin may increase the chance of you getting side effects that affect your heart;
- protease inhibitors (used to treat viral infections e.g. saquinavir);
- oral contraceptives.

This is also important if you are taking medicines called:

- colchicine (used to treat gout and arthritis);
- cimetidine and omeprazole (used to treat acid reflux and other related conditions);
- clarithromycin, rifabutin, or rifampicin (medicines used to treat different types of bacterial infection);
- fluconazole, ketoconazole and itraconazole (medicines used to treat fungal infections);
- digoxin, quinidine or disopyramide (used to treat heart problems);
- cilostazol (a medicine used to treat peripheral circulation problems);
- hexobarbitone, phenobarbital or midazolam (used as sedatives);
- Anticoagulants e.g. warfarin, acenocoumarol and rivaroxaban (used to thin the blood);
- valproate, carbamazepine or phenytoin (used to control epilepsy);
- theophylline (used to treat asthma and other breathing problems);
- ciclosporin or tacrolimus (used following organ transplants);
- bromocriptine (used to treat Parkinson's disease);
- zopiclone or triazolam/alprazolam (used to help you sleep or relieve states of anxiety);
- alfentanil (a medicine used to provide pain relief);
- methylprednisolone (used to help suppress the body's immune system – this is useful in treating a wide range of conditions);
- St John's Wort (a herbal medicine used to treat depression);
- verapamil (used to treat high blood pressure and chest pain);
- vinblastine (used to treat certain types of cancer);

- sildenafil (used to treat erectile dysfunction).
- corticosteroids, given by mouth, by injection or inhaled (used to help suppress the body's immune system - this is useful in treating a wide range of conditions).

If you or your child goes for any medical tests, tell your doctor that you are receiving Erythromycin Lactobionate I.V., as this may interfere with some test results.

Pregnancy and breast-feeding

Erythromycin should be used by women during pregnancy only if clearly needed.

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist before taking this medicine.

The active ingredient of Erythromycin Lactobionate I.V may cross the placenta in pregnant women and is excreted in breast milk. Information from studies regarding the risk of birth defects is inconsistent, but some studies have reported heart defects following Erythromycin Lactobionate I.V use in early pregnancy.

Driving and using machines

None reported.

3. How you will be given Erythromycin Lactobionate I.V.

For patients with severe infections or those who are at particular risk of developing infections, the usual dose of Erythromycin Lactobionate I.V. is:

For adults:

50 mg per kg of body weight per day. For patients with mild to moderate infections who cannot swallow tablets, the usual dose is 25 mg per kg of bodyweight per day.

For Children:

12.5 mg per kg of body weight four times daily

For newborn infants (birth to 1 month):

10-15 mg per kg of body weight three times daily. Doses can be doubled in severe infections. Your doctor will calculate the correct dose for you. Erythromycin Lactobionate I.V. will be given either in divided doses throughout the day or as a continuous slow infusion. You should not receive Erythromycin Lactobionate I.V. as an injection directly into your vein via a syringe. If you have any further questions on the use of this product ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following, contact your doctor immediately:

- difficulty breathing;
- fainting;
- swelling of the face, lips or throat;
- skin rashes;
- severe skin reactions including large fluid-filled blisters, sores and ulcers;
- ulcers in the mouth and throat; as these may be signs of an allergic reaction;
- a life-threatening irregular heart beat called torsades de pointes or abnormal ECG heart tracing) or heart stopping (cardiac arrest);
- various liver or gall-bladder problems, which can cause yellowing of the skin and/or eyes (jaundice) or pale stools with dark urine;
- serious skin rashes that may involve blistering and can cover large areas of the torso, face and limbs (conditions known as Stevens Johnson syndrome, toxic epidermal necrolysis and erythema multiforme);
- diarrhoea which may be severe or prolonged and may contain blood or mucus.

Contact a doctor immediately if you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). The frequency of this side effect is not known (cannot be estimated from the available data).

Other side effects of Erythromycin Lactobionate I.V. include:

Not known: frequency cannot be estimated from the available data

- feeling sick or being sick;
- increase in a particular type of white blood cells (eosinophilia);
- stomach pains; these may be a symptom of an inflamed pancreas (pancreatitis);
- ringing in the ears (tinnitus);
- reversible loss of hearing (usually associated with high doses or in patients with kidney problems);
- chest pains;
- abnormal heart rhythms (including palpitations, a faster heartbeat);
- fever;
- anorexia;
- confusion;
- fits (seizures);
- vertigo (problems with balance that can result in feelings of dizziness or sickness – particularly on standing);
- hallucinations (seeing or hearing things that aren't there);
- feeling generally unwell (malaise);
- inflammation of the kidneys (a condition known as interstitial nephritis);
- low blood pressure;
- vomiting and irritability in young children between the age of 1 month and 12 months;
- visual impairment/blurred vision (Mitochondrial optic neuropathy).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ERYTHROMYCIN LACTOBIONATE I.V.

Your medicine will be stored by the hospital or clinic. Once the vial of Erythromycin Lactobionate I.V. has been mixed ready for use it should be used immediately.

This medication should not be used after the expiry date shown on the label. The expiry date refers to the last day of that month.

Keep this medicine out of the sight and reach of children.

6. Contents of the pack and other information

What Erythromycin Lactobionate I.V. contains

Each vial of Erythromycin Lactobionate I.V. Injection contains 1 g of the active ingredient erythromycin lactobionate. When made up with 20 ml of Water for Injections, each ml of solution contains 50 mg of erythromycin lactobionate.

This solution must be further diluted prior to use.

There are no other ingredients in the product.

Erythromycin Lactobionate I.V. is available as single 1g vials.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Amdipharm UK Limited,
Dashwood House,
69 Old Broad Street,
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Manufacturer:

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This leaflet applies only to Erythromycin Lactobionate I.V. and This leaflet was last revised in January 2024.