

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Erythromycin 1 g 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Erythromycin is and what it is used for
2. What you need to know before you use Erythromycin
3. How you will be given Erythromycin
4. Possible side effects
5. How to store Erythromycin
6. Contents of the pack and other information

1. What Erythromycin is and what it is used for

The name of your treatment is Erythromycin 1 g powder for solution for infusion.

Erythromycin contains the active substance erythromycin lactobionate which belongs to a group of antibacterial substances for systemic use (suitable for intravenous infusion). Erythromycin is used in adults and children (including newborn babies).

Erythromycin 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 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
- Endocarditis

Erythromycin can also be used to treat patients for which bacteria spread into the blood.

2. What you need to know before you use Erythromycin

Do not use Erythromycin:

- if you are allergic to erythromycin or any of antibiotics from the same group 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 (widely taken for hayfever and allergies), cisapride (for stomach disorders) or pimozone (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.

Warnings and precautions

Talk to your doctor or nurse before taking Erythromycin if you:

- are taking colchicine (used for treatment of gout and arthritis) whilst taking erythromycin as this may cause serious side effects
- have any liver problems or have been told that any drugs you are taking can cause liver problems

- have previously experienced diarrhoea following the use of antibiotics
- 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 your pregnancy and your child is under 1 year and is prescribed erythromycin, consult your doctor before giving erythromycin to your child

- are treating a young child with antibiotics and they are irritable or vomit when fed, you should contact your doctor immediately
- suffer from a condition called myasthenia gravis, which causes muscle weakness
- are taking erythromycin with "statins" such as simvastatin or lovastatin (used to lower cholesterol) as serious side effects can occur.

If any of these apply to you, or if you are not sure, tell your doctor.

Other medicines and Erythromycin

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

The section "*Do not use Erythromycin*" above lists medicines that may not be taken together with Erythromycin.

Erythromycin can affect or be affected by certain medicines from the following families:

- astemizole, terfenadine or mizolastine (used to treat allergies such as hayfever)
- pimozone (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)
- protease inhibitors (used to treat viral infections e.g. saquinavir)
- 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)
- warfarin and acenocoumarol (used to help 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)

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THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY:

The full information can be found in the Summary of Product Characteristics for Erythromycin.

RECOMMENDED ADMINISTRATION

Bolus injection (IV) push is contraindicated.

Continuous infusion of Erythromycin is preferred due to the slower infusion rate and lower concentration of erythromycin; however, intermittent infusion at intervals not greater than every six hours is also effective.

Intravenous erythromycin should be replaced by oral erythromycin as soon as possible.

Preparations for administration:

For Intermittent Infusion of 1 gram dose:

Step 1 - add 20 ml of Water for Injections to the 1 g vial.

Step 2 - add 20 ml of Step 1 solution to 200-250 ml of 0.9% (9 mg/ml) sodium chloride solution for injection. The resulting diluted solution contains 5 mg/ml – 4 mg/ml (0.5 – 0.4%) of erythromycin.

If it is decided to administer the daily dose as an intermittent infusion, then the erythromycin concentration should not exceed 5 mg/ml and the time of each infusion should be between 20 and 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 Continuous Infusion of 1 gram dose:

Step 1 - add 20 ml of Water for Injections to the 1 g vial.

Step 2 - add 20 ml of Step 1 solution to 500-1000 ml of 0.9% (9 mg/ml) sodium chloride solution for injection. The resulting diluted solution contains 2 mg/ml – 1 mg/ml (0.2 – 0.1%) of erythromycin.

Alternative Step 2 diluents:

Compound Sodium Lactate Injection (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: Glucose Injection (5%), or Sodium Chloride and Glucose Injection (usually 0.18% sodium chloride and 4.0% glucose).

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

Special precautions for disposal and other handling

Continuous intravenous infusion with an erythromycin concentration of 1 mg/ml (0.1% solution) is recommended. The infusion should be completed within 8 hours of preparation to ensure potency.

If required, solution strengths up to 5 mg/ml (0.5% solution) may be used, but should not be exceeded. Higher concentrations may result in pain along the vein. Bolus injection is not recommended.

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

Pregnancy, breast-feeding and fertility

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

Erythromycin should be used by woman during pregnancy only if clearly needed and only if prescribed by a doctor.

Driving and using machines

No side effect that can affect your ability to drive and use machines has been reported with Erythromycin.

3. How you will be given Erythromycin

For patients with severe infections or those who are at particular risk of developing infections, the recommended dose of Erythromycin is:

For adults:

50 mg per kg body weight per day.

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

For children:

12.5 mg per 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 will be given either in divided doses throughout the day or as a continuous slow infusion.

4. Possible side effects

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

Conditions you need to look out for

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.

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).

Common side effects

These may affect **up to 1 in 10** people:

- Diarrhoea
- Feeling sick
- Skin eruptions

Uncommon side effects

These may affect **up to 1 in 100** people:

- Urticaria

Rare side effects

These may affect **up to 1 in 1000** people:

- Severe allergic reaction
- Reversible loss of hearing (usually associated with high doses or in patients with kidney problems)

Rare side effects that may show up in blood tests:

- Increase in liver enzymes

Other side effects

Other side effects have occurred in a small number of people but their exact frequency is unknown:

- Allergic reaction
- Hallucinations (seeing or hearing things that aren't there)
- Fits (seizures)

Special precautions for storage:

After reconstitution:

After reconstitution, chemical and physical in-use stability in water for injection has been demonstrated for 24 hours when stored at room temperature and for 14 days when stored in a refrigerator at 2-8° C.

After reconstitution and dilution:

After reconstitution and dilution, chemical and physical in-use stability has been demonstrated for 24 hours at room temperature when the solution is diluted in 0.9% (9 mg/ml) sodium chloride solution for injection or Glucose 5% and for 12 hours at room temperature when the solution is diluted in Hartman's solution.

From a microbiological point of view, once opened, the product should be used immediately.

If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

Prescribing Information

Erythromycin: 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 pimozide use. Administration via I.M. or I.V. bolus

- Confusion
- Vertigo (problems with balance that can result in feelings of dizziness or sickness – particular on standing)
- Ringing in the ears (tinnitus)
- Loss of hearing
- Abnormal heart rhythms (including palpitations)
- Low blood pressure
- Diarrhoea which may be severe or prolonged and may contain blood or mucus
- Stomach pains; these may be a symptom of an inflamed pancreas (pancreatitis)
- Being sick
- Anorexia
- 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)
- Inflammation of the kidneys (a condition known as interstitial nephritis)
- Chest pains
- Fever
- Feeling generally unwell (malaise)

Other side effects that may show up in blood tests:

- Increase in a particular type of white blood cells (eosinophilia)

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme.

Website: www.mhra.gov.uk/yellowcard

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

5. How to store Erythromycin

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

Do not use Erythromycin after the expiry date which is stated on the carton after "Do not use after:" or "EXP:." The expiry date refers to the last day of that month.

Unopened: This product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Erythromycin contains

The active substance is erythromycin. Each vial of Erythromycin contains erythromycin lactobionate equivalent to erythromycin 1 g. There are no other ingredients in the product.

What Erythromycin looks like and contents of the pack

Erythromycin is available as a powder for solution for infusion. The powder is white to yellowish. The powder is supplied as a single dose vial packed in a carton box. Each carton box contains 1 vial or 10 vials.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

STRAGEN UK Ltd.

Castle Court, 41 London Road

Reigate, Surrey RH2 9RJ

Manufacturer

FISIOPHARMA S.r.l.

Nucleo Industriale, 84020 - Palomonte (SA)

ITALY

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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: Erythromycin should be used with caution in patients with impaired liver function.

Infrequently, hepatic dysfunction including increased liver enzymes and/or cholestatic hepatitis, with or without jaundice has been reported during erythromycin administration. Myasthenia gravis can exacerbate during erythromycin treatment.

Rarely pseudomembranous colitis has been reported in patients receiving erythromycin. If the patient has ever experienced diarrhoea following antibiotics course, erythromycin should be used with caution. Rhabdomyolysis with or without renal impairment has been reported in seriously ill patients receiving erythromycin concomitantly with drugs known as "statins".

Prolonged QTc interval and ventricular arrhythmias have rarely been reported in patients receiving erythromycin.

Erythromycin can potentiate drugs metabolised by the cytochrome P450 system.

Product License Number: PL21844/0034

Further information: Contains no sodium.

Legal category: POM

Marketed by: STRAGEN UK Ltd.