Warning and precautions

Read all of this leaflet carefully before you start using 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.
- This leaflet does not replace the information given to you by your doctor and nurse. If you get any side effects, talk to your doctor or nurse.
- These include topics that are not found in this leaflet. See section 4.

What is in this leaflet

1. What ERYTHROMYCIN is and what it is used for
2. How to take ERYTHROMYCIN
3. Possible side effects
4. How to stop taking ERYTHROMYCIN
5. How to store ERYTHROMYCIN
6. Further information

What is ERYTHROMYCIN?

The name of your medicine is ‘Erythromycin Phosphate’. It is a powder for solution for infusion but will be referred to as ‘ERYTHROMYCIN’ in this leaflet.

1. What ERYTHROMYCIN is and what it is used for

ERYTHROMYCIN is an antibiotic that contains erythromycin (as erythromycin lactobionate). It is a type of antibiotic called macrolide which acts by preventing the growth and multiplication of bacteria.

ERYTHROMYCIN is used in the treatment of serious infections caused by bacteria in patients adults and children where an alternative of erythromycin is not possible or insufficient or in patients in whom the infection requires high levels of erythromycin. ERYTHROMYCIN is not recommended or these antibiotics are not appropriate for other reasons.

The usual dose is 1 to 2 g per day equivalent to 25 mg/kg/day in divided doses (generally 3-4 single doses).

Posology

- When treating serious infections: 1 to 2 g per day or when these antibiotics are not appropriate for other reasons.

- In patients with impaired renal function (with a level of serum creatinine of 2.0 mg/dl, kidney failure with anuria), the maximum daily dose for ERYTHROMYCIN is generally not recommended to combine with other antibiotics.

- In patients with acute renal insufficiency (creatinine clearance levels lower than 10ml/min), the erythromycin dose must be reduced to 50% to 75% of the usual dose. If you have any side effects, talk to your doctor or nurse.

- In patients with impaired hepatic function: the administration of ERYTHROMYCIN should be adjusted on the basis of the reduction in plasma protein binding and the half-life of ERYTHROMYCIN.

- In patients with impaired hepatic function with a creatinine clearance levels higher than 10ml/min) may not be necessary.

- If you are allergic (or hypersensible) to other erythromycin antibiotics;

- If you are allergic (or hypersensible) to other macrolide antibiotics;

- If you have any other serious allergic reactions;

- If you are allergic to certain other drugs of the macrolides class of antibiotics, talk to your doctor, pharmacist or nurse before using ERYTHROMYCIN.

- If you have myasthenia gravis, erythromycin may aggravate the symptoms of this disease. Your doctor will adjust your dose and take into account the way your body responds to ERYTHROMYCIN.

- If you have any other serious allergic reactions;

- If you have myasthenia gravis, erythromycin may aggravate the symptoms of this disease. Your doctor will adjust your dose and take into account the way your body responds to ERYTHROMYCIN.

- If you have any further questions, ask your doctor or nurse.

- If you have any side effects, talk to your doctor or nurse.

- If you get any side effects, talk to your doctor or nurse. This includes topics that are not found in this leaflet. See section 4.

The following information is intended for healthcare professionals only

For information on resistance data for ERYTHROMYCIN, please see the technical information on Erythromycin. Please refer to these data before starting the treatment.

Package

1. Adults and children over 12 years of age or weighing ≥45 kg

The usual dose is 1 to 2 g per day equivalent to 25 mg/kg/day in divided doses (generally 3-4 single doses).

2. Newborn infants

Dose can be increased up to 4 g per day equivalent to 50 mg/kg/day in severe infections.

- In patients with renal insufficiency; weight divided over 3-4 single doses. This dose may be doubled depending on the indication.

3. Children under 12 years or weighing < 45 kg

1 month to 12 years old: the daily dose for infants and children under 12 years old for most infections is 15-20 mg of erythromycin/kg of body weight divided over 3-4 single doses. This dose may be disabled depending on the indication.

Term newborn infants (birth to 4 months)

10 mg/kg per day.

- In patients with acute renal insufficiency; creatinine clearance levels higher than 10ml/min, the erythromycin dose must be reduced to 50% to 75% of the normal dose, to be administered in accordance with the habitual treatment. The maximum daily dose must not exceed 2 g.

- In patients with acute renal insufficiency; creatinine clearance levels lower than 10ml/min, the erythromycin dose must be reduced to 125% to 175% of the normal dose, to be administered in accordance with the habitual treatment. The maximum daily dose must not exceed 2 g.

ERYTHROMYCIN is not removed by haemodialysis or peritoneal dialysis. For patients who have regular dialysis, an additional dose is therefore not recommended.

Use

Use adult dosage with care. Elderly patients, particularly those with reduced renal or hepatic function may be at increased risk for developing other drugs of the macrolides class of antibiotics, talk to your doctor, pharmacist or nurse before using ERYTHROMYCIN.

- Severe allergic reactions can occur; do not use ERYTHROMYCIN if you have allergies or hypersensitivity to other macrolide antibiotics;

- If you are allergic (or hypersensible) to other erythromycin antibiotics;

- If you have any side effects, talk to your doctor or nurse.

- If you get any side effects, talk to your doctor or nurse. This includes topics that are not found in this leaflet. See section 4.

- The occurrence of side effects of ERYTHROMYCIN may affect the ability to concentrate and react. It is generally not recommended to combine erythromycin with:

- If you have any further questions, ask your doctor or nurse.

- If you have any side effects, talk to your doctor or nurse.

- If you get any side effects, talk to your doctor or nurse. This includes topics that are not found in this leaflet. See section 4.

- It is generally not recommended to combine erythromycin with:

- If you are allergic (or hypersensible) to other macrolide antibiotics;

- If you have any other serious allergic reactions;

- If you are allergic to certain other drugs of the macrolides class of antibiotics, talk to your doctor, pharmacist or nurse before using ERYTHROMYCIN.

- If you are allergic (or hypersensible) to other macrolide antibiotics;

- If you have any other serious allergic reactions;

- If you are allergic (or hypersensible) to other macrolide antibiotics;

- If you have any side effects, talk to your doctor or nurse.

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3. How to use ERYTHROMYCIN

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. This medicine will always be administered to you by your doctor or a healthcare professional. It will be given intravenously twice a day over 60 minutes.

Adults and children over 12 years of age weighing > 40 kg

The usual dose is 1.0 to 2.0 g per day divided into 3 or 4 doses (total of 3–4 single doses). The first dose may be given on the first day if your infection is very severe.

It is important that you complete your full course of antibiotics; do not stop taking your infection treatment early even if you feel better.

Children over 1 month to 12 years of age weighing < 40 kg

Your doctor will calculate the exact dose your child will receive taking into account the way your child’s body weight.

Term newborns/infants (birth to 1 month)
The dose is calculated based on body weight and divided into 3 or 4 single doses.

Your doctor will calculate the exact dose your child will receive taking into account the way your child’s body weight.

Use in patients with severe kidney problems
Your doctor will calculate the exact dose according to the way your kidney is working.

Use in elderly patients
You should decide with your doctor if your age will change the dose and the way you take this medicine.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone may experience them.

If you develop an allergic reaction, this may result in a rash and swelling of parts of your body, including the face and neck, accompanied by difficulty in breathing. If this happens to you, stop using this medicine and seek urgent medical help immediately.

The following side effects are anorexia (lack of appetite), vomiting, abdominal pain, nausea, flatulence, diarrhoea, constipation, diarrhoea, and loss of appetite (anorexia). The following side effects have been reported:

Uncommon (may affect up to 1 in 100 people):

- Swelling or feeling of swelling in one part of your body including face and neck
- Ringing or buzzing of the ears
- Problems with vision
- Allergic reactions
- Mildness of the rash (urticaria exanthema)
- Skin redness
- Fainting or dizziness
- Chest discomfort, difficulty breathing, abnormally fast and superficial breathing
- Irregular heartbeat, the heart beating forcefully or rapidly
- Epileptic seizures, convulsions
- Bloody diarrhoea or black stools
- Blood disorders affecting the cell components of the blood
- Chest discomfort, difficulty breathing

Rare (may affect up to 1 in 1,000 people):

- Swelling of certain part of your body including face and neck (allergic reaction, angioedema, oedema/angioedema, anaphylaxis)
- Stomach pain with nausea, vomiting, diarrhoea, and loss of appetite (gastritis)
- Headache
- Sweating
- Heartburn
- Nausea
- Vomiting
- Diarrhoea
- Loss of appetite
- Weight loss (infantile hypertrophic pyloric stenosis).

Unknown (frequency cannot be estimated from the available data):

- Irregular heartbeat, the heart beating forcefully or rapidly
- Abnormalities of the blood (abnormally low or high levels of blood cells and blood platelets)
- Ulceration of the stomach and intestines
- Sensation of coldness
- Skin eruptions
- Skin reactions (Stevens-Johnson syndrome and erythema multiforme)
- Skin peeling (epidermal neocytodermis)

Erythromycin can be administered in continuous or intermittent perfusion.

The usual rate of infusion is 50 to 100 ml of 0.9% sodium chloride infusion as a rapid infusion. The infusion rate is more likely to be associated with local irritative effects than as QT interval prolongation, arrhythmias or hypotension. A longer period of infusion should be used in patients with risk factors or previous evidence of arrhythmia. For 15 to 20 ml of 0.9% sodium chloride solution, this corresponds to about 35 drops/minute, for 250 ml of infused solution 85–100 drops/minute and for 500 ml of infused solution 110–170 drops/minute.

The erythromycin concentration should not exceed 5mg per ml and an erythromycin concentration of 1mg/ml solution is recommended. Erythromycin should not be mixed with any other medicine. The erythromycin injection is strictly contraindicated. It can lead to: I parenthesis with schisms.

Intramuscular administration and IV infusion solutions are also contraindicated.

Indication of the end of therapy: Treatment should be continued for a further 3–4 days after symptoms have disappeared.

5. How to store ERYTHROMYCIN

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

Do not use this medicine after the expiry date which is stated on the vial and carton after PACK (the expiry date refers to the last day of that month).

After reconstitution:

The diluted solution must not be mixed with other medicines except those used for reconstitution.

ERYTHROMYCIN lactobionate in solution does not blend, mainly because of the pH shifts, with β-lactam antibiotics, aminoglycosides, tetracyclines, chloramphenicol, colistin, amphotericin B, barbital, diphenhydramine, hydantoin, phenobarbital, rifampicin (stabilised), and vitamin B6 and vitamin C. The original preparation must be used.

The addition of other solutions, which alter the range from pH 6.6–8.6, reduces the stability of erythromycin lactobionate.

Additional side effects in newborn infants and children

Vomiting (generally due to the presence of inorganic salts) and loss of appetite.

6. Contents of the pack and other information

ERYTHROMYCIN contains the active substance erythromycin lactobionate. Each vial contains 1 g of erythromycin. There are no other ingredients in this medicine.

ERYTHROMYCIN looks like contents of the pack

Before reconstitution, ERYTHROMYCIN is a white to slightly yellow hygroscopic powder for solution for intravenous use. After reconstitution, the solution is clear and colourless.

ERYTHROMYCIN is available as containing 10 or 20 ml glass vials. Not all pack sizes may be marketed.

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