

Package leaflet: Information for the patient

Erythrocin® 250 mg and 500 mg TABLETS

Erythromycin stearate

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Throughout the leaflet the medicine is referred to as “your” medicine, but it may have been given to you to give to your child. In that case, remember that the information will apply to your child, and not to you.

The name of your medicine is Erythrocin 250 mg Tablets or Erythrocin 500 mg Tablets (will be referred to Erythrocin Tablets throughout this leaflet). Erythrocin Tablets are available as either 250 mg or 500 mg film-coated tablets.

What is in this leaflet

1. What Erythrocin Tablets are and what they are used for
2. What you need to know before you take Erythrocin Tablets
3. How to take Erythrocin Tablets
4. Possible side effects
5. How to store Erythrocin Tablets
6. Contents of the pack and other information

1. What Erythrocin Tablets are and what they are used for

Erythrocin Tablets contains the active substance erythromycin stearate. They belong to a group of drugs called antibiotics and are used in adults and children aged over 8 years to treat infections which are caused by bacteria.

2 What you need to know before you take Erythrocin Tablets

Do not take Erythrocin Tablets:

- 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 currently taking a medicine called:
 - ergotamine or dihydroergotamine (used to treat migraines) while taking erythromycin as this may cause serious side effects;
 - 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;
 - domperidone (used to treat nausea (feeling sick) and vomiting (being sick));

- lovastatin or simvastatin (used to lower cholesterol levels) as abnormal muscle breakdown leading to kidney problems (rhabdomyolysis) can occur.
- 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.
- 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”.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Erythrocin Tablets:

- if you have any liver problems or have been told that any drugs you are taking can cause liver 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 your 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 physician immediately;
- if you suffer from a condition called myasthenia gravis, which causes muscle weakness, consult your doctor before receiving erythromycin;
- if you are using erythromycin for a long period of time;
- if you suffer from a genetic problem that interferes with the metabolism of mitochondria (Leber’s hereditary optic neuropathy or autosomal dominant optic atrophy);
- if you have heart problems such as an abnormal ECG heart tracing (prolonged QT interval) or a slow heart beat (bradycardia);
- if you are receiving drugs to treat heart problems;
- if you are taking other medicines which are known to cause serious disturbances in heart rhythm;
- if you have uncorrected hypokalaemia or hypomagnesaemia (low blood levels of potassium or magnesium, which can cause muscle weakness, twitching or abnormal heart rhythm);
- if you are elderly;
- if you are about to undergo laboratory tests for signs of pheochromocytoma (a rare tumor of the adrenal glands) as erythromycin may interfere with the test results.

Children under 8 years of age

Erythrocin Tablets are not recommended for use in children less than 8 years of age.

Other medicines and Erythrocin Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any medicines obtained without a prescription.

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));
- 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);
- beta-lactam antibiotics (used to treat bacterial infections, e.g. penicillin and cephalosporin);
- 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);
- clindamycin, lincomycin, chloramphenicol, streptomycin, tetracyclines, colistin, rifabutin, or rifampicin (used to treat different types of bacterial infection);
- fluconazole, ketoconazole and itraconazole (used to treat fungal infections);
- digoxin, quinidine or disopyramide (used to treat heart problems);
- cilostazol (used to treat peripheral circulation problems);
- hexobarbitone, phenobarbital or midazolam (used as sedatives);
- zopiclone or triazolam/alprazolam (used to help you sleep or relieve states of anxiety);
- 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);
- alfentanil (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);
- 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 getting abnormal heart rhythms and other serious side effects that affect your heart.

Pregnancy and breast-feeding

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

The active ingredient of Erythrocin Tablets 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 Erythrocin Tablets use in early pregnancy.

Erythromycin should be used by women during pregnancy or while breast-feeding only if clearly needed.

3. How to take Erythrocin Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children over 8 years of age

The recommended dose of Erythrocin Tablets for adults and children over 8 years is 1 - 2 g daily in divided doses. If you have a bad infection you may be told to take up to 4 g daily.

Use in children under 8 years of age

Erythrocin Tablets are not recommended for use in children aged under 8 years.

Other forms of this medicine may be more suitable for children; ask your doctor or pharmacist.

If you take more Erythrocin Tablets than you should

If you accidentally take more tablets in one day than your doctor has told you to, or if a child has taken some of the tablets, seek medical advice urgently. An overdose could cause temporary hearing loss, nausea, vomiting and diarrhoea.

If you forget to take Erythrocin Tablets

If you forget to take a tablet, take one as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Erythrocin Tablets

Ask your doctor before stopping treatment with Erythrocin Tablets. Do not stop taking Erythrocin Tablets just because you feel better. If you stop the treatment too early your problem could come back.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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 (angioedema), 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;
- irritability and vomiting in a feeding infant (pyloric stenosis);
- abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis);
- inflammation of the kidneys (a condition known as tubulointerstitial nephritis);
- liver failure and various liver or gall-bladder problems, which can cause yellowing of the skin and/or whites of the eyes (jaundice) or pale stools with dark urine;
- abnormal heart rhythms (including palpitations, a faster heart beat, a life-threatening irregular heart beat called torsades de pointes) or abnormal ECG heart tracing) or heart stopping (cardiac arrest);
- serious skin rashes that may involve blistering and can cover large areas of the torso, face, genitals and limbs (conditions known as Stevens Johnson syndrome, toxic epidermal necrolysis and erythema multiforme);
- 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 Erythrocin Tablets are included below with the following frequency:

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

- bowel disease with diarrhoea and abdominal pain (pseudomembranous colitis).

Not known (frequency cannot be estimated from the available data)

- diarrhoea which may be severe or prolonged and may contain blood or mucus;
- feeling sick or being sick;
- stomach pains these may be a symptom of an inflamed pancreas (pancreatitis);
- loss of appetite (anorexia);
- increase in a particular type of white blood cells (eosinophilia);
- ringing in the ears (tinnitus);
- reversible loss of hearing (usually associated with high doses);
- disturbance in vision (double vision, blurred vision);
- chest pains;
- fever;
- confusion;
- fits (seizures);
- dizziness;
- vertigo (problems with balance that can result in feelings of dizziness, a spinning sensation or sickness – particularly on standing);
- hallucinations (seeing or hearing things that aren't there);
- feeling generally unwell (malaise);
- low blood pressure;
- itching or hives;
- increase levels of liver enzymes.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance,
Website: www.hpra.ie

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

5. How to store Erythrocin Tablets

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 label. The expiry date refers to the last day of that month. If the tablets are out of date, return them to your pharmacist and, if necessary, get a new prescription from your doctor.

Do not store above 25°C. Store in the original container. Keep the container tightly closed.

If your doctor decides to stop your treatment with Erythrocin Tablets, return any remaining tablets to a pharmacist.

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 Erythrocin Tablets contain

- The active substance is erythromycin as erythromycin stearate.

Erythrocin 250 mg Tablets – each tablet contains 250 mg of erythromycin stearate.

Erythrocin 500 mg Tablets – each tablet contains 500 mg of erythromycin stearate.

- The other ingredients are povidone, maize starch, magnesium hydroxide, polacrillin potassium, macrogol 8000, macrogol 400, hypromellose and sorbic acid.

What Erythrocin Tablets look like and contents of the pack

Erythrocin Tablets are white, elongated oval tablets with a monogram on one side.

Erythrocin 250 mg Tablets are available in glass or polyethylene bottles containing 100, 500 or 1000 tablets.

Erythrocin 500 mg Tablets are available in cartons containing 10, 15 or 56 tablets, and in glass bottles containing 100 or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Amdipharm Limited
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Manufacturer

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