

Package leaflet: Information for the user

ERYTHROCIN[®] 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 or pharmacist.
- This medicine has been prescribed for you. 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 Erythrocin[®] 250 or Erythrocin[®] 500. These medicines will collectively be referred to as Erythrocin[®] Tablets in this leaflet.

What is in this leaflet

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2. What you need to know before you take Erythrocin[®] Tablets
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1. What Erythrocin[®] Tablets are and what they are used for

The name of your medicine is Erythrocin[®] Tablets.

Erythrocin Tablets contains the active ingredient erythromycin which belongs to a group of medicines called macrolide antibiotics.

Erythrocin Tablets are 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 infections or scarlet fever

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 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 or mizolastine (widely taken for hayfever and allergies), domperidone (for nausea (feeling sick) and vomiting (being sick)), cisapride (for stomach disorders) or pimoziide 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.
 - 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)

- 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 or pharmacist 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 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.
- if you are taking other medicines which are known to cause serious disturbances in heart rhythm.
- if you have heart problems.

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 Erythrocin® Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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));
- 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);
- oral contraceptives.
- hydroxychloroquine or chloroquine (used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria). Taking these medicines at the same time as <clarithromycin/erythromycin> may increase the chance of you getting side effects that affect your heart.

This is also important if you are taking medicines called:

- colchicine (used to treat gout and arthritis) whilst taking erythromycin as this may cause serious side effects;
- 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 taking Erythrocin® Tablets, as this may interfere with some test results.

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® film-coated tablet 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® film-coated tablet use in early pregnancy.

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

Driving and using machines

None reported

Erythrocin® contains sorbic acid which may cause local skin reactions, (e.g. contact dermatitis).

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.

The recommended dose is:

Erythrocin Tablets for adults and children over 8 years is:

1-2 g daily in divided doses i.e. four to eight 250 mg tablets daily or two to four 500 mg tablets daily, taken just before or with meals or food. If you have a severe infection you may be told to take up to 4 g daily.

Use in children (below 8 years)

For younger children, infants and babies, Erythroped, erythromycin ethylsuccinate suspensions, are normally recommended. The recommended dose for children age 2-8 years, for mild to moderate infections, is 1 gram daily in divided doses. The recommended dose for infants and babies, for mild to moderate infections, is 500 mg daily in divided doses.

Continue to take this medicine until the course is completed or until your doctor tells you to stop; **do not stop** taking your medicine, even if you feel better. If you stop the treatment too early your problem could come back.

If you take more Erythrocin® Tablets than you should

If you accidentally take more medicine in one day than your doctor has told you to, or if a child has taken some of the medicine by mistake, contact your doctor or go to your nearest hospital emergency department immediately.

An overdose of Erythrocin[®] Tablets could cause temporary hearing loss, nausea, vomiting and diarrhoea.

If you forget to take Erythrocin[®] Tablets

If you forget to take a dose of your medicine, take it as soon as you remember. Do not take more medicine in one day than your doctor tells you to. Do not take a double dose to make up for a forgotten dose.

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):
- 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 Erythrocin Tablets 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).

Additional side effects in children and adolescents

Adverse drug reactions in children are similar to those in adults.

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 Erythrocin® tablets

Do not store above 25°C. Store in the original package.

Do not use these medicines after the expiry date which is stated on the blister/label after EXP. The expiry date refers to the last day of that month.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

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 to 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– each tablet contains 250 mg of erythromycin stearate.

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

- The other ingredients are hydroxypropyl methyl cellulose, maize starch, povidone, magnesium hydroxide, sorbic acid, polyethylene glycol and polacrillin potassium.

What Erythrocin® Tablets look like and the contents of the pack

Erythrocin® tablets are practically white, uniform smooth, film-seal coating tablet..

The Erythrocin® 250 tablets are available in containers of 50, 100 or 1000 tablets, or blister packs of 28 tablets.

The Erythrocin® 500 tablets are available in containers of 50, 100 or 1000 tablets, or blister packs of 10, 14, 15, 28 or 56 tablets.

Not all pack sizes may be marketed.

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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