

PATIENT INFORMATION LEAFLET ON

ERYTHROCIN® TABLETS (Erythromycin)

Read all of this leaflet carefully before you start taking this medicine.

- Please 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 symptoms are the same as yours.
- If any of the side effects becomes severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT ERYTHROCIN® TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Erythrocin® Tablets.

Erythrocin® 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. BEFORE YOU TAKE ERYTHROCIN

You should not receive Erythrocin Tablets if you:

- have been told that you are allergic to erythromycin or other macrolide antibiotics such as clarithromycin or azithromycin or any of the other ingredients in these tablets.
- are currently taking a medicine called
 - are taking ergotamine or dihydroergotamine (used to treat migraines) while taking erythromycin as this may cause serious side effects.
 - 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.
 - 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)
- have abnormally low levels of potassium or magnesium in your blood (hypomagnesaemia or hypokalaemia).

- 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”.
- 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 physician immediately.
- suffer from a condition called myasthenia gravis, which causes muscle weakness, consult your doctor before receiving erythromycin.
- are taking erythromycin with ‘statins’ such as simvastatin or lovastatin (used to lower cholesterol) as serious side effects can occur.
- You are taking other medicines which are known to cause serious disturbances in heart rhythm.
- If you have heart problems.

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

Taking other medicines

Please tell your doctor if you are taking, or have recently taken 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));
- pimozide (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.

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).

If you or your child goes for any medical tests, tell your doctor that you are taking Erythrocin[®], 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 think you may be pregnant, or if you are breast-feeding, please consult your doctor before taking this medicine.

3. HOW TO TAKE ERYTHROCIN[®] TABLETS

Always take Erythrocin[®] Tablets exactly as your doctor has told you. You should check with your doctor if you are not sure.

The usual dose of 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 bad infection you may be told to take up to 4 g daily.

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[®] 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[®] could cause temporary hearing loss, nausea, vomiting and diarrhoea.

If you forget to take Erythrocin[®]

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.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Erythrocin[®] Tablets 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.

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[®] include:

- diarrhoea which may be severe or prolonged and may contain blood or mucus;
- 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);

- various liver or gall-bladder problems, which can cause yellowing of the skin and/or eyes (jaundice) or pale stools with dark urine;
- chest pains;
- abnormal heart rhythms (including palpitations, a faster heartbeat, a life-threatening irregular heart beat called torsades de pointes or abnormal ECG heart tracing) or heart stopping (cardiac arrest);
- 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;
- 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).
- vomiting and irritability in young children between the age of 1 month and 12 months;
- visual impairment/blurred vision (Mitochondrial optic neuropathy).

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 at: 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 ERYTHROCIN® TABLETS

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

Do not use these tablets after the expiry date shown on the blister/label. The expiry date refers to the last day of that month.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Erythrocin® Tablets contain

Each Erythrocin® 250 tablet contains 250 mg of the active ingredient erythromycin.

Each Erythrocin® 500 tablet contains 500 mg of the active ingredient erythromycin.

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

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

Erythrocin® tablets are white.

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.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Amdipharm UK Limited,
Capital House,
85 King William Street,

London EC4N 7BL, UK

Manufacturer:

Aesica Queenborough Limited,
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Kent ME11 5EL.
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This leaflet applies only to Erythrocin[®] and This leaflet was last revised in February 2020.

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