

Package leaflet: Information for the patient

Erythromycin 250 mg Tablets Erythromycin

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 Erythromycin 250 mg Tablets (will be referred Erythromycin Tablets throughout this leaflet).

What is in this leaflet

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

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

Erythromycin Tablets 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 Erythromycin Tablets

Do not take Erythromycin Tablets:

- if you are allergic to erythromycin or other macrolide antibiotics such as clarithromycin or azithromycin 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 (widely taken for hayfever and allergies), cisapride (for stomach disorders) or pimozide (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.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Erythromycin 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 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 tumour of the adrenal glands) as erythromycin may interfere with the test results.

Children under 8 years of age

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

Other medicines and Erythromycin Tablets

Tell your doctor 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 the following medicines or 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));

- pimoziide (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 (a medicine 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);
- 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);
- 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).

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 Erythromycin Tablets may cross the placenta in pregnant women and is excreted in breast milk.

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

3. How to take Erythromycin 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 Erythromycin Tablets for adults and children over 8 years is 1-2 g daily in divided doses i.e. two tablets twice a day or two tablets four times a day, taken just before or with meals or food. If you have a bad infection you may be told to take up to 4 g (16 tablets) daily.

If you are not sure about the dose you or your child should be taking or if your dose is different to that recommended in this leaflet, speak to your doctor if you have not already done so.

Use in children under 8 years of age

Erythromycin 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 Erythromycin Tablets than you should

If you or your children 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, seek medical advice urgently. An overdose of Erythromycin Tablets could cause temporary hearing loss, nausea, vomiting and diarrhoea.

If you forget to take Erythromycin Tablets

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

If you stop using Erythromycin Tablets

Ask your doctor before stopping treatment with Erythromycin Tablets. Do not stop taking Erythromycin 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;
- 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.

Other side effects of Erythromycin Tablets are included below with the following frequency:

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);
- irritability and vomiting in a feeding infant due to narrowing of outlet of stomach (pyloric stenosis);
- increase in a particular type of white blood cells (eosinophilia);
- ringing in the ears (tinnitus);
- reversible loss of hearing (usually associated with high doses or in patients with kidney problems);
- disturbance in vision (double vision, blurred vision);
- 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;
- chest pains;
- abnormal heart rhythms (including palpitations, a faster heart beat, a life-threatening irregular heart beat or abnormal ECG heart tracing);
- 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);
- abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis);
- inflammation of the kidneys (a condition known as tubulointerstitial nephritis);
- low blood pressure;
- itching or hives;
- 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).

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 HPRÁ Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store Erythromycin 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 and carton. 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 in order to protect from light.

If your doctor decides to stop your treatment with Erythromycin 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 Erythromycin Tablets contain

- The active substance is erythromycin. Each tablet contains 250 mg erythromycin.
- The other ingredients are carmellose sodium, cellulose microcrystalline, povidone, polacrillin potassium, talc, magnesium stearate, hypromellose, hydroxypropylcellulose, propylene glycol, sorbitan oleate, methacrylic acid - ethyl acrylate copolymer, titanium dioxide, triethyl citrate and antifoam emulsion.

What Erythromycin Tablets look like and the contents of the pack

Erythromycin Tablets are white tablets with the letter 'T' embossed on one side.

Erythromycin Tablets are available in cartons containing 28, 40 and 56 tablets, in glass bottles containing 100 tablets and in polypropylene bottles containing 50, 100, 500 and 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Amdipharm Limited
Temple Chambers
3 Burlington Road
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Manufacturer

Aesica Queenborough Limited
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