

PACKAGE LEAFLET

Package leaflet: Information for the user

Erythromycin 250mg Gastro-resistant 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The Erythromycin 250mg Gastro-resistant Tablets will be referred to as Erythromycin Tablets throughout this leaflet.

What is in this leaflet:

1. What Erythromycin Tablets is and what it is 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 is and what it is used for

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

Do not take Erythromycin Tablets:

- if you are allergic (hypersensitive) 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 pimozone 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);
- ivabradine (heart medicine used for chest pain)
- tolterodine (used for treating overactive bladder with symptoms of urinary frequency, urgency, and leakage)
- 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”.
- 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.

Warnings and precautions

Talk to your doctor or pharmacist 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 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 Erythromycin 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));
- 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;
- 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.

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 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);
- 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 test, tell your doctor that you are taking Erythromycin as this may interfere with some test results.

Pregnancy, breast-feeding and fertility

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

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 erythromycin 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 erythromycin film-coated tablet use in early pregnancy.

Driving and using machines

None reported

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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.

For **oral use** only. Swallow whole with a glass of water. Do not crush or chew.

The recommended dose of Erythromycin 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 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.

Use in children (below 8 years)

For younger children, infants and babies, 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 Erythromycin 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 Erythromycin Tablets could cause temporary hearing loss, nausea, vomiting and diarrhoea.

If you forget to take Erythromycin 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone 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 Erythromycin tablets include:

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

- inflammation (swelling, irritation) of the large intestine (Pseudomembranous colitis)

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 Yellow Card Scheme at 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 Erythromycin tablets

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

Do not store Erythromycin Tablets above 25°C. Store in the original package and keep the container tightly closed.

Do not use this medicine after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of that month.

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, 250mg per tablet.

The **other** ingredients are Maize starch, Croscarmellose sodium Type A, Povidone, Talc, Magnesium stearate (E572), Hypromellose (E464), Macrogol 6000, Erythrosine (E127), Methacrylic acid ethylacrylate copolymer (1:1) and Polysorbate 80 (E433).

What Erythromycin Tablets look like and contents of the pack

The tablets are reddish-orange biconvex, coated tablets.

They are available in containers of 500 tablets, and also in blister packs of 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised on **10/2023**.