

Package leaflet: Information for the user

ERYTHROMYCIN TABLETS BP 250 mg (Erythromycin)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 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 effect not listed in this leaflet. See section 4.

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

The name of your medicine is Erythromycin Tablets BP 250 mg (referred to as Erythromycin Tablets in this leaflet). Erythromycin Tablets contain 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 to Erythromycin Tablets or any of the other ingredients of this medicine (listed in section 6).
- if you are currently taking a medicine called
- 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.

- ergotamine or dihydroergotamine (used to treat migraines) as this may cause serious side effects while taking erythromycin.
- astemizole, terfenadine or mizolastine (widely taken for allergies and hay fever), 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 of heart rhythm. Consult your doctor for advice on alternative medicines you can take instead.
- you have abnormally low levels of potassium or magnesium in your blood (hypomagnesaemia or hypokalaemia).
- 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".
- simvastatin (used to lower cholesterol and triglycerides (types of fat)) in the blood.
- tolterodine (used for treating an overactive bladder with symptoms of urinary frequency, urgency and leakage).

Warnings and precautions

Talk to your doctor before taking Erythromycin Tablets if you

- have any liver problems or are taking any medicines which you have been told 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 doctor 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.

Children

Erythromycin Tablets are not for use in children under 8 years. Ask your doctor or pharmacist for advice before taking Erythromycin Tablets.

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 and herbal medicines.

This is especially important if you are taking medicines called:

- astemizole, terfenadine or mizolastine (used to treat allergies such as hay fever),
- 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 infection),
- digoxin, disopyramide or quinidine (used to treat heart problems),
- cilostazol (a medicine used to treat peripheral circulation problems),
- hexobarbitone, phenobarbitone 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 relieves 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 Erythromycin 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 Erythromycin 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 Erythromycin Tablets use in early pregnancy.

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

Erythromycin Tablets contain Sunset Yellow E110 and Ponceau Red E124

Erythromycin Tablets contain Sunset Yellow E110 and Ponceau Red E124 which may cause allergic reactions.

Driving and using machines

None reported

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.

The recommended dose is

For adults and children over 8 years:

One (250 mg) tablet every 4 to 6 hours.

If you have a bad infection you may be told to take up to 4 g (16 tablets) daily.

Use in children

Erythromycin Tablets are not for use in children under 8 years.

If you take more Erythromycin Tablets than you should

If you realize you have taken more Erythromycin Tablets than your doctor has recommended (or if someone else has taken some of your Erythromycin Tablets), contact your doctor right away. If you cannot reach your doctor, go to the nearest hospital and take the pack with you.

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, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for the forgotten dose.

If you stop taking Erythromycin Tablets

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 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 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

- diarrhoea which may be severe or prolonged and may contain blood or mucus
- 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)
- various liver or gall-bladder problems, which can cause yellowing of the skin and/or eyes (jaundice) or pale stools with dark urine.
- a life-threatening irregular heart beat **called torsades de pointes** or abnormal ECG heart tracing) or heart stopping (cardiac arrest),

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-:

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 pain,
- fever,
- abnormal heart rhythms (including palpitations, a faster heartbeat)
- confusion,
- Anorexia,
- fits (seizures),
- vertigo (problems with balance that can result in feelings of dizziness or sickness – particularly on standing),
- hallucinations (seeing or hearing things that are not there),
- feeling generally unwell (malaise),
- inflammation of the kidneys (a condition known as interstitial nephritis),
- low blood pressure,
- 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 at: 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 above 25°C. Store in the original package.

Do not use this medicine after the expiry date which is stated on the carton and the blister 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.

If your tablets become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Erythromycin Tablets contain

Each Erythromycin Tablet contains 250 mg of the active ingredient erythromycin.

The other ingredients are maize starch, croscarmellose sodium, povidone, talc, magnesium stearate, hypromellose 6cP, titanium dioxide (E171), triacetin, methacrylic acid copolymer, talc, triethyl citrate, colloidal anhydrous silica, sodium bicarbonate, sodium lauryl sulphate, sunset yellow (E110) and ponceau red (E124).

What Erythromycin Tablets look like and the contents of the pack

Erythromycin Tablets are red coloured, round, biconvex, enteric-coated tablets.

They are available in blister packs containing 28, 56, 84 and 100 tablets or in containers of 21, 100, 250, 500 and 1000 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sovereign Medical, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, UK

Manufacturer

Waymade Plc, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, UK

This leaflet was last revised in: December 2025

PL 06464/1422 Erythromycin Tablets BP 250 mg

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