



PACKAGE LEAFLET: INFORMATION FOR THE USER

Erythromycin Tablets 250 mg (erythromycin)

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

- 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.

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
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1. WHAT ERYTHROMYCIN TABLETS ARE AND WHAT THEY ARE USED FOR

Erythromycin is an antibiotic for the treatment and prevention of infections caused by erythromycin-sensitive organisms, such as:

- Upper and lower respiratory tract infections
- Eye, ear infections
- Oral infections
- Skin and soft tissue infections
- Gastrointestinal infections.
- Prophylaxis pre- and post- operative trauma, burns, rheumatic fever
- Other infections: osteomyelitis, urethritis, gonorrhoea, syphilis, lymphogranuloma venereum, diphtheria, prostatitis, 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 in the product (see Section 6 'What Erythromycin Tablets contain's')
- Taking simvastatin, tolterodine, mizolastine, amisulpiride, astemizole, terfenadine, domperidone, cisapride or pimozone, ergotamine and dihydroergotamine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Erythromycin Tablets

- Kidney problem, Liver disease
- Myasthenia gravis (a muscle disorder)
- irregular heart rhythm
- a condition called porphyria
- have previously experienced diarrhoea following the use of antibiotics

- are treating a young child with antibiotics and they are irritable or vomit when fed, you should contact your physician immediately.
- 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 body. Consult your doctor before receiving erythromycin. Alternatively if you were treated for early stages of syphilis during your pregnancy, and child is under 1 year and is prescribed erythromycin, consult your doctor before giving erythromycin to your child.
- are taking erythromycin with 'statins' such as simvastatin or lovastatin (used to lower cholesterol) as serious side effects can occur.

Other medicines and Erythromycin Tablets

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

- warfarin (thins the blood)
- cisapride (used for stomach disorders)
- pimozone (used in the treatment of psychiatric disorders)
- clarithromycin (antibiotic used to treat certain infections)
- ergotamine or dihydroergotamine (for migraine)
- theophylline (helps breathing)
- cilostazol (for blood circulation problems)
- rifabutin (for tuberculosis)
- sildenafil (for erectile dysfunction)
- vinblastine (for cancer)
- antifungals e.g. fluconazole, ketoconazole and itraconazole
- colchicine (for gout)
- Other drug interactions include: bromocriptine (used to treat Parkinson's disease), digoxin or disopyramide or quinidine (all heart drugs), hexobarbitone, midazolam (used as a sedative), cyclosporin or tacrolimus (used following organ transplants), alfentanil, zopiclone or triazolam (induces sleep)
Phenytoin or carbamazepine, valproate (drugs for epilepsy), lovastatin (a cholesterol lowering agent), your doctor should monitor you appropriately and may adjust your dosage of erythromycin as necessary.

Do not take simvastatin, tolterodine, mizolastine, amisulpride, terfenadine, domperidone or astemizole (for the treatment of hayfever and other allergies) if you have been prescribed Erythromycin ethylsuccinate granules for oral suspension.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant or planning to become pregnant. Erythromycin has been reported to cross the placental barrier.

Erythromycin passes into breast milk.

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant and treated with an oral erythromycin tablets for early syphilis, Please consult your doctor as erythromycin may not be effective in preventing infection to the baby.

Driving and using machines

Erythromycin Tablets are not expected to affect your ability to drive or operate machinery.

3. HOW TO TAKE ERYTHROMYCIN TABLETS

- Always take these tablets exactly as advised by your doctor. You should check with your doctor or pharmacist if you are not sure.
- The dosage and duration of treatment will depend on the type and severity of the infection.
- Swallow the tablets whole with a glass of water.

The usual dose of Erythromycin 250mg tablets for adults and children over 8 years is: 1-2g daily in divided doses i. e. four to eight 250mg tablets daily taken just before or with meals or food. If you have a bad infection you may be told to take up to 4g daily.

If you take more Erythromycin Tablets than you should

If you or a child accidentally takes too much medicine, contact your doctor or nearest hospital emergency department immediately. Take this leaflet, the box and any tablets remaining with you, if possible. **Symptoms** of overdose include nausea, vomiting and diarrhoea and loss of hearing.

If you forget to take Erythromycin Tablets

If you miss a dose, take the tablets as soon as you remember and carry on as before. If it is almost time for your next dose, skip the missed dose and continue as usual (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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Erythromycin may sometimes cause side effects, although not everybody gets them.

STOP taking this medicine and **seek medical help IMMEDIATELY** if you experience any of the following reactions:

- a allergic reaction causing difficulty in breathing and swelling of certain parts of your body, including the face and neck.

Other side effects which may occur are:

- increase number of eosinophils (white blood cells)
- irregular heartbeats, palpitations and ventricular tachyarrhythmias
- hearing loss (usually taking high doses)
- upper abdominal discomfort, nausea, vomiting, diarrhoea, pancreatitis, anorexia, infantile hypertrophic pyloric stenosis
- general symptoms such as chest pain, fever, malaise
- cholestatic hepatitis, jaundice, hepatic dysfunction, hepatic failure
- allergic reactions such as urticaria and mild skin eruption
- confusion, seizures and vertigo
- hallucinations (seeing or hearing things that are not real)
- interstitial nephritis
- hypotension (low blood pressure)

Reporting 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: 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 ERYTHROMYCIN TABLETS

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

Do not store above 25°C. Store in the original package and keep container tightly closed. Do not use the tablets after the expiry date is stated on the package.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to 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 looks like and contents of the pack

The tablets are reddish orange coloured, biconvex enteric/film-coated and round in shape. They are available in containers of 21, 100, 250, 500 and 1000 tablets as well as in blisters of 28, 56, 84, and 100 tablets. In addition bags of 5,000 and 10,000 tablets are also available(Not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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