



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. 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Erythromycin Tablets are and what they are used for
2. Before you take Erythromycin Tablets
3. How to take Erythromycin Tablets
4. Possible side effects
5. How to store 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. 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')

Take special care with Erythromycin Tablets

Speak to your doctor if you have:

- Kidney problem, Liver disease
- Myasthenia gravis (a muscle disorder)
- irregular heart rhythm
- a condition called porphyria

Taking other medicines

Please inform your doctor if you are taking or have recently taken any other medicines, including those obtained without a prescription, particularly:

- Warfarin (thins the blood)
- Cisapride (used for stomach disorders)
- Pimozide (used in the treatment of psychiatric disorders)
- Clarithromycin (antibiotic used to treat certain infections)
- Ergotamine or dihydroergotamine (for migraine)
- Zopiclone (induces sleep)
- Theophylline (helps breathing)
- Lovastatin (blood cholesterol lowering drugs)

Other drug interactions include: alfentanil, bromocriptine, carbamazepine, cyclosporin, digoxin, disopyramide, hexobarbitone, midazolam, phenytoin, quinidine, tacrolimus, triazolam, valproate. Your doctor should monitor you appropriately and may adjust your dosage of erythromycin as necessary.

DO NOT take simvastatin, tolterodine, mizolastine, amisulpride, terfenadine or astemizole if you have been prescribed erythromycin.

If you are asked to provide a urine test, tell your doctor that you are taking Erythromycin as it may interfere with some tests.

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 Erythromycin Tablets exactly as your doctor has told you. The pharmacist's label should tell you how much to take and how often.

For **oral use** only.

Adults: The usual dosage is one 250mg tablet every four to six hours, increased to 4g per day, if infection is very severe

Children: The usual regimen is 30mg/kg/day in divided doses. For more severe infections, this dosage should be 50mg/kg/day.

If administration on a twice daily schedule is desirable in adults or children, one half of the total daily dose may be given every 12 hours, one hour before meals. It is important that you complete your full course of antibiotics; do not stop taking the tablets early if you feel better.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Erythromycin Tablets can cause side effects, although not everyone gets them.

If you develop an allergic reaction, this may result in swelling of certain parts of your body, including the face and neck, accompanied by difficulty in breathing. If this happens to you, stop taking the tablets and seek urgent medical help.

The following have also been reported:

- Nausea, vomiting and diarrhoea
- Hearing loss
- Liver problems, accompanied with or without jaundice (yellowing of the skin and whites of eyes).
- Abdominal discomfort.
- Anaphylaxis (sudden, severe allergic reaction)
- Erythema multiforme, (a red rash caused by hypersensitivity to a drug or disease or other allergen)
- Stevens-Johnson syndrome (A severe inflammatory eruption of the skin and mucous membranes)
- Damage to the blood, kidneys or central nervous system
- Cardiac arrhythmia (an abnormal rate of muscle contractions in the heart)
- Toxic epidermal necrolysis (large portion of the skin becomes intensely red and peels off)
- Chest pain, Dizziness and Palpitations (irregular, hard, or rapid heartbeat)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ERYTHROMYCIN TABLETS

Keep out of the reach and sight 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. FURTHER 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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