

Patient Information leaflet (PIL)**1. Product Name:** Erythromycin Tablets BP 250 mg**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, health care provider 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, health care provider 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****6. Further information****a) What Erythromycin Tablets are and what they are used for**

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.

b) Before you take Erythromycin Tablets

- if you are allergic to erythromycin or any of the other ingredients of this medicine
- 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 pimozide 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).
 - tolterodine (used for treating overactive bladder with symptoms of urinary frequency, urgency, and leakage)
 - 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
- 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”.

Warnings and precautions

Talk to your doctor or pharmacist before taking Erythromycin Stearate 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 Stearate Tablets

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

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 <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 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 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 tests, tell your doctor that you are taking Erythromycin Stearate 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 Stearate film-coated tablet 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.

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

Driving and using machines

None reported

Erythromycin contains sorbic acid which may cause local skin reactions, (e.g. contact dermatitis).

c) 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:

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 or two to four 500 mg tablets daily, taken just before or with meals or food. If you have a severe infection you may be told to take up to 4 g daily.

- Use in children (below 8 years)

For younger children, infants and babies, Erythroped, 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 500mg 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 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.

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 product ask your doctor or pharmacist.

d) 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;
- 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 Erythrocin 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 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).

e) How to store Erythromycin tablets

Store below 30°C, and dry place. Protect from light

“Keep all medicines out of reach of children”

Do not use these medicines after the expiry date which is stated on the blister/label after EXP.

The expiry date refers to the last day of that month.

f) Further information**What Erythromycin Tablets contains**

- The active substances are of erythromycin as erythromycin stearate.

Each Film coated tablet contains: Erythromycin BP equivalent to

Erythromycin 250 mg

- The other ingredients are:

MILAN LABORATORIES (INDIA) PVT. LTD.

Erythromycin Stearate Tablets BP 250 mg



Dummy Granules, Sodium starch glycolate, Purified Talc (Talc), Magnesium Stearate, Colour Wincoat WT-AQ 1163 PINK, Polyethylene Glycol-6000

What Erythromycin Tablets looks like and contents of the pack

Erythromycin Pink coloured, film coated caplet plain on one side and breakline on other side.

PRESENTATION:

Blister Pack:

Alu-PVC Blister of 10 x10 Tablets packed in a carton along with the pack Insert.

Bulk Pack:

1000 Tablets in P.P. Bag packed in a HDPE Container.

Marketing Authorisation Holder and Manufacturing Site Addresses

MILAN LABORATORIES (INDIA) PVT. LTD.

Plot Nos. 35,36, 63, 64, 65, 67 & 87

Jawahar CO-OP Industrial Estate Ltd.,

Kamothe, Raigad 410209 Maharashtra State,

India.