

PATIENT INFORMATION LEAFLET:

Erythroren Tablets

Erythromycin Stearate BP equivalent to Erythromycin 250 mg

Read all of this leaflet carefully before you start giving 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, health care worker or pharmacist.
- Do not pass it on to others. It may harm them, even if their symptoms are the same.
- 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 worker or pharmacist

In this leaflet:

- a. What Erythroren Tablets is and what they are used for
- b. What you need to know before you take Erythroren Tablets
- c. How to take Erythroren Tablets
- d. Possible side effects
- e. How to store Erythroren Tablets
- f. Further information

a. What Erythroren Tablets Are and what they are used for

Erythroren Tablets contains the active ingredient Erythromycin Stearate BP equivalent to Erythromycin 250 mg which belongs to a group of medicines called macrolide antibiotics. Erythroren tablets are used to prevent and treat infections such as:

1. Upper Respiratory Tract infections: tonsillitis, peritonsillar abscess, pharyngitis, laryngitis, sinusitis, secondary infections in influenza and common colds
2. Lower Respiratory Tract infections: tracheitis, acute and chronic bronchitis, pneumonia (lobar pneumonia, bronchopneumonia, primary atypical pneumonia), bronchiectasis, Legionnaire's disease
3. Ear infection: otitis media and otitis externa, mastoiditis
4. Oral infections: gingivitis, Vincent's angina
5. Eye infections: blepharitis
6. Skin and soft tissue infections: boils and carbuncles, paronychia, abscesses, pustular acne, impetigo, cellulitis, erysipelas.
7. Gastrointestinal infections: cholecystitis, staphylococcal enterocolitis
8. Prophylaxis: pre- and post- operative trauma, burns, rheumatic fever
9. Other infections: osteomyelitis, urethritis, gonorrhoea, syphilis, lymphogranuloma venereum, diphtheria, prostatitis, scarlet fever

b. What you need to know before you take Erythroren

Do not take Erythroren Tablets:

- if you are allergic to erythromycin or other macrolide antibiotics such as clarithromycin or azithromycin or any of the other ingredients of this medicine (listed in section f).
- 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 (widely taken for hayfever and allergies), cisapride (for stomach disorders) or pimozide (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;
 - domperidone (used to treat nausea (feeling sick) and vomiting (being sick));
 - lovastatin or simvastatin (used to lower cholesterol levels) as abnormal muscle breakdown leading to kidney problems (rhabdomyolysis) can occur

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Erythroren 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 are treating a young child with antibiotics and they are irritable or vomit when fed, you should contact your physician immediately;
- if you suffer from a condition called myasthenia gravis, which causes muscle weakness, consult your doctor before receiving erythromycin;
- if you are using erythromycin for a long period of time;
- if you suffer from a genetic problem that interferes with the metabolism of mitochondria (Leber's hereditary optic neuropathy or autosomal dominant optic atrophy);
- if you have heart problems such as an abnormal ECG heart tracing (prolonged QT interval) or a slow heart beat (bradycardia);
- if you are receiving drugs to treat heart problems;

- if you have uncorrected hypokalaemia or hypomagnesaemia (low blood levels of potassium or magnesium, which can cause muscle weakness, twitching or abnormal heart rhythm);
- if you are elderly;
- if you are about to undergo laboratory tests for signs of pheochromocytoma (a rare tumour of the adrenal glands) as erythromycin may interfere with the test results.

Children under 8 years of age

Erythroren Tablets are not recommended for use in children less than 8 years of age.

Other medicines and Erythroren Tablets

Tell your doctor 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 the following medicines or 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));
- 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);
- beta-lactam antibiotics (used to treat bacterial infections, e.g. penicillin and cephalosporin);
- protease inhibitors (used to treat viral infections, e.g. saquinavir);
- oral contraceptives.

This is also important if you are taking medicines called:

- colchicine (used to treat gout and arthritis);
- cimetidine and omeprazole (used to treat acid reflux and other related conditions);
- clindamycin, lincomycin, chloramphenicol, streptomycin, tetracyclines, colistin, rifabutin, or rifampicin (used to treat different types of bacterial infection);
- fluconazole, ketoconazole and itraconazole (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);
- zopiclone or triazolam/alprazolam (used to help you sleep or relieve states of anxiety);
- warfarin and acenocoumarol (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);
- alfentanil (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).

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 Erythroren Tablets may cross the placenta in pregnant women and is excreted in breast milk.

Erythromycin should be used by women during pregnancy or while breast-feeding only if clearly needed.

c. How to take Erythroren Tablets

In streptococcal infections, erythromycin stearate should be administered at therapeutic dosage for at least 10 days. For continuous prophylaxis of streptococcal infections or rheumatic fever recurrences in persons with a history of rheumatic heart disease, the dose is 250 mg twice a day.

When used prior to surgery to prevent endocarditis: a recommended schedule for adults is 1 g before the procedure and 500 mg every 6 hours for 8 doses after the procedure.

Treatment of primary syphilis: 2 - 4 grams per day given in divided doses over a period of 10 to 15 days.

Treatment of gonorrhoea: 500 mg four times daily for 5 days.

Posology and mode of administration: In order to obtain optimal blood levels, Erythromycin should be given on an empty stomach.

Dosage:

For Adults: 250 mg to 500mg every 6 hours depending on the severity of the infection. For Children: The basic recommendation ranges from 30 to 50 mg /kg/day or more. Depending on the severity of the infections; these amounts are administered in four divided dose Erythromycin is primarily a bacteriostatic antibiotic with a broad spectrum of action, which was recommended in the treatment of a wide variety of infections caused by susceptible organisms.

It has been used in cases such as: bronchitis, gastroenteritis Campylobacter severe diphtheria, Legionnaires' disease Legionella and other infections, neonatal conjunctivitis, pertussis, pneumonia, sinusitis and in combination with neomycin.

Erythromycin can be administered in lieu of penicillin in patients allergic to penicillin with a variety of conditions including coal, prophylaxis of endocarditis, leptospirosis, otitis media (usually with a sulphonylurea such as sulfisoxazole), pharyngitis and prevention of rheumatic fever and skin infections, staphylococcus and streptococcus.

If you forget to take Erythroren Tablets

If you forget to take a tablet, take it as soon as you remember. Do not take a double dose to make for a forgotten dose.

If you stop using Erythroren Tablets

Ask your doctor before stopping treatment with Erythroren Tablets. Do not stop taking Erythroren Tablets just because 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, pharmacist or nurse.

d. Possible side effects

Blood and lymphatic system disorders: Eosinophilia. Cardiac disorders QTc interval prolongation, torsades de pointes, palpitations, and cardiac rhythm disorders including ventricular tachyarrhythmias. Gastrointestinal disorders the most frequent side effects of oral erythromycin preparations are gastrointestinal and are dose related. The following have been reported: upper abdominal discomfort, nausea, vomiting, diarrhoea, pancreatitis, anorexia, infantile hypertrophic pyloric stenosis. Pseudomembranous colitis has been rarely reported in association with erythromycin therapy. General disorders and administration site conditions. Chest pain, fever, malaise. Hepatobiliary disorders Cholestatic hepatitis, jaundice, hepatic dysfunction, hepatomegaly, hepatic failure, hepatocellular hepatitis. Immune system disorders Allergic reactions ranging from urticaria and mild skin eruptions to anaphylaxis have occurred. Investigations Increased liver enzyme values. Nervous system disorders: There have been isolated reports of transient central nervous system side effects including confusion, seizures and vertigo; however, a cause and effect relationship has not been established. Psychiatric disorders Hallucinations Renal and urinary disorders Interstitial nephritis Skin and subcutaneous tissue disorders Skin eruptions, pruritus, urticaria, exanthema, angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme. Vascular disorders, Hypotension.

e. How to store Erythroren Tablets

Do not store above 30⁰ C. Protect from light and Keep out of reach of children

Do not use this medicine after the expiry date which is stated on the label. 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.

f. Contents of the pack and other information**What Erythroren Tablets contain:**

Each film coated tablet contains Erythromycin Stearate BP equivalent to Erythromycin 250 mg
The other ingredients are Maize starch, Sodium starch glycollate, Microcrystalline cellulose, Magnesium stearate.

What Erythroren Tablets looks like and contents of the pack:

Pink coloured round biconvex film coated tablets plain on both sides

Aluminium/PVC blister strip of 10 tablets, 10 of such blister strips are packed in a unit box with pack insert.

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