

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Erythromycin Stearate Tablets BP 250mg

ERYTHROKANT-250

Read all of this leaflet carefully before you starts 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:

- 1. What Erythromycin Stearate Tablets BP 250mg are and what they are used for**
- 2. What you need to know before you take Erythromycin Stearate Tablets BP 250mg**
- 3. How to take Erythromycin Stearate Tablets BP 250mg**
- 4. Possible side effects**
- 5. How to store your Erythromycin Stearate Tablets BP 250mg**
- 6. Contents of the pack and other information**

1. What Erythromycin Stearate Tablets BP 250 mg Are and what they are used for

Erythromycin Stearate Tablets BP 250 mg contains the active ingredient erythromycin which belongs to a group of medicines called macrolide antibiotics. Erythromycin Stearate Tablets BP 250 mg 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

2. What you need to know before you take Erythromycin Stearate Tablets BP 250 mg

You should not receive Erythromycin Stearate Tablets BP 250mg if you:

- have been told that you are allergic to erythromycin or other macrolide antibiotics such as clarithromycin or azithromycin or any of the other ingredients in these tablets;
- are currently taking a medicine called- are taking ergotamine or dihydroergotamine (used to treat migraines) while taking erythromycin as this may cause serious side effects;- are taking 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 pimozone 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);
- are taking colchicine (used for treatment of gout and arthritis) whilst taking erythromycin as this may cause serious side effects;
- have any liver problems or have been told that any drugs you are taking 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 physician 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.If any of these apply to you, or if you are not sure, tell your doctor.Taking other medicinesPlease tell your doctor if you are taking, or have recently taken any other medicines, including any medicines obtained without a prescription.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. 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);
- 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);
- 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);
- 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). If you or your child goes for any medical tests, tell your doctor that you are taking Erythromycin Stearate Tablets BP 250mg, as this may interfere with some test results

3. How to take Erythromycin Stearate Tablets BP 250mg

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 (see hemolytic streptococcus) 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.

Mode Of Administration: Oral.

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.

4. 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.

5. How to store Erythromycin Stearate Tablets BP 250mg

Store below 30°C, in a dry place.

Protect from light.

Keep the medicine 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.

6. Contents of the pack and other information

What Erythromycin Stearate Tablets BP 250mg contain:

Each tablet contains Erythromycin Stearate BP equivalent to Erythromycin 250mg. The other ingredients are Maize Starch BP, Colloidal Anhydrous Silica BP, Sodium Starch Glycolate BP, Croscarmellose Sodium BP, Purified Talc BP, Purified Water BP, Coating Ready mix pink (Wincoat WT- 1683 pink/Instacoat Sol -A04R00161-pink) IHS, Isopropyl Alcohol BP, Dichloromethane BP

What Erythromycin Stearate Tablets BP 250mg looks like and contents of the pack:

Erythromycin Stearate Tablets BP 250mg are Pink coloured, circular, film coated biconvex tablet having central breakline on one side and plain on other side.

They are packaged in blister packs 10 tablets , 10 blisters packed in a printed carton with a printed insert.

1000 tablets packed in HDPE jar

Manufactured by:



1802-1805, G.I.D.C., Phase III,

Vapi - 396 195. Gujarat, INDIA.