

PACKAGE LEAFLET: INFORMATION FOR THE USER

ERYTHROMYCIN TABLETS BP

250 mg

Erythromycin

Read all of this leaflet carefully before you start taking 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, nurse or pharmacist.
- auctor, nurse 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,
- pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4. What is in this leaflet:
- hat is in this leaflet: What Erythromycin Tablets are and what they are used for What you need to know before you take Erythromycin Tablets How to take Erythromycin Tablets Possible side effects
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- How to store Erythromycin Tablets Contents of the pack and other information 5. 6.

1. What Erythromycin Tablets are and what they are used for Erythromycin belongs to the group of medicines known as antibiotics.

Erythromycin is used to treat bacterial infections causing infections of the ear, nose, mouth, throat, gut and chest. It can be used to treat skin infections including burns and to treat urinary infections and sexually transmitted infections. It may be used before or after operations to prevent infection

2. What you need to know before you take Erythromycin Tablets

Do not take Erythromycin Tablets and tell your doctor if you:

- octor if you: are hypersensitive (allergic) to erythromycin or any of the other ingredients in this medicine (See section 6. Further information) are taking terfenadine or astemizole (widely taken for hayfever and allergies), cisapide (for stomach disorders) or pimozide (for psychiatric conditions) while receiving erythromycin, as combining these drugs can sometimes cause serious disturbances in heart thythm. Consult your doctor for advice on alternative medicines you can take instead:
- your doctor for advice on alternative medicines you can take instead; have abnormally low levels of potassium or magnesium in your blood (hypomagnesaemia or hypokalaemia) 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". are taking medicines known as ergot derivatives which are used to freat migraine and speed up labour (e.g. ergotamine, dihydroergotamine and Methysergide) arrinos and precautions

- dihydroergotamine and Methysergide) Warnings and precautions Taik to your doctor, pharmacist or nurse before taking this medicine if you: suffer from liver disease; your doctor may want to monitor your liver during treatment have myasthenia gravis (muscle condition causing weakness) as erythromycin may aggravate your condition are taking other medicines which are known to cause serious disturbances in heart rhythm have heart prohlems
- have heart problems are treating a young child with antibiotics and they are irritable or vomit when fed.

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medicine as it may cause serious side effects are taking 'statins' such as simvastatin or lovastatin (used to lower cholesterol) as serious side effects may occur.

Other medicines and Erythromycin tablets Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any medicines obtained without a prescription.

Especially:

- 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)

- principide (used to treat mental problems) simvastatin tolterodine ergotamine or dihydroergotamine (used to relieve migraine) cisapride (used to treat stomach problems) statins (used to lower cholesterol levels) e.g simvaststin or lovastatin
- protease inhibitors (used to treat viral
- infections e.g. saquinavir) oral contraceptives.

- :

- oral contracéptivés.
 This is also important if you are taking the following medicines:
 colchicine (used to treat gout and arthritis)
 cimetidine and omeprazole (used to treat acid reflux and other related conditions)
 clarithromycin, rifabutino rrifampacin (used to treat different types of bacterial infection)
 fluconazole, ketaconazole and itraconazole (used to treat fungal infections)
 digoxin, quinidine or disopyramide (used to treat heart problems)
 clostazol (used to treat peripheral circulation problems)
- problems) hexobarbitone, Phenobarbital or midazolam

- hexobarbitone, Phenobarbital or midazolam (used as a sedative) anticoagulants e.g. warfarin, acenocoumarol and rivaroxaban (used to thin the blood) valporate, carbamazepine or phenytoin (used to control epilepsy) theophylline (used to treat asthma and other breathing problems) ciclosporin or tacrolimus (used after organ transplants)
- transplants) bromocriptine (use to treat Parkinson's disease) zopicione or triazolarn/alprazolarn (used to help you sleep or relieve states of anxiety) alfentaril (used for pair relief) methylprednisolone (used to suppress the

- methylprednisolone (used to suppress the body's immune system) 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); SI 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)

- cancer) sildenafil (used to treat erectile dysfunction) Hydroxychloroquine or chloroquine (used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria). Taking these medicines at the same time as erythromycin
- medicines at the same time as erythromycin may increase the chance of getting abnormal heart rhythms and other serious side effects that affect your heart. Iomitapide (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 oroblems. lead to liver problems.
- Whilst you are taking Erythromycin Tablets your doctor may occasionally check your liver function.
- If you are asked to provide a urine test, tell your doctor that you are taking Erythromycin as it may interfere with certain tests. Pregnancy and breast-feeding

Product

Buyer/Country

New Item Code

Colour Shades

Design/Style Substrate

Special Instructions

Autocartonator

Requirements

Dimension

Pregnancy and breast-feeding If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a bay, ask your doctor or pharmacist for advice before taking this medicine. The active ingredient of erythromycin tablets may cross the placenta in pregnant women and is excreted in breast mik. Information from studies regarding the risk of birth defects is inconsistent, but some studies have reported heart defects following erythromycin use in early pregnancy.

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ERYTHROMYCIN Tablets BP 250 mg Strides Pharma UK Ltd.

Front & Back Printing. To be supplied in the unfolded size

PRINTING CLARITY TO BE CLEAR AND SHARP.

FRONT SIZE

ARTWORK DETAIL LABEL

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.

150 x 310 mm

Component

Old Item Code

Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.

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

Severe skin disorders, which is blistering and

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).

Nausea (feeling sick), vomiting (being sick), stomach pain and discomfort which may occu at higher dose levels Liver problems which may have symptoms of

ther side effects ringing in the ears (tinnitus) Superinfections including colitis (with symptoms of severe diarrhoea) and stomach pain Confusion, hallucinations (seeing or hearing things that aren't there) fits, vertigo (feeling that the room is spinning) these may stop when the medication ceases Chest pain Feeling generally unwell (malaise) Fever

Fever Inflammation of the kidneys (a condition

Low blood pressure Increase in a particular type of white blood cells (cosinophilia) Reversible loss of hearing (usually associated with high doses or in patients with kidney

Anorexia Changes to the results of liver tests visual impairment/blurred vision (Mitochondrial optic neuropathy)

Reporting of side effects If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via the Vellow Card Scheme at: www.mhra govuk/yellowcard or search for MHRA Yellow Card in the Google Play

or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Erythromycin Tablets Keep out of the sight and reach of children

Keep the tablets in a cool, dry place away from direct light and heat, store below 25°C.

The task 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

Croscarmellose sodium, Povidone, Purified Talc and Magnesium Stearate.

Ingredients for Coating: Hypromeliose, Dispersed red lake 18152 (E110 and E124), polyethylene glycol 6000, Purified Talc, Polysorbate 80 and methacrylic acid – ethyl

What Erythromycin Tablets look like and contents of the pack Description: Reddish orange coloured, opaque

enteric coated round tablet. Contents of pack: Tablet container with polyethylene tamper evident seals Pack sizes: 21, 100, 200, 500 and 1000 tablets. Alu/PVC Bisters of 28, 56, 84 and 100 tablets.

This leaflet was last revised in February 2023.

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BACK SIZE

Marketing Authorisation Holder and Manufacturer Wanutacturer Strides Pharma UK Ltd. Unit 4, The Metro Centre, Dwight Road, Watford, WD18 9SS,

What Erythromycin Tablets contain The tablets contain 250mg of the active substance Erythromycin BP/Ph.Eur

The other ingredients are Maize starch

and E124), polyeur Talc, Polysorbate 80 acrylate Copolymer

United Kingdom

Do not use this medicine after the expiry date which is stated on the label. The expiry refers to the last day of that month.

known as interstitial nephritis)

jaundice (yellowing of the eyes and skin)

Rash which may be red or itchy

nay occur

painful Serious skin reaction: a red, scaly rash

The following side effects have also been

eported

Rarely

Less common:

Other side effects

problems)

Reporting of side effects

Driving and using machines Erythromycin tablets may cause dizziness, if you are affected do not drive or operate machines. Ervthromycin Tablets contain Sunset E124 and E110

E110 Erythromycin Tablets contain the colouring dispersed red lake which also contains sunset yellow (E124 and E110), these can cause hypersensitivity (allergic) reactions including asthma; this is more common in people allergic to aspirin. Do not take Erythromycin Tablets if you are allergic to sunset yellow or dispersed red lake.

Information on sodium content.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Erythromycin Tablets

Always take Erythromycin Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The tablets should be swallowed whole by mouth.

Adults and the Elderly:

Adults and the Elderly: The usual does is 250mg every 6 hours one hour before meals. However, your doctor may suggest a different dose. The dose may increas to 4000mg per day according to the severity of the condition.

Children:

Children: Your doctor will determine the correct dose to use which depends on the age and weight of your child and severity of the infection. The dose should be given 1 hour before meals. The usual dose is 30 – 50mg/kg/day in divided doseg given twice daily or every 6 hours. For more severe infections, this dosage may be doubled.

If you take more Erythromycin Tablets than you should

should If you accidently take too many Erythromycin Tablets tell your doctor at once. If you can't do this, go to the nearest hospital casually department. The symptoms of an overdose are nausea, vomiting (being sick) and diarrhoea. Take along any tablets that are left, the container and the label so that the hospital staff can easily tell what you have taken.

If you forget to take Erythromycin Tablets If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Erythromycin Tablets Even if your condition has improved it is important to complete the prescribed course of Erythromycia. If you stop taking this medicine too soon your infection may come back and could be more difficult to treat.

If you have any further questions on the use of this medicine, ask your doctor, or pharmacist or nurse.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them Stop taking this medicine and tell your doctor immediately if you have sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) as these may be signs of an allergic reaction.

Serious side effects

- If you develop any of the following side effects, contact your doctor immediately
 Abnormal heart rhythms (including liately: Abnormal near myuning including palpitations, a faster heartbeat, a life-threatening irregular heart beat called torsades de pointes or abnormal ECG heart tracing) or
- heart stopping (cardiac arrest); Increased risk of bleeding following drug interaction with Rivaroxaban

serious disorder (inflammation of the colon pancreatitis) Yellowing of the skin and eyes which may indicate a liver disorder

Pack

No. of Colours 1

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fits (seizures) Severe stomach pain and diarrhoea which Severe stormach pain and olarmoea which may be watery or bloody and high temperature (fever), as these may be symptoms of a serious disorder (inflammation of the colon or pagesericitie)

Pack Insert

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