



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.
This medicine has been prescribed for you only. Do not pass it on to others.
If you get any side effects, talk to your doctor, pharmacist or nurse.

What is in this leaflet:

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

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.

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

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

- are hypersensitive (allergic) to erythromycin or any of the other ingredients in this medicine
are taking terfenadine or astemizole
have taken or are taking other medicines for stomach disorders
have a history of heart rhythm disorders
are taking medicines known as ergot derivatives
are taking medicines known as ergot derivatives which are used to treat migraine

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking this medicine if you:

- suffer from liver disease
have myasthenia gravis
are pregnant and have been told that you have a sexually transmitted disease called syphilis
are taking other medicines which are known to cause serious disturbances in heart rhythm
are treating a young child with antibiotics
are taking medicines which are known to cause serious disturbances in heart rhythm

medicine as it may cause serious side effects are taking 'statins' such as simvastatin or lovastatin

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

Especially:

- astemizole, terfenadine or mizolastine
domperidone
clarithromycin, rifabutin or rifampicin
pimozide
simvastatin
tortolodine
ergotamine or dihydroergotamine
cisapride
statins
protease inhibitors
oral contraceptives

This is also important if you are taking the following medicines:

- colchicine
cimetidine and omeprazole
clarithromycin, rifabutin or rifampicin
fluconazole, ketoconazole and itraconazole
digoxin, quinidine or disopyramide
ciclosporin or tacrolimus
bromocriptine
zopiclone or trazolam/alprazolam
alfentanil
methylprednisolone
Corticosteroids
verapamil
vinblastine
sildenafil
Hydroxychloroquine or chloroquine

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

If you are pregnant or breast-feeding, think you might 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 tablets may cross the placenta in pregnant women and is excreted in breast milk.



FRONT SIZE

150 x 310 mm

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

Driving and using machines

Erythromycin tablets may cause dizziness, if you are affected do not drive or operate machines.

Erythromycin Tablets contain Sunset E124 and 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.

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.

Adults and the Elderly: The usual dose is 250mg every 6 hours one hour before meals. However, your doctor may suggest a different dose.

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.

If you take more Erythromycin Tablets than you should

If you accidentally take too many Erythromycin Tablets tell your doctor at once. If you can't do this, go to the nearest hospital casualty department.

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.

If you stop taking Erythromycin Tablets

Even if your condition has improved it is important to complete the prescribed course of Erythromycin.

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
Increased risk of bleeding following drug interaction with Rivaroxaban
fits (seizures)
Severe stomach pain and diarrhoea which may be watery or bloody and high temperature (fever), as these may be symptoms of a serious disorder (inflammation of the colon or pancreatitis)
Yellowing of the skin and eyes which may indicate a liver disorder

- Severe skin disorders, which is blistering and painful
Serious skin reaction: a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis).

The following side effects have also been reported:

- Nausea (feeling sick), vomiting (being sick), stomach pain and discomfort which may occur at higher dose levels
Liver problems which may have symptoms of jaundice (yellowing of the eyes and skin)

- Rash which may be red or itchy

Other side effects

- ringing in the ears (tinnitus)
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
Inflammation of the kidneys (a condition known as interstitial nephritis)
Low blood pressure
Increase in a particular type of white blood cells (eosinophilia)
Reversible loss of hearing (usually associated with high doses or in patients with kidney problems)
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.

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.

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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

6. Contents of the pack and other information

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

The other ingredients are Maize starch, Croscarmellose sodium, Povidone, Purified Talc and Magnesium Stearate.

Ingredients for Coating: Hypromellose, Dispersed red lake 18152 (E110 and E124), polyethylene glycol 6000, Purified Talc, Polyborate 80 and methacrylic acid - ethyl acrylate Copolymer.

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 Blisters of 28, 56, 84 and 100 tablets.

Marketing Authorisation Holder and Manufacturer

Strides Pharma UK Ltd. Unit 4, The Metro Centre, Dwight Road, Watford, WD18 9SS, United Kingdom

This leaflet was last revised in February 2023.



BACK SIZE

150 x 310 mm

ARTWORK DETAIL LABEL

Table with 4 columns: Product, Buyer/Country, Dimension, New Item Code, Colour Shades. Product: ERYTHROMYCIN Tablets BP 250 mg. Buyer/Country: Strides Pharma UK Ltd. Dimension: 150 x 310 mm. New Item Code: 1048425. Colour Shades: BLACK.

Table with 4 columns: Change Control No., Design/Style, Substrate, Special Instructions, Autocartanator Requirements. Change Control No.: PC-TSG/2023/031 - Record No.: 373669. Design/Style: Front & Back Printing. Substrate: 60 GSM Paper. Special Instructions: PRINTING CLARITY TO BE CLEAR AND SHARP. Autocartanator Requirements: Pack insert supply should be as per auto-cartanator.

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.