

i PACKAGE LEAFLET:
Information for the patient

ERITROMICINE

Tablets - 250 mg

(Erythromycin estolate)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor 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 becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Eritromicine is and what it is used for?
2. Before you take Eritromicine
3. How to take Eritromicine?
4. Possible side effects
5. How to store Eritromicine?
6. Further information

1. WHAT ERITROMICINE IS AND WHAT IT IS USED FOR?

Erythromycin is an antibiotic that belongs to a group of medicines called macrolides. These antibiotics act by killing or stopping the proliferation of bacteria that are causing the infection to you. Erythromycin, like other antibiotics, does not act on viral infections such as influenza.

Erythromycin is used for the treatment of infections in different parts of the body caused by bacteria, such as:

- alternative to penicillin in cases of hypersensitivity to penicillin;
- diptheria and pertussis;
- Legionnaires's disease;
- acute bronchitis (infection of bronchi which causes cough);
- pneumonia (lung infection characterized by fever, malaise, headache);
- campylobacter enteritis;
- non-gonococcal urethritis, chronic prostatitis;
- syphilis, acne vulgaris and rosacea.

Your doctor may have given you Eritromicine for another purpose. Ask your doctor if you want to know why you are given Eritromicine.

2. BEFORE YOU TAKE ERITROMICINE

Do not take Eritromicine if you:

- are allergic to erythromycin or to any other macrolide antibiotic such as: azithromycin, clarithromycin, roxithromycin;
- are allergic to any of the other ingredients mentioned in the end of this leaflet;
- have history of gastrointestinal disease;
- have severe problems with your liver or gall bladder;
- have hearing problems;
- have porphyria.

Eritromicine is contraindicated in patients who are taking astemizole, terfenadine, cisapride, pimozide, ergotamine or dihydroergotamine.

If you think that you have one of the above-mentioned states, do not take the tablets. Talk first with your doctor and follow his instructions.

Take special care with Eritromicine

Tell your doctor if you:

- are planning a pregnancy during the time that you are taking Eritromicine;
- are breastfeeding or planning to breastfeed;
- have or have ever had a health problem, especially the below ones:
 - impaired hepatic and biliary tract function because it increases the risk for hepatotoxicity (also if you use hepatotoxic drugs);
 - myasthenia gravis;
 - arrhythmias or a predisposition to QT interval prolongation.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tell your doctor if you are taking any of these drugs:

- theophylline, a drug used for the treatment of asthma;
- some medicines to treat migraine as ergotamine or dihydroergotamine (contraindicated);
- carbamazepine, a drug used for the treatment of epilepsy;
- terfenadine and astemizole, drugs used for the treatment of allergies (contraindicated);
- warfarin, a drug used to prevent blood clots;
- digoxin, a drug used for the treatment of heart failure;
- lovastatin, a drug that is used to reduce cholesterol;
- cyclosporin, a drug used to prevent transplant rejection or to treat certain problems of the immune system;
- cisapride, a drug used to treat gastrointestinal problems (contraindicated);
- pimozide, an antipsychotic drug (contraindicated);
- quetiapine;
- simvastatin;
- vinblastine;
- mizolastin.

Erythromycin may interact also with: alfentanil, bromocriptine, buspirone, clozapine, colchicin, disopyramid, midazolam, sildenafil, tacrolimus, sirolimus, valproate, calcium channel blockers, zopiclon, cilostazol.

These drugs may be affected by Eritromicine, or may affect on the way it acts. You may need to use different doses of this drug or take other drugs. Your doctor or pharmacist will advise you.

Taking Eritromicine with food and drinks

Food does not influence the absorption of erythromycin estolate.

Pregnancy

Tell your doctor or pharmacist if you are pregnant or planning to become pregnant.

Like most of the drugs of this kind, it is not recommended to use Eritromicine during pregnancy. Your doctor or pharmacist will discuss on the risks and benefits of its use during pregnancy.

Breastfeeding

Tell your doctor or pharmacist if you are breastfeeding. Erythromycin passes in breast milk. Your doctor or pharmacist will discuss on the risks and benefits of its use if you are breastfeeding or planning to breastfeed.

Driving and using machines

Be careful while driving and using machines until you see how Eritromicine affects you. Eritromicine may cause drowsiness or dizziness in some patients, especially after taking the first dose.

3. HOW TO TAKE ERITROMICINE

Always take Eritromicine tablets exactly as your doctor has told you. If you feel that the effects of Eritromicine are too strong or too weak, talk to your doctor or pharmacist. The tablets can be taken with or without food. It is better to take the tablets at the same time every day.

The recommended dose for adults and children over 8 years: 250 – 500 mg, every 6 hours or 0.5 – 1 g, every 12 hours; up to 4 g daily in severe infections.

The recommended dose for children up to 2 years: 125 mg, every 6 hours; 2 - 8 years: 250 mg, every 6 hours; the dose can be doubled in severe infections.

In early syphilis 500 mg 4 times daily for 14 days are used. Whereas in uncomplicated genital Chlamydia and non-gonococcal urethritis 500 mg twice daily for 14 days are used.

However, your doctor may advise you to take another dose depending on your condition and response to the drug.

Your doctor may ask you to take Eritromicine for a longer time. Ask your doctor for advice if you are not sure for how long you should take it. Erythromycin tablets should be swallowed whole with a full glass of water.

If you take more Eritromicine than you should

If you take more Eritromicine than you should, or if the children have been taking the medicine by accident, please contact your doctor, the hospital or call the emergency to get an opinion of the risk and advice on the actions to be taken.

If you forget to take Eritromicine

If you forget a dose, take the next dose when it is the normal time to take it.

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.

4. POSSIBLE SIDE EFFECTS

All medicines may cause side effects. Sometimes they are serious, sometimes not. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Inform your doctor if any of the following side effects bothers you:

- nausea, vomiting, diarrhea, (the gravity of these effects is dose-related);
 - dizziness and drowsiness;
 - allergic reactions – exanthema, urticaria;
 - reversible hearing loss after using high doses and in elderly patients or with renal and hepatic failure;
 - cholestatic jaundice if used longer than 14 days;
 - effects on the heart (including chest pain and arrhythmias);
 - Stevens – Johnson syndrome;
 - toxic epidermal necrolysis.
- If you notice side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ERITROMICINE

Keep out of the reach and sight of children. Do not use after the expiry date which is stated on the package. Do not store above 25°C.

6. FURTHER INFORMATION

What Eritromicine contains

The active substance is erythromycin estolate. Each tablet contains 360 mg erythromycin estolate equivalent to 250 mg erythromycin. The other ingredients: maize starch, gelatin, magnesium stearate, talc, sodium starch glycolate.

Contents of the pack

Box with 30 tablets.
Box with 50 tablets.

Explanatory of the illustration icons on the packaging:



Ask your doctor or pharmacist.



Content.



Warning.



Tablet shape.

Marketing authorisation holder (MAH) and manufacturer



PROFARMA Sh.a.
Rruga „Myslym Keta”
Tel.: 00355 4 23 89 602
Tirana – ALBANIA

This leaflet was last revised in April 2015.

