

PACKAGE LEAFLET: Information for the patient

ERITROMICINE

Film-coated 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;
- diphtheria 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 excipients 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;
- have abnormally low levels of potassium or magnesium in your blood (hypomagnesaemia or hypokalaemia);
- you 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”.

Eritromicine is also contraindicated in patients who are taking astemizole or terfenadine (widely taken for hayfever and allergies), cisapride (for stomach disorders), pimozide (for psychiatric conditions), ergotamine or dihydroergotamine, domperidone, simvastatin, tolterodine, mizolastine, amisulpride, as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines you can take instead.

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;
- are treating a young child with antibiotics and they are irritable or vomit when fed;
- are taking other medicines which are known to cause serious disturbances in heart rhythm;
- 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;
 - heart problems, arrhythmias or a predisposition to QT interval prolongation.
 - diarrhoea following the use of antibiotics.
- are taking other medicines which are known to cause serious disturbances in heart rhythm;
- have heart problems.

Eritromicine may affect the results of some laboratory tests. Consult your doctor before you undergo any type of test if you are taking Eritromicine.

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;
- domperidon, a drug used to treat vomiting and nausea (contraindicated);
- tolterodine, a drug used to treat the overactive bladder with symptoms such as: frequent and involuntary urination etc. (contraindicated);
- some medicines to treat migraine as ergotamine or dihydroergotamine (contraindicated);
- carbamazepine, a drug used for the treatment of epilepsy;
- terfenadine, astemizole or mizolastine, drugs used for the treatment of allergies (contraindicated);
- anticoagulants e.g. warfarin, acenocoumarol and rivaroxaban, drugs (used to thin the blood);
- digoxin, a drug used for the treatment of heart failure;
- 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 and amisulpride, antipsychotic drugs (contraindicated);

- quetiapine, an antipsychotic drug;
- simvastatin, a drug used to lower cholesterol (contraindicated); Eritromicine should also be used with caution with other statins such as lovastatin, atorvastatin, pravastatin, etc.;
- vinblastine, a drug that is used against cancer;
- HIV-protease inhibitors, drugs used to treat viral infections, particularly saquinavir, which is advised not to be used with Eritromicine;
- antifungals, azoles (e.g. fluconazole, ketoconazole, etc.).

Erythromycin may interact also with: opioids (such as: alfentanil, buprenorphine, oxycodone etc.), bromocriptine, buspirone, clozapine, colchicin, disopyramide, midazolam, alprazolam, phosphodiesterase type 5 inhibitors (sildenafil, avanafil, vardenafil etc.), tacrolimus, sirolimus, valproate, calcium channel blockers, zopiclone, cilostazol, oral contraceptives, corticosteroids (e.g. methylprednisolone), rifabutin, cimetidine.

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.

This list is not complete. There are also other drugs that may interact with erythromycin. Always consult your doctor before.

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 taken 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 medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

All medicines may cause side effects. Sometimes they are serious, sometimes not. Do not get 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), pancreatitis, anorexia, pseudomembranous colitis, infantile hypertrophic pyloric stenosis with symptoms such as: vomiting and irritability;
- dizziness and drowsiness, seizures, hallucinations;
- allergic reactions – exanthema, urticaria;
- ringing in the ears (tinnitus), reversible hearing loss after using high doses and in elderly patients or in those with renal and hepatic failure;
- cholestatic jaundice if used longer than 14 days, and other disorders such as: hepatomegaly (enlargement of the liver), hepatic failure etc.;
- increased liver enzyme values;
- vision impairment / blurred vision;
- renal inflammation (interstitial nephritis);
- increase of the number of a type of white blood cells (eosinophilia);
- fever, malaise;
- abnormal heart rhythms (including palpitations, a faster heartbeat, a life-threatening irregular heart beat called torsades de pointes or abnormal ECG heart tracing), heart stopping (cardiac arrest), hypotension;
- Stevens-Johnson syndrome;
- toxic epidermal necrolysis, erythema multiforme etc.

Contact a doctor immediately if you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). The frequency of this effect is not known (cannot be determined by the available data).

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 film-coated tablet contains 360 mg erythromycin estolate equivalent to 250 mg erythromycin.

The **excipients** are:

tablet core: maize starch, gelatin, magnesium stearate, talc, sodium starch glycolate;

film coat: polyvinyl alcohol, titanium dioxide, macrogol, talc.

Contents of the pack

Box with 30 or 50 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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