

ERITROMICIN HEMOFARM

250 mg Film-coated tablet

ERYTHROMYCIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 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 or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

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1. WHAT ERITROMICIN HEMOFARM IS AND WHAT IT IS USED FOR

ERITROMICIN HEMOFARM contains Erythromycin which belongs to a group of medicines called macrolide antibiotics. This medicine prevents the protein synthesis of bacteria by binding to the 50S ribosomal subunit and it has bacteriostatic effect on a large number of microorganisms.

It is used in the treatment of:

- pneumonia caused by atypical pathogens (*Mycoplasma pneumoniae*, *Legionella* and *Chlamydia*)
- streptococcal infections of the upper respiratory tract (inflammation of the middle ear, tonsils, pharynx and larynx) and lower respiratory tract (tracheitis, bronchitis, pneumonia),
- whooping cough and diphtheria,
- infections in people who are allergic to penicillin (pharyngitis, scarlet fever, erysipelas, bronchitis, pneumonia, staphylococcal skin infections and wounds, gonorrhea, syphilis)
- infections caused by chlamydia (inclusion conjunctivitis, second-line therapy for uncomplicated urethritis, endocervicitis, epididymitis, an infection of the prostate and the rectum)
- chlamydial infection during pregnancy
- inflammation of the stomach and small intestine
- streptococcal and staphylococcal infections of the skin and soft tissues

- Early stages of Lyme disease in patients with contraindications to penicillins and tetracyclines
- if tetracyclines are contraindicated or not tolerated by the patient, then erythromycin is used to treat inflammation of the urethra (caused by *U. urealyticum*)
- prophylaxis of bacterial endocarditis and rheumatic fever in patients allergic to penicillin,
- prevention of initial attacks of rheumatic fever in people allergic to penicillin,
- preventing recurrence of attacks of rheumatic fever in patients allergic to penicillin and sulfonamides.

2. BEFORE YOU TAKE ERITROMICIN HEMOFARM

This medicine is suitable for most adults and children aged over 12 years but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

Do not take ERITROMICIN HEMOFARM

- If you are allergic (hypersensitive) to erythromycin or any of the other ingredients in the product (see Section 6)
- If you are taking simvastatin, tolterodine, mizolastine, amisulpiride, astemizole, terfenadine, domperidone, cisapride or prazosin, ergotamine and dihydroergotamine.
- if you have blood disorder (porphyria)
- if you have serious liver disorder

Take special care with ERITROMICIN HEMOFARM

Tell your doctor if you:

- have liver or kidney problems
- severe heart disease with a tendency toward arrhythmias (prolonged QT interval in the ECG)
- myasthenia gravis (a disease characterized by excessive muscle weakness).

If you develop severe or prolonged diarrhea during or after taking this medicine, immediately contact your doctor.

Taking other medicines

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

Erythromycin enhances the effects of theophylline, carbamazepine, phenytoin, and valproate, clozapine, cyclosporine, alfentanil, bromocriptine, quinidine and disopyramide, felodipine, methylprednisolone, midazolam, or triazolam, tacrolimus, anticoagulants, ritonavir, omeprazole, digoxin, sildenafil.

Co-administration of erythromycin with antihistamines (terfenadine, astemizole) or cisapride (used for stomach problems) or prazosin (for the treatment of mental illnesses), can lead to highly dangerous arrhythmia.

Cimetidine (to reduce gastric acid) enhances the effect of erythromycin and penicillins decrease it.

Erythromycin strongly reinforces the effect of ergotamine and dihydroergotamine (for migraine pain), so that peripheral spasms may occur. The contraceptive effect of oral contraceptives may be reduced during co-administration with erythromycin. Therefore, it is necessary to use additional non-hormonal contraceptive methods. In very rare cases, the concomitant use of erythromycin and lovastatin may potentiate rhabdomyolysis (severe muscle damage), but because of the risk of myopathy and rhabdomyolysis concomitant use of simvastatin is contraindicated. Lovastatin and simvastatin are cholesterol-lowering drugs.

Co-administration with tolterodine is contraindicated due to the increased risk of overdose.

Co-administration of erythromycin with high doses of theophylline (to treat asthma) may lead to increased levels of theophylline in serum and occurrence of toxicity. In case of toxicity, and / or for theophylline in serum, it is necessary to reduce the dose of theophylline in patients treated with erythromycin. When erythromycin is orally administered at the same time as theophylline, there is a significant decrease of its concentration in the serum, which can reduce its therapeutic effect. Because of the possible competitive inhibition, caution is

required with concomitant administration of erythromycin with lincomycin, clindamycin or chloramphenicol (antibiotics).

Co-administration of erythromycin with alfentanil can significantly reduce the clearance of alfentanil and increase the risk of prolonged or late respiratory depression. Erythromycin can affect the detection of catecholamines and 17-hydroxy-corticosteroids in urine. If you need to take urine laboratory tests, tell your doctor that you are taking Erythromycin Hemofarm.

Taking the medicine Erythromycin HEMOFARM with food and drink

It is recommended to take the medicine on an empty stomach, because food reduces the absorption of medicine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Caution is required with the use of erythromycin during pregnancy and lactation. It can be used in pregnant and lactating women only when absolutely necessary and when a doctor determines that a therapeutic benefit to the mother outweighs the potential risk to the fetus.

Driving and using machines

Erythromycin Tablets are not expected to affect your ability to drive or operate machinery.

Important information about some of the ingredients of ERITROMICIN HEMOFARM
Not implacable.

3. HOW TO TAKE ERITROMICIN HEMOFARM

Always take ERITROMICIN HEMOFARM exactly as indicated in this package leaflet. If you are unsure, please ask your doctor or pharmacist for advice.

ERITROMICIN HEMOFARM tablets are administered orally.

Swallow the tablets whole with a glass of water.

The usual dose for adults and children over 12 years, for the treatment of moderate infections, is 1-2 g of erythromycin in 4 divided doses (1 or 2 tablets of 250 mg every 6 hours, depending on the severity of the infection). For the treatment of serious and severe infections, the dose may be increased to 4 g of erythromycin per day taken in 4 divided doses (every 6 hours). Erythromycin can be administered at intervals of 6 or 12 hours.

Duration of treatment

The standard duration of treatment: upper respiratory tract infections are treated 5 - 10 days; lower respiratory tract 7-14 days; infection transmitted through sexual intercourse 10 - 21 days; skin and soft tissue 5-10 days; abdominal infection for at least 5 days. Streptococcal infections mandatory 10 days.

If you take more ERITROMICIN HEMOFARM than you should

If anyone has taken too many tablets contact a doctor or your nearest Emergency Department taking this leaflet and pack with you.

Symptoms of overdose include nausea, vomiting and diarrhea and loss of hearing.

If you forget to take ERITROMICIN HEMOFARM

If you miss a dose, take the tablets as soon as you remember and carry on as before. If it is almost time for your next dose, skip the missed dose and continue as usual (do not take a double dose to make up for the forgotten dose).

If you stop taking ERITROMICIN HEMOFARM

Continue to take this medicine until the course is completed or until your doctor tells you to stop; do not stop taking your medicine, even if you feel better. If you stop the treatment too early your problem could come back.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects that occur very often (the frequency is greater than 1 in 10 patients):

- nausea
- bloating
- vomiting
- stomach pains
- diarrhea.

These side effects are more common in children than in adults.

Side effects that occur rarely (incidence is less than 1 in 1000 patients):

- hives (urticaria) and other types of skin rash
- eosinophilia
- inflammation of the pancreas.

High doses of erythromycin can cause transient hearing loss, most often in the elderly who have kidneys and / or liver failure.

Side effects that occur very rarely (incidence is less than 1 in 10,000 patients):

- pseudomembranous colitis
- cholestatic hepatitis in long-term use
- cardiac arrhythmias
- chest pain.

Erythromycin can cause weakness in people with myasthenia gravis (a disease in which there is excessive muscle weakness).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE ERITROMICIN HEMOFARM

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container and box after "EXP". The expiry date refers to last day of that month.

Expiration date:

3 years

Store below 25 °C. Store in the original container to protect from moisture and light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What ERITROMICIN HEMOFARM contains

The active substances are:

1 tablet contains:
250 mg of erythromycin

The other ingredients are:

Core: Starch, corn, cellulose, microcrystalline, magnesium stearate.

Film: Opadry White YS-1-7002 (polydextrose, hypromellose, talc, titanium dioxide, fractionated coconut oil, maltodextrin).

What ERITROMICIN HEMOFARM looks like and contents of the pack

Round, biconvex tablets, white.

The complex cardboard box contains 2 are blisters of PVC / aluminum foil with 10 film-coated tablets of 250 mg.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Hemofarm d.o.o. Banja Luka
Novakovići bb, Banja Luka, BiH

Manufacturer of the medicinal product

Hemofarm d.o.o. Banja Luka
Novakovići bb, Banja Luka, BiH