

PACKAGE LEAFLET: INFORMATION FOR THE USER

ERITROMICIN HEMOFARM

500 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?

1. What ERITROMICIN HEMOFARM is and what it is used for
2. Before you take ERITROMICIN HEMOFARM
3. How to take use ERITROMICIN HEMOFARM
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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. It is used for the treatment and prevention of infections caused by •erythromycin-sensitive organisms, such as:

- Upper and lower respiratory tract infections
- Eye, ear infections
- Oral infections
- Skin and soft tissue infections
- Gastrointestinal infections.
- Prophylaxis pre- and post- operative trauma, burns, rheumatic fever
- Other infections: osteomyelitis, urethritis, gonorrhea, syphilis, lymphogranuloma venereum, diphtheria, prostatitis, scarlet fever

2. BEFORE YOU TAKE ERITROMICIN HEMOFARM

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 ergotamine or dihydroergotamine (used to treat migraines)
- if you are taking terfenadine or astemizole (widely taken for hayfever and allergies), cisapride (for stomach disorders) or pimozide (for psychiatric conditions)
- if you are taking colchicine (used for treatment of gout and arthritis)

Take special care with ERITROMICIN HEMOFARM

Tell your doctor if you:

- have liver or kidney problems
- have 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.

- warfarin (thins the blood)
- cisapride (used for stomach disorders)
- pimozide (used in the treatment of psychiatric disorders)
- clarithromycin (antibiotic used to treat certain infections)
- ergotamine or dihydroergotamine (for migraine)
- theophylline (helps breathing)
- cilostazol (for blood circulation problems)
- rifabutin (for tuberculosis)
- sildenafil (for erectile dysfunction)
- vinblastine (for cancer)
- antifungals e.g. fluconazole, ketoconazole and itraconazole
- colchicine (for gout)
- bromocriptine (used to treat Parkinson's disease)
- digoxin or disopyramide or quinidine (all heart drugs)
- hexobarbitone, midazolam (used as a sedative)
- cyclosporin or tacrolimus (used following organ transplants)
- alfentanil, zopiclone or triazolam (induces sleep)
- Phenytoin or carbamazepine, valproate (drugs for epilepsy)
- lovastatin (a cholesterol lowering agent)

If you or your child goes for any medical tests, tell your doctor that you are taking ERITROMICIN, as this may interfere with some test results.

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.

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.

Adults and children over 8 years

The usual dose is 2 g per day in divided doses (2 tablets twice a day), before the meal. For severe infections, the maximum recommended dose is 4 g per day (total of 8 tablets per day).

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 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 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.

If you notice any of the following, contact your doctor immediately as these may be signs of an allergic reaction:

- difficulty breathing;
- fainting;
- swelling of the face, lips or throat;
- skin rashes;
- severe skin reactions including large fluid-filled blisters, sores and ulcers;
- ulcers in the mouth and throat

Other side effects of ERITROMICIN include:

- Diarrhea which may be severe or prolonged and may contain blood or mucus;
- Feeling of weakness or illness,
- Pain in the stomach,
- Reversible loss of hearing (usually after the administration of high doses)
- Damage to blood, kidney or nervous system,
- Yellow color of the skin and / or eyes, which are signs of liver problems such as jaundice,
- Chest pain,
- Dizziness,
- Abnormal heart rhythms.

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.

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:

500 mg of erythromycin

The other ingredients are:

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

Film: Opadry White YS-1-7002 (Hypromellose, macrogol 8000, titanium dioxide E171, C.I.77891).

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 500 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