

Package leaflet: Information for the patient

Erythroped® PI SF 125 mg/5 ml Granules for Oral Suspension

Erythroped® SF 250 mg/5 ml Granules for Oral Suspension

Erythromycin ethylsuccinate

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Throughout the leaflet the medicine is referred to as “Erythroped Granules”, but it may have been given to you to give to your child. In that case, remember that the information will apply to your child, and not to you.

The name of your medicine is Erythroped PI SF 125 mg/ 5ml Granules for Oral Suspension or Erythroped SF 250 mg/5 ml Granules for Oral Suspension or Erythroped Forte SF 500 mg/5 ml Granules for Oral Suspension (all will be referred to Erythroped Granules throughout this leaflet).

What is in this leaflet

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2. What you need to know before you take Erythroped Granules
3. How to take Erythroped Granules
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1 What Erythroped Granules are and what they are used for

Erythroped Granules contains the active substance erythromycin as erythromycin ethylsuccinate. They belong to a group of drugs called antibiotics and are used in adults and children to treat infections caused by bacteria.

2. What you need to know before you take Erythroped Granules

Do not take Erythroped Granules:

- if you are allergic to erythromycin or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to other macrolide antibiotics such as clarithromycin or azithromycin.

- if you are currently taking a medicine called
 - ergotamine or dihydroergotamine (used to treat migraines) while taking erythromycin as this may cause serious side effects;
 - terfenadine or astemizole (widely taken for hayfever and allergies), cisapride (for stomach disorders) or pimozone (for psychiatric conditions) while receiving erythromycin, as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines you can take instead;
 - domperidone (used to treat nausea (feeling sick) and vomiting (being sick));
 - lovastatin or simvastatin (used to lower cholesterol levels) as abnormal muscle breakdown leading to kidney problems (rhabdomyolysis) can occur;
 - lomitapide (used to lower increased blood fats such as cholesterol and triglycerides). Taking this medicine at the same time as erythromycin may lead to a rise in enzymes produced by liver cells (transaminases), which indicates that the liver is under stress and may lead to liver problems.

- if you have abnormally low levels of potassium or magnesium in your blood (hypomagnesaemia or hypokalaemia).

- if 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”.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Erythroped Granules if you:

- have any liver problems or have been told that any drugs you are taking can cause liver problems;
- are taking other medicines which are known to cause serious disturbances in heart rhythm;
- have previously experienced diarrhoea following the use of antibiotics;
- are pregnant and have been told that you have a sexually transmitted disease called syphilis. In this case erythromycin may not be effective for preventing the transfer of this infection to your baby. Consult your doctor before receiving erythromycin. Alternatively if you were treated for early stages of syphilis during your pregnancy, and your child is under 1 year and is prescribed erythromycin, consult your doctor before giving erythromycin to your child;
- are treating a young child with antibiotics and they are irritable or vomit when fed, you should contact your physician immediately;
- suffer from a condition called myasthenia gravis, which causes muscle weakness, consult your doctor before receiving erythromycin;
- are using erythromycin for a long period of time;
- suffer from a genetic problem that interferes with the metabolism of mitochondria (Leber’s hereditary optic neuropathy or autosomal dominant optic atrophy);
- have heart problems such as an abnormal ECG heart tracing (prolonged QT interval) or a slow heart beat (bradycardia);
- are receiving drugs to treat heart problems;

- have uncorrected hypokalaemia or hypomagnesaemia (low blood levels of potassium or magnesium, which can cause muscle weakness, twitching or abnormal heart rhythm);
- are elderly;
- are about to undergo laboratory tests for signs of pheochromocytoma (a rare tumour of the adrenal glands) as erythromycin may interfere with the test results.

Other medicines and Erythroped Granules

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

This is especially important if you are taking the following medicines or medicines from the following families:

- astemizole, terfenadine or mizolastine (used to treat allergies such as hayfever);
- domperidone (used to treat nausea (feeling sick) and vomiting (being sick));
- pimozide (used to treat mental problems);
- ergotamine or dihydroergotamine (used to relieve migraines);
- cisapride (used to treat stomach disorders);
- statins (used to help lower cholesterol levels, e.g. lovastatin and simvastatin);
- beta-lactam antibiotics (used to treat bacterial infections, e.g. penicillin and cephalosporin);
- protease inhibitors (used to treat viral infections, e.g. saquinavir);
- oral contraceptives.

This is also important if you are taking medicines called:

- colchicine (used to treat gout and arthritis);
- cimetidine and omeprazole (used to treat acid reflux and other related conditions);
- clindamycin, lincomycin, chloramphenicol, streptomycin, tetracyclines, colistin, rifabutin, or rifampicin (used to treat different types of bacterial infection);
- fluconazole, ketoconazole and itraconazole (used to treat fungal infections);
- digoxin, quinidine or disopyramide (used to treat heart problems);
- cilostazol (used to treat peripheral circulation problems);
- hexobarbitone, phenobarbital or midazolam (used as sedatives);
- zopiclone or triazolam/alprazolam (used to help you sleep or relieve states of anxiety);
- anticoagulants e.g. warfarin, acenocoumarol and rivaroxaban (used to thin the blood);
- valproate, carbamazepine or phenytoin (used to control epilepsy);
- theophylline (used to treat asthma and other breathing problems);
- ciclosporin or tacrolimus (used following organ transplants);
- bromocriptine (used to treat Parkinson's disease);
- alfentanil (used to provide pain relief);
- methylprednisolone (used to help suppress the body's immune system – this is useful in treating a wide range of conditions);
- St John's Wort (a herbal medicine used to treat depression);
- verapamil (used to treat high blood pressure and chest pain);
- vinblastine (used to treat certain types of cancer);
- sildenafil (used to treat erectile dysfunction);

- Corticosteroids, given by mouth, by injection or inhaled (used to help suppress the body's immune system - this is useful in treating a wide range of conditions);
- hydroxychloroquine or chloroquine (used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria). Taking these medicines at the same time as erythromycin may increase the chance of getting abnormal heart rhythms and other serious side effects that affect your heart.

Pregnancy and breast-feeding

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

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

The active ingredient of Erythroped Granules may cross the placenta in pregnant women and is excreted in breast milk. Information from studies regarding the risk of birth defects is inconsistent, but some studies have reported heart defects following Erythroped Granules use in early pregnancy.

Driving and using machines

Dizziness and blurred vision have been reported with erythromycin use. Do not drive or use machines unless you are sure you are not affected.

Erythroped Granules contains:

- **sorbitol.**

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

- **parahydroxybenzoates**

May cause allergic reactions (possibly delayed).

- **sodium**

This medicinal product contains 69.34 mg sodium per 5ml dose, equivalent to 3.47% of the WHO recommended maximum daily intake of 2 g sodium for an adult. To be taken into consideration by patients on a controlled sodium diet.

3. How to take Erythroped Granules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children over 8 years of age

The recommended dose of Erythroped Granules for adults and children over 8 years is 1 - 2 g daily in divided doses. This is 500 mg two to four times a day. For severe infections up to 4 g daily in divided doses may be given.

Use in children between 2-8 years of age

For children the recommended dose is 30 mg per kilogram of body weight daily in divided doses. For severe infections this may be increased to 50 mg per kilogram of body weight daily in divided doses.

The normal dose in children aged 2 to 8 years is 250 mg four times a day or 500 mg twice daily.

Use in children under 2 years of age

The normal dose in children up to 2 years is 125 mg four times a day or 250 mg twice daily.

If you are unsure about how your child's dose of medicine has been worked out or what your child's dose should be, consult your doctor or pharmacist.

Erythroped Granules can be taken without regard to meals.

If you take more Erythroped Granules than you should

If you accidentally take more medicine in one day than your doctor has told you to, or if a child has taken some of the medicine, stop taking the medicine and seek medical advice urgently. An overdose could cause temporary hearing loss, nausea, vomiting and diarrhoea.

If you forget to take Erythroped Granules

If you forget to take a dose of Erythroped Granules, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Erythroped Granules

Ask your doctor before stopping treatment with Erythroped Granules. Do not stop taking Erythroped Granules just because you feel better. If you stop the treatment too early your problem could come back.

If you have any further questions about the use of this medicine, ask your doctor, pharmacist or nurse.

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**:

- 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 as these may be signs of an allergic reaction.
- serious skin rashes that may involve blistering and can cover large areas of the torso, face, genitals and limbs (conditions known as Stevens Johnson syndrome, toxic epidermal necrolysis and erythema multiforme).
- abnormal heart rhythms (including palpitations, a faster heart beat, a life-threatening irregular heart beat called torsades de pointes or abnormal ECG heart tracing) or heart stopping (cardiac arrest).

- liver failure, liver enlargement and various liver or gall-bladder problems, which can cause yellowing of the skin and/or whites of the eyes (jaundice) or pale stools with dark urine.
- abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis).
- inflammation of the kidneys (a condition known as tubulointerstitial nephritis).
- Vomiting and irritability in young children between the age of 1 month and 12 months (Infantile Hypertrophic Pyloric Stenosis).
- 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 side effect is not known (cannot be estimated from the available data).

Other side effects of Erythroped Granules are included below with the following frequency:

Rare: may affect up to 1 in 1,000 people

pseudomembranous colitis (bowel disease with diarrhoea and abdominal pain).

Not known (frequency cannot be estimated from the available data)

- diarrhoea which may be severe or prolonged and may contain blood or mucus;
- feeling sick or being sick;
- stomach pains; these may be a symptom of an inflamed pancreas (pancreatitis);
- loss of appetite (anorexia);
- irritability and vomiting in a feeding infant;
- increase in a particular type of white blood cells (eosinophilia);
- ringing in the ears (tinnitus);
- reversible loss of hearing (usually associated with high doses or in patients with kidney problems);
- disturbance in vision (double vision, blurred vision);
- chest pains;
- fever;
- confusion;
- fits (seizures);
- dizziness;
- vertigo (problems with balance that can result in feelings of dizziness, a spinning sensation or sickness – particularly on standing);
- hallucinations (seeing or hearing things that aren't there);
- feeling generally unwell (malaise);
- low blood pressure;
- itching or hives.

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. You can also report side effects directly via HPRA Pharmacovigilance,

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Erythroped Granules

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle after 'EXP'. The expiry date refers to the last day of that month. If the medicine is out of date, return it to your pharmacist and if necessary, get a new prescription from your doctor.

Do not store above 25°C and keep the bottle tightly closed.

If your doctor decides to stop your treatment with Erythroped Granules, return any remaining medicine to a pharmacist.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Erythroped Granules contains

- The active substance is erythromycin as erythromycin ethylsuccinate.

Erythroped PI SF 125 mg/5 ml Granules for Oral Suspension - every 5 ml contains 125 mg of erythromycin as erythromycin ethylsuccinate.

Erythroped SF 250 mg/5 ml Granules for Oral Suspension – every 5 ml contains 250 mg of erythromycin as erythromycin ethylsuccinate.

Erythroped Forte SF 500 mg/5 ml Granules for Oral Suspension – every 5 ml contains 500 mg of erythromycin as erythromycin ethylsuccinate.

- The other ingredients are sodium citrate, saccharin sodium, xanthan gum, surfactant poloxamer, sodium methyl hydroxybenzoate (E219), sodium propyl hydroxybenzoate (E217), colloidal anhydrous silica, imitation banana No. 2 flavour, imitation cream flavour, sorbitol (E420) and acesulfame potassium (K).

What Erythroped Granules look like and the contents of the pack

Erythroped Granules are white, free-flowing granules with a banana flavour.

Erythroped Granules are available in 100 ml or 140 ml bottles. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Amdipharm Limited
Temple Chambers
3 Burlington Road

Dublin 4
Ireland

Manufacturer:

Aesica Queenborough Limited
Queenborough
Kent
ME11 5EL
UK

Alternate Manufacturer:

Aesica Pharmaceuticals S.r.l.
Via Praglia,15
10044 Pianezza (TO)
Italy

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