

Package leaflet: Information for the patient
ERYTHROPED SUGAR FREE (SF) SUSPENSIONS
(Erythromycin ethylsuccinate)

This leaflet contains information about Erythroped SF, Erythroped PI SF and Erythroped Forte SF.

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. 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. See section 4.

What is in this leaflet

1. What Erythroped Sugar Free (SF) Suspensions are and what they are used for
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1. What Erythroped Sugar Free (SF) Suspensions are and what they are used for

The name of your medicine is Erythroped SF suspension. Erythroped SF suspension contains the active ingredient erythromycin which belongs to a group of medicines called macrolide antibiotics.

Erythroped SF Suspensions are used to prevent and treat infections such as:

- Throat and sinus infections
- Chest infections, such as bronchitis and pneumonia
- Ear infections
- Mouth and dental infections
- Eye infections
- Skin and tissue infections, such as acne
- Stomach and intestinal infections
- Prevention of infection following burns, operations or dental procedures
- Other infections, such as sexually transmitted diseases, bone infections or scarlet fever.

2. What you need to know before you take Erythroped Sugar Free (SF) Suspensions

Do not take Erythroped SF Suspensions:

- If you have been told you that you are allergic to erythromycin or other macrolide antibiotics such as clarithromycin or azithromycin or any of the other ingredients of Erythroped Sugar Free Suspensions.
- If you are currently taking a medicine called

- ergotamine or dihydroergotamine (used to treat migraines) as this may cause serious side effects while taking erythromycin;
- terfenadine or astemizole or mizolastine (widely taken for hayfever and allergies), domperidone (for nausea (feeling sick) and vomiting (being sick)), cisapride (for stomach disorders) or pimozone or amisulpride (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;
- simvastatin (used to lower cholesterol and triglycerides (types of fat) in the blood);
- tolterodine (used for treating overactive bladder with symptoms of urinary frequency, urgency, and leakage).
- 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 or pharmacist before taking Erythroped SF Suspensions

- If you are taking colchicine (used for treatment of gout and arthritis) as this may cause serious side effects while taking erythromycin;
- If you have any liver problems or have been told that any drugs you are taking can cause liver problems;
- If you are taking other medicines which are known to cause serious disturbances in heart rhythm;
- If you have heart problems;
- If you have previously experienced diarrhoea following the use of antibiotics;
- If you 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;
- If you are treating a young child with antibiotics and they are irritable or vomit when fed, you should contact your physician immediately;
- If you suffer from a condition called myasthenia gravis, which causes muscle weakness, consult your doctor before receiving erythromycin;
- If you are taking erythromycin with ‘statins’ such as simvastatin or lovastatin (used to lower cholesterol) as serious side effects can occur.

Other medicines and Erythroped Sugar Free (SF) Suspensions

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is especially important if you are taking 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 migraine);
- cisapride (used to treat stomach disorders);
- statins (used to help lower cholesterol levels e.g. lovastatin and simvastatin);
- 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);
- clarithromycin, rifabutin, or rifampicin (medicines used to treat different types of bacterial infection);
- fluconazole, ketoconazole and itraconazole (medicines used to treat fungal infections);
- digoxin, quinidine or disopyramide (used to treat heart problems);
- cilostazol (a medicine used to treat peripheral circulation problems);
- hexobarbitone, phenobarbital or midazolam (used as sedatives);
- 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);
- zopiclone or triazolam/alprazolam (used to help you sleep or relieve states of anxiety);
- alfentanil (a medicine 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).

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

Pregnancy and breast-feeding

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

The active ingredient of Erythroped Sugar Free (SF) Suspensions 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 Sugar Free (SF) Suspensions use in early pregnancy. Erythromycin should be used by women during pregnancy or while breast-feeding only if clearly needed.

Erythroped Sugar Free (SF) Suspensions contains:

Sorbitol: This product contains 1.2 g of sorbitol in each 5ml. 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. This is equivalent to 3.47% of the WHO recommended maximum daily intake of sodium for an adult.

Talk to your doctor or pharmacist if you need 6 or more 5ml dose daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to take Erythroped Sugar Free (Sf) Suspensions

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

The recommended doses are:

For adults and children over 8 years of age:

2 g per day in divided doses. In severe infections, this can increase up to 4 g per day in divided doses (see table).

Use in children

For children aged 2-8 years:

30 mg per kg of bodyweight per day in divided doses. In severe infections, this can increase up to 50 mg per kg of bodyweight per day in divided doses (see table).

For infants under 2 years of age:

30 mg per kg of bodyweight per day in divided doses. In severe infections, this can increase up to 50 mg per kg of bodyweight per day in divided doses (see table).

Normal doses

Which type of suspension do I have	How many 5 ml teaspoonfuls should be taken?		
	For patients under 2 years	For patients Between 2 - 8 years	For patients over 8 years
Erythroped PI SF	1 teaspoonful	four	2 teaspoonfuls
			4 teaspoonfuls

125 mg/5 ml	times a day	four times a day	four times a day
Erythroped SF 250 mg/5 ml		1 teaspoonful four times a day	2 teaspoonfuls four times a day
Erythroped Forte SF 500mg/5ml			1 teaspoonful four times a 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 Erythroped SF Suspensions 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 by mistake, contact your doctor or go to your nearest hospital emergency department immediately. An overdose could cause temporary hearing loss, nausea, vomiting and diarrhoea.

If you forget to take Erythroped SF Suspensions

If you forget to take a dose of your medicine, take it as soon as you remember.

Do not take more medicine in one day than your doctor tells you to.

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**:

- 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.
- liver failure, various liver or gall-bladder problems, which can cause yellowing of the skin and/or eyes (jaundice) or pale stools with dark urine;
- abnormal heart rhythms (including palpitations, a faster heartbeat, a life-threatening irregular heartbeat called torsades de pointes or abnormal ECG heart tracing) or heart stopping (cardiac arrest);
- serious skin rashes that may involve blistering and can cover large areas of the torso, face and limbs (conditions known as Stevens Johnson syndrome, toxic epidermal necrolysis and erythema multiforme);
- vomiting and irritability in young children between the age of 1 month and 12 months;
- inflammation of the kidneys (a condition known as interstitial nephritis);
- 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 SF Suspensions include:

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

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

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;
- increase in a particular type of white blood cells (eosinophilia);
- stomach pains; these may be a symptom of an inflamed pancreas (pancreatitis);
- ringing in the ears (tinnitus);
- reversible loss of hearing (usually associated with high doses or in patients with kidney problems);
- chest pains;
- fever;
- loss of appetite (anorexia);
- confusion;
- convulsions (seizures);
- vertigo (problems with balance that can result in feelings of dizziness or sickness – particularly on standing);
- hallucinations (seeing or hearing things that aren't there);
- feeling generally unwell (malaise);
- low blood pressure;
- visual impairment/blurred vision (Mitochondrial optic neuropathy);
- increase levels of liver enzymes.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Erythroped Sugar Free (SF) Suspensions

Your medicine will be stored by the pharmacist and reconstituted to a suspension before giving it to you. It should be used within 7 days of reconstitution.

Do not use these suspensions after the expiry date shown on the bottle.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

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. Contents in the pack and other Information

What Erythroped SF Suspensions contain

There are three different strengths of Erythroped SF Suspension available.

They all contain the active ingredient erythromycin.

Erythroped PI SF contains 125 mg of erythromycin as erythromycin ethylsuccinate in every 5 ml.

Erythroped SF contains 250 mg of erythromycin as erythromycin ethylsuccinate in every 5 ml.

Erythroped Forte SF contains 500 mg of erythromycin as erythromycin ethylsuccinate in every 5 ml.

The other ingredients are: sodium citrate, saccharin sodium, xanthan gum, poloxamer, sodium methylhydroxybenzoate, sodium propylhydroxybenzoate, purified water, colloidal silica, imitation banana No. 2 flavour and imitation cream flavour, sorbitol and acesulfame (K).

What Erythroped SF looks like and the contents of the pack

Erythroped SF Suspensions are granules which are made up to a white, opaque suspension by the pharmacist.

Erythroped SF Suspensions are available in bottles of 100 ml or 140 ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Amdipharm UK Limited,
Dashwood House,
69 Old Broad Street,
London, EC2M 1QS, United Kingdom

Manufacturer:

Aesica Queenborough Limited,
Queenborough,
Kent ME11 5EL.
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