PATIENT INFORMATION LEAFLET ON GBR 726-6059-APIL



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.

- Please 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 severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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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. 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.
- 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 (widely taken for hayfever and allergies), cisapride (for stomach disorders) or pimozide (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.

Take special care with 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:
- have any liver problems or have been told that any drugs you are taking can cause liver problems:
- 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 erthyromycin, 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 taking erythromycin with 'statins' such as simvastatin or lovastatin (used to lower cholesterol) as serious side effects can occur.

If any of these apply to you, or if you are not sure, tell your doctor.

Taking other medicines

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

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

- astemizole, terfenadine or mizolastine (used to treat allergies such as hayfever);
- 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);
- warfarin and acenocoumarol (used to help 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).

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 think you may be pregnant, or if you are breast-feeding please consult your doctor before taking this medicine.

Important information about some of the ingredients of Erythroped SF Suspensions

Each 5 ml teaspoon of this product contains approximately 1.2 g of sorbitol. Hence this product may be unsuitable if you or your child have been told you have hereditary fructose intolerance (a carbohydrate metabolism disorder), and therefore you should contact your doctor.

Sorbitol can cause stomach upset or diarrhoea.

3. HOW TO TAKE ERYTHROPED SUGAR FREE (SF) SUSPENSIONS

Always take Erythroped SF Suspensions exactly as your doctor has told you. You should check with your doctor if you are not sure.

The usual doses are:

For adults and children over 8 years of age:

 $2\,\mathrm{g}$ per day in divided doses. In severe infections, this can increase up to $4\,\mathrm{g}$ per

day in divided doses (see table);

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 mgper 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 mgper 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 2 - 8 years	For patients between	For patients over 8 years
Erythroped PI SF 125 mg/5 ml	1 teaspoonful four times a day	2 teaspoonfuls four times a day	4 teaspoonfuls 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/5 ml			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 yourdoctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Erythroped SF Suspensions 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.

Other side effects of Erythroped SF Suspensions include:

- 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);
- various liver or gall-bladder problems, which can cause yellowing of the skin and/or eyes (jaundice) or pale stools with dark urine;
- chest pains;
- abnormal heart rhythms (including palpitations);
- fever:
- anorexia;

confusion:

- fits (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);
- inflammation of the kidneys (a condition known as interstitial nephritis);
- low blood pressure;
- 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).

If any of the side effects becomes severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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. FURTHER INFORMATION

What Erythroped SF Suspensions contain

There are three different strengths of Erythroped SF Suspension available. They all contain the active ingredient erythromycin.

Erythroped SF contains 250 mg of erythromycin as erythromycin ethylsuccinate

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

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,

Regency House, Miles Grav Road.

Basildon,

Essex SS14 3AF. UK

Manufacturer:

Aesica Queenborough Limited, Queenborough,

Kent ME11 5EL.

This leaflet was prepared in June 1998. Revised in August 2013.

