

PATIENT INFORMATION LEAFLET

Artemether 40 mg and Lumefantrine 240 mg Tablets -ESKAFAN DS

Read all of this leaflet carefully before you start taking this medicine.

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

In this leaflet:

1. What ESKAFAN DS is and what it is used for
2. Before you take or give ESKAFAN DS to your child
3. How to take or give ESKAFAN DS to your child
4. Possible side effects
5. How to store ESKAFAN DS
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1. WHAT ESKAFAN DS IS AND WHAT IT IS USED FOR

ESKAFAN DS contains two substances called artemether and lumefantrine. They belong to a group of medicines called anti-malarials.

ESKAFAN DS is only used for the treatment of acute uncomplicated malaria infections caused by a parasite called “Plasmodium falciparum”. This parasite is a tiny organism made up of one cell that is found inside red blood cells.

ESKAFAN DS is used to treat adults, children and infants of 5 kg body weight and above.

ESKAFAN DS is not used to prevent malaria or to treat severe malaria (where it has affected the brain, lungs or kidneys).

2. BEFORE YOU TAKE OR GIVE ESKAFAN DS TO YOUR CHILD

Do not take ESKAFAN DS

- If you are allergic (hypersensitive) to artemether, lumefantrine, or any of the other ingredients of ESKAFAN DS listed at the end of this leaflet.
- If you have a severe type of malaria infection where it has affected parts of your body such as the brain, lungs or kidneys.
- If you have a heart condition, such as changes in the rhythm or rate of the heart beat, a slow heart beat, or severe heart disease.
- If any member of your family (parents, grandparents, brothers or sisters) has died suddenly due to a heart problem or was born with heart problems.
- If your doctor has told you that you have low levels of electrolytes such as potassium or magnesium in your blood.
- If you are taking the following medicines: flecainide, metoprolol, imipramine, amitriptyline, clomipramine, certain antibiotics (macrolides, fluoroquinolones, imidazole), triazole antifungal agents, terfenadine, astemizole, cisapride (see also “Taking other medicines”).
- If you are taking certain medicines (see also “Taking other medicines”). If any of the above applies to you, tell your doctor without taking ESKAFAN DS.

Take special care with ESKAFAN DS

Check with your doctor or pharmacist before taking ESKAFAN DS:

If you have severe liver or kidney problems.

If you have a heart disorder, such as an abnormal electrical signal called “prolongation of the QT interval”.

If you are infected with both the “Plasmodium falciparum” and “Plasmodium vivax” parasites.

If you are taking or have taken any other medicines for the treatment of malaria. Some of these

medicines must not be given together with ESKAFAN DS.

If you are in the first 3 months of pregnancy or intend to become pregnant. Your doctor will try to

give you an alternative medicine first.

If you feel worse, or if you feel too unwell to eat and drink.

If any of these apply to you, talk to your doctor before you take ESKAFAN DS.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines,

including medicines obtained without a prescription.

In particular, do not take this medicine and tell your doctor if you are taking any of the following:

- Medicines used to treat heart rhythm problems such as flecainide or metoprolol.
- Medicines used to treat depression such as imipramine, amitriptyline or clomipramine.
- Medicines used to treat infections called:
 - rifampin, an antibiotic to treat leprosy or tuberculosis
 - antibiotics, including the following types: macrolides, fluoroquinolones or imidazole,
 - triazole antifungal agents.
- Medicines used to treat allergies or inflammation called “non-sedating antihistamics” such as terfenadine or astemizole.
- Cisapride - a medicine used to treat stomach problems.
- Medicines used to treat epilepsy (such as carbamazepine, phenytoin)
- John's wort (*Hypericum perforatum*) a medicinal plant or extract of this medicinal plant used to treat for example depressed mood.

If you are taking any of the above medicines, do not take ESKAFAN DS.

Please tell your doctor if you are taking:

- Any other medicines to treat malaria.
- Medicines to treat HIV infections or AIDS
- Hormonal birth control medicine (in this case you should follow an additional method of birth control).

Taking ESKAFAN DS with food and drink

ESKAFAN DS should be taken with food or drinks rich in fat such as milk. Grapefruit juice should be used cautiously. Please ask your doctor for advice on the best food or drinks to take ESKAFAN DS with.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you may be pregnant or become pregnant while taking

ESKAFAN DS.

ESKAFAN DS must not be used during the first 3 months of pregnancy if it is possible for the doctor to give an alternative medicine first. In the later stages of pregnancy, you should take ESKAFAN DS only if clearly necessary.

Your doctor will discuss with you the potential risk of taking ESKAFAN DS during pregnancy. If you are taking hormonal birth control medicine, you should also use an additional method of birth control for about one month.

You should not breast-feed while you are taking ESKAFAN DS. Once you have stopped taking ESKAFAN DS, you should wait at least 1 week before starting to breast-feed again. Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or while you are breast-feeding.

Driving and using machines

ESKAFAN DS may make you feel sleepy, dizzy or generally weak. If this happens to you, do not drive or use any tools or machines.

3. HOW TO TAKE OR GIVE ESKAFAN DS TO YOUR CHILD

Always take or give ESKAFAN DS exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking or giving ESKAFAN DS

- The tablets should be taken with food or drinks rich in fat such as milk. Please ask your doctor

for advice on the best food or drinks to take ESKAFAN DS with.

- If you feel worse or are too unwell to eat or drink, please talk to your doctor.

- If you are sick (vomit) within 1 hour of taking the tablets take another dose. If in doubt, talk to your doctor.

- When given to small children or infants, the tablets may be crushed.

When treating your child, a 24-tablet pack will be provided. Follow your doctor's instructions carefully and use only the number of tablets needed. Return the remaining tablets to your pharmacist.

How much to take or give

A six-dose regimen over 3 days is recommended, as described below:

Adults and adolescents weighing 35kg and above

1st dosage, at the time of initial diagnosis 2 Tablets

2nd dosage, at 8 hours after 1st dose 2 Tablets

3rd dosage, at 24 hours after 1st dose 2 Tablets

4th dosage, at 36 hours after 1st dose 2 Tablets

5th dosage, at 48 hours after 1st dose 2 Tablets

6th dosage, at 60 hours after 1st dose 2 Tablets

If the malaria infection returns

A second course of ESKAFAN DS may be necessary if the malaria infection returns, or if you are reinfected with the parasite "Plasmodium falciparum" after having been cured. If this happens to you please talk to your doctor.

If you take more ESKAFAN DS than you should

If you have accidentally taken too many tablets, talk to your doctor straight away, or go to your nearest emergency unit. You may require medical attention. Remember to take your

medicine with you, and show it to your doctor or the staff of the emergency unit. If you have run out of tablets, take the empty packaging along with you.

If you forget to take ESKAFAN DS

Try to make sure that you do not miss any doses. However, if you do forget a dose of ESKAFAN DS, take the missed dose as soon as you remember unless it is almost time for your next dose. Then take your next dose at the usual time. Ask your doctor for advice. Do not take a double dose to make up for a forgotten dose.

If you stop taking ESKAFAN DS

Do not stop taking your medicine unless your doctor tells you to. Always follow your doctor's

instructions carefully, and complete the course of medication.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, ESKAFAN DS can cause side effects, although not everybody gets them. Most of the side effects are mild to moderate and generally disappear after a few days to a few weeks after treatment. Some side effects are more commonly reported in children and others are more commonly reported in adults. In cases where there is a difference, the frequency listed below is the more common one.

Some side effects could be serious and need immediate medical attention.

Rare (*affecting less than 1 in 1,000 patients*)

If you get a rash, swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing, tell your doctor straight away. These are signs of an allergic reaction.

Other side effects are:

Very common (*affecting more than 1 in 10 patients*)

Fast heart beat, headache, dizziness, cough, being sick (vomiting), stomach pain, feeling sick (nausea), joints or muscles aching, loss of appetite, general weakness, tiredness, trouble with sleeping.

Common (*affecting less than 1 in 10 patients*)

Involuntary muscle contractions (sometimes in rapid spasms), heart rhythm disturbances (called QTc prolongation), Symptoms such as unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness or weakness (signs of liver problems), diarrhoea, abnormal walking*), tingling or numbness of the hands and feet*), a rash or itching on the skin, insomnia.

Uncommon (*affecting less than 1 in 100 patients*)

inability to coordinate movements*), decreased skin sensitivity*), sleepiness, itching rash.

*) These side effects have been reported in adults and adolescents above 12 years of age.

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

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

(www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ESKAFAN DS

Keep out of the reach and sight of children.

Do not use ESKAFAN DS after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store in a dry place below 30°C. Protect from light.

Do not use ESKAFAN DS if you notice that the pack is damaged or shows signs of tampering.

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 ESKAFAN DS contains

- The active substances of ESKAFAN DS are artemether and lumefantrine.
- The other ingredients are Microcrystalline Cellulose Powder, Hydroxyl Propyl Methyl Cellulose, Polysorbate 80, Maize Starch, Purified water, Purified Talc, Magnesium Stearate, Crospovidone, Colloidal Anhydrous Silica.

What ESKAFAN DS looks like and contents of the pack

Yellow coloured, circular, uncoated flat beveled edges tablet, having break line on one side and plain on other side. ESKAFAN DS tablets are available in blister packs containing 12's tablets along with an insert

Name and full physical address of Marketing Authorization Holder and Manufacturing site

Marketing Authorization Holder

Eskay Therapeutics Ltd.

42, South Industrial Area,

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