

PACKAGE LEAFLET: INFORMATION FOR THE USER

DAROB MITE

80 mg TABLETS

SOTALOL HYDROCHLORIDE

• 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?

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1. WHAT ARE DAROB MITE TABLETS AND WHAT ARE THEY USED FOR

Sotalol belongs to a group of medicines called 'Beta-blockers' or beta-adrenergic receptor blocking drugs.

Darob Mite tablets are used for the treatment of certain types of irregular heartbeats.

2. BEFORE YOU TAKE DAROB MITE TABLETS Do not take Darob Mite tablets if any of the following apply to you.
- If you are allergic (hypersensitive) to sotalol, or to any of the ingredients of Darob Mite tablets. An allergic reaction may include rash, itching, swelling of face, lips, tongue, or hands/feet or breathing difficulties.
 - If you suffer from asthma, attacks of wheezing, emphysema (lung disease) or bronchitis (inflammation of bronchii).
 - If you suffer from an untreated tumour of the adrenal gland (phaeochromocytoma).
 - If you have a very slow heart beat (bradycardia) or low blood pressure.
 - If you suffer from any severe circulation disorders.
 - If you suffer from a condition called Raynaud's syndrome [discolouration(white or purple colour) of the hands and feet].
 - If you suffer from a condition called metabolic acidosis (abnormal levels of acid in your blood, usually as a result of severe illness).
 - If you suffer from kidney failure.

- If you have suffered from heart disease (such as untreated heart failure) or had a recent heart attack that your doctor does not know about.

If you are affected by any of the above, you should tell your doctor before taking this medicine.

Your doctor may wish to check the level of potassium and magnesium in your blood before you start taking Darob Mite tablets. Patients with low levels should not take Darob Mite tablets.

Regular blood tests may be required during your treatment with Darob Mite tablets. Darob Mite tablets are not recommended for use in children.

Take special care with Darob Mite tablets if

- you are pregnant, planning to become pregnant or are breastfeeding.
- you have any kidney problems, as your dose of Sotalol may need to be changed.
- you suffer from diarrhoea or have recently suffered from diarrhoea or if you have recently had severe diarrhoea, or an attack that lasted a long time. This is because it can affect the levels of potassium and magnesium in the body, and you may not be able to take Darob Mite tablets.
- you suffer from psoriasis (a skin disease that causes itchy, red, sore patches of skin).
- you suffer from diabetes, as it may be necessary to change the dose of insulin or any other medicines you take to treat your diabetes. Sotalol may also hide or reduce the warning symptoms of a drop in your blood sugar levels (hypoglycaemia).
- you have thyrotoxicosis (a condition caused by an overactive thyroid gland). Sotalol may hide the symptoms of thyrotoxicosis or make them worse if treatment with Sotalol is stopped suddenly.

If you are due to have surgery

You should tell the doctor or anaesthetist that you are taking Darob Mite tablets as it can affect anaesthetics. You may have to stop taking Darob Mite tablets before surgery and it should be gradually stopped over a period of one week. Your doctor will tell you if this is necessary.

Taking other medicines

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

Care is needed if you are taking:

- Other medicines used for treating abnormal heart rhythms such as disopyramide, quinidine, procainamide, amiodarone and bepridil.
- Other beta blocking agents such as propranolol, atenolol, metoprolol.
- Medicines used for treating mental illnesses such as phenothiazines (e.g. chlorpromazine, trifluoperazine), or tricyclic antidepressants (e.g. imipramine, amitriptyline, clomipramine, desipramine).
- Terfenadine, astemizole (used for treatment of allergies).
- Erythromycin (intravenous), quinolone antibiotics (e.g. ciprofloxacin, ofloxacin, levofloxacin, norfloxacin, gatifloxacin).
- Halofantrine (belongs to a group of medicines known as antimalarials. It is used to treat malaria, a red blood cell infection transmitted by the bite of a mosquito).
- Pentamidine (used to treat *Pneumocystis carinii* pneumonia, a very serious kind of pneumonia. This kind of pneumonia occurs commonly in patients whose immune system is not working normally, such as cancer patients, transplant patients, and patients with acquired immune deficiency syndrome (AIDS)).
- Floctafenine (a pain relieving medicine belonging to a group of medicines known as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)).
- Calcium channel blocking drugs such as verapamil and diltiazem (used for treatment of high blood pressure and certain heart conditions).

- Water tablets (diuretics) (e.g. furosemide, hydrochlorothiazide).
- Amphotericin B (intravenous) (an antifungal, used for treating infections due to certain fungi).
- Corticosteroids (systemic administration) (used for treatment of immune disorders).
- Laxatives.
- Clonidine (used for high blood pressure or migraine (headache)).
- Digitalis glycosides (used for certain heart conditions).
- Catecholamine-depleting agents such as reserpine, guanethidine, or alpha methyl dopa (medicines used to treat high blood pressure).
- Insulin and oral hypoglycaemics (used for treatment of diabetes).
- Neuromuscular blocking agents like tubocurarine.
- Beta-2-receptor stimulants (e.g., salbutamol, terbutaline and isoprenaline) (used for the treatment of asthma).

Pregnancy and Breastfeeding

Make sure you tell your doctor if you are pregnant or planning to become pregnant. You should not be given Sotalol tablets during pregnancy unless your doctor thinks it is essential.

You should not breastfeed while you are being treated with Darob Mite tablets.

Taking with Food and Drink

Moderate amounts of alcohol will not affect Sotalol, however you should check with your doctor first to see if drinking is advisable for you.

Driving or operating machinery

Sotalol does not usually affect your ability to drive. However, if you feel light-headed or dizzy, do not drive or operate machinery.

Important information about some of the ingredients of Darob Mite tablets

These tablets contain lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking Darob Mite tablets.

3. HOW TO TAKE DAROB MITE TABLETS

Always take Darob Mite tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the tablet whole with a glass of water. The tablet may be taken with or without food.

Adults

The usual starting dose is one sotalol 80 mg tablet taken daily as a single dose. The dose is then increased gradually over the next few days whilst checking the heart beat. Most patients respond to a daily dose of 160 – 320 mg sotalol taken daily in two divided doses. Some patients with severe life threatening forms of heart rhythm disturbances may require up to 480 - 640 mg of sotalol daily.

Patients with kidney problems

You may be prescribed a lower dose if you have kidney problems.

For the first few weeks after you start your Sotalol treatment your doctor will need to see you regularly to check on your response and may need to adjust the dose to one that suits you.

Children

Darob Mite tablets are not recommended for use in children.

If you take more Darob Mite tablets than you should

If you or someone else swallows several of these tablets all together, or you think a child has swallowed any of these tablets, contact your doctor or pharmacist or hospital emergency department immediately. Always take any tablets left over with you, also the box and leaflet as this will allow easier identification of the tablets.

If you forget to take Darob Mite tablets

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose and just carry on as before. Do not take a double dose to make up for a 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, Darob Mite tablets can cause side effects, although not everybody gets them.

If any of the following happens, stop taking Darob Mite tablets and tell your doctor immediately or go to the casualty department at your nearest hospital.

- Rashes, hives, itching, swelling of face, lips, tongue and /or throat with difficulty in swallowing or breathing.

Tell your doctor if you notice any of the following:

Side effects seen with Darob Mite tablets (affecting more than 1 in 100 patients) include the following:

- Slow, fast or irregular heartbeats.
- Chest pain.
- Fainting, light headedness (may be a manifestation of low blood pressure).
- Breathlessness.
- Swelling over hands/feet.
- Muscle cramps.
- Hearing disturbances, vision disturbances, altered sense of taste.
- Fever.
- Headache, dizziness, sleep disturbances, mood changes, depressed mood, anxiety.
- Sexual dysfunction.
- Nausea (feeling sick), vomiting (being sick), indigestion, pain in the belly, diarrhoea or loose stools, wind.
- General feeling of being unwell, tiredness.
- Tingling in feet and hands (pins and needles).

Patients taking this type of medicine have complained of cold and/or blue fingers and toes, worsening of aches in their legs when walking, skin rash or dry eyes.

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.

5 HOW TO STORE DAROB MITE TABLETS Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original package.

Do not use your tablets after the expiry date stated on the label or carton.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

This leaflet was last approved in {05/2012}.