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Patient Information

Sotalol Hydrochloride Tablets, USP (AF)

What You Should Know About Sotalol Hydrochloride Tablets (AF)

This summary contains important patient information that has been reviewed and approved by the U.S. Food and Drug Administration. This summary is not meant to take the place of your doctor's instructions. Read this patient information carefully before you start taking sotalol hydrochloride tablets (AF). Each time you get a refill, you will receive patient information. Be sure to read it because it may contain new information that you need to know.

What is the most important information I should know about sotalol hydrochloride tablets (AF)?

Because you have irregular heartbeats (atrial fibrillation) that are troublesome to you, sotalol hydrochloride tablets (AF) has been prescribed to help your heart to beat in a more normal way. However, in some patients sotalol hydrochloride tablets (AF) can cause a different type of abnormal heartbeat that can be dangerous, and in rare instances can even cause death. You may feel this different type of abnormal heartbeat as a fast beating of the heart with lightheadedness and fainting. The possibility of this different type of abnormal heartbeat is the reason you and your doctor have discussed whether your symptoms are troublesome enough for you to start taking sotalol hydrochloride tablets (AF).

Clinical studies using sotalol hydrochloride tablets (AF) have shown that the most important way to decrease your chance of getting this different type of dangerous abnormal heartbeat is for you to take the dose of sotalol hydrochloride tablets (AF) that are right for you. If this abnormal heartbeat occurs, it usually happens during the first few days of treatment. This is why you should be started on sotalol hydrochloride tablets (AF) in a hospital or another place where your heartbeat can be watched closely by healthcare professionals for the first few days. They can help you if problems occur. When sotalol hydrochloride tablets (AF) are started this way, this different type of abnormal heartbeat is rare and the hospital staff is there to treat it.

It is important that when you go home, you take the exact dose the doctor prescribed for you. At any time while you are taking sotalol hydrochloride tablets (AF), watch for signs that you may be getting this different type of abnormal heartbeat and call your doctor if they occur. Call your doctor right away if you:

- faint,
- become dizzy, or
- have fast heartbeats.

If you cannot reach your doctor, go to the nearest hospital emergency room. Take your sotalol hydrochloride (AF) tablets with you and show them to the doctor or nurse.

Also, call your doctor right away if you have any of the following conditions:

- severe diarrhea
- unusual sweating
- vomiting

- less appetite than normal, or
- more thirst than normal.

These are conditions that will make you more likely to get the different type of abnormal heartbeat.

If you take sotalol hydrochloride tablets (AF) with certain other medicines, you will increase your chance of getting this different type of abnormal heartbeat. These medicines are listed below under **“Who should not take sotalol hydrochloride tablets (AF)?”**

Once your doctor finds the right dose for you, always take that exact amount of sotalol hydrochloride tablets (AF). Never take an extra dose and never skip a dose of sotalol hydrochloride tablets (AF).

What are sotalol hydrochloride tablets (AF)?

Sotalol hydrochloride tablets (AF) are a medicine that is given to patients with atrial fibrillation (irregular heartbeats). Atrial fibrillation happens when certain parts of the heart (the chambers known as atria) beat too fast or irregularly. When this happens, your heart cannot pump blood through your body as well as it should. This may make you feel weak and tired, or get out of breath easily. You may get an uncomfortable feeling in your chest and “fluttering” or “palpitations.” Atrial fibrillation can be changed back (converted) to normal heart rhythm by an electric shock or by using certain medicines. However, atrial fibrillation can return. Sotalol hydrochloride tablets (AF) may help your heart stay beating regularly for a longer period of time.

This information about sotalol hydrochloride tablets (AF) was developed to ensure that you and your doctor get the right information about your type of irregular heartbeats. Consult your doctor before you accept any other sotalol product that does not provide this patient information.

Who should not take sotalol hydrochloride tablets (AF)?

Sotalol hydrochloride tablets (AF) are not for everyone with irregular heartbeats (atrial fibrillation). This is why you and your doctor need to discuss the benefits and risks of sotalol hydrochloride tablets (AF) and whether your symptoms are troublesome enough for you to start taking sotalol hydrochloride tablets (AF).

Do not take sotalol hydrochloride tablets (AF) if you:

- have serious kidney problems or are on kidney dialysis;
- have lung disease causing shortness of breath (such as asthma, chronic bronchitis or emphysema);
- have symptoms of heart failure (such as shortness of breath when you exercise or are physically active and swelling of the ankles or legs);
- have a very slow heart beat and do not have an implanted artificial pacemaker;

Taking certain other medicines with sotalol hydrochloride tablets (AF) can increase the chance that you will get the dangerous abnormal heartbeat discussed in **“What is the most important information I should know about sotalol hydrochloride tablets (AF)?”** These include medicines used to treat abnormal heart rhythms and some other heart problems as well as medicines used to treat depression and other mental problems, night-time heartburn, asthma and infections.

Therefore, you should be sure to tell your healthcare provider about all prescription and non-prescription medicines you are taking, as well as vitamins, dietary supplements, and any natural or herbal remedies. In addition, tell your doctor about any problems you have with your heart or kidneys.

If you are pregnant, you should know that there is no information about the safety of **sotalol hydrochloride tablets (AF)** in pregnant women. Some reports indicate that sotalol hydrochloride is passed into the breast milk. Women who are taking sotalol hydrochloride tablets (AF) should not breast-feed a child.

How should I take sotalol hydrochloride tablets (AF)?

Your doctor will start you on sotalol hydrochloride tablets (AF) in the hospital and will check your heart rhythm for the first 2 or more days of treatment. This will allow your doctor to find the right dose for you. Always take the exact amount your doctor prescribes. Never change your sotalol hydrochloride tablet (AF) dose unless your doctor tells you to. Your doctor will do regular tests to check that the amount you're taking is still right for you.

Keep taking your sotalol hydrochloride tablets (AF) until your doctor tells you to stop. Keep taking it even if you feel fine. However, never take an extra dose of sotalol hydrochloride tablets (AF) even if you do not feel well. When it is time to stop taking sotalol hydrochloride tablets (AF), your doctor will give you instructions on how to gradually reduce your dose over a period of 1 to 2 weeks.

You may take sotalol hydrochloride tablets (AF) with or without food. However, it is important to take sotalol hydrochloride tablets (AF) at the same time every day. This gives your heart a steady supply of the medicine. It might be helpful to take sotalol hydrochloride tablets (AF) at the same time as something you regularly do every day.

If you are taking an antacid containing aluminum or magnesium to treat heartburn or upset stomach wait at least 2 hours after your dose of sotalol hydrochloride tablets (AF) before you take the antacid.

Never try to make up for a missed dose of sotalol hydrochloride tablets (AF). You could increase your chance of getting the different type of abnormal heartbeat. If you miss taking a dose of sotalol hydrochloride tablets (AF), just take your normal amount at the next scheduled time.

If you take more sotalol hydrochloride tablets (AF) than you should have, call your doctor right away. If you cannot reach your doctor, go to the nearest hospital emergency room. Take your sotalol hydrochloride (AF) tablets with you to show to the doctor or nurse.

What should I avoid while taking sotalol hydrochloride tablets (AF)?

Certain other medicines taken with sotalol hydrochloride tablets (AF) may increase the chance that you will get the dangerous abnormal heartbeat (see **“Who should not take sotalol hydrochloride tablets (AF)?”**). Do not take sotalol hydrochloride tablets (AF) with these medicines. Before you start taking sotalol hydrochloride tablets (AF) tell your doctor about all prescription and non-prescription medicines you are taking (see also **“Who should not take sotalol hydrochloride tablets (AF)?”**). Once you begin taking sotalol hydrochloride tablets (AF), do not start taking any new medicines until you check with your doctor.

Carry a list of all the medicines and supplements you take. If you have to go to the hospital or are treated by new or different health care providers, tell them you are taking sotalol hydrochloride tablets (AF) and show them the list of other medicines you take. They need this information to make sure your medicines are safe to take at the same time.

Tell your doctor or dentist you are taking sotalol hydrochloride tablets (AF) before you have an operation or dental surgery. Sotalol hydrochloride tablets (AF) can affect how well some anesthetics work.

What are the possible side effects of sotalol hydrochloride tablets (AF)?

Sotalol hydrochloride tablets (AF)'s most serious side effect, a different type of dangerous abnormal heartbeat, is discussed in **“What is the most important information I should know about sotalol hydrochloride tablets (AF)?”** Dangerous abnormal heartbeats happen rarely. But they can be serious and, in rare instances, can even cause death.

Sotalol hydrochloride tablet (AF)'s most common side effects are tiredness, slow rate, shortness of breath, and dizziness. Sotalol hydrochloride tablets (AF) can also cause other side effects. If you are concerned about these or any other side effects, ask your doctor.

Important points about sotalol hydrochloride tablets (AF)

Sotalol hydrochloride tablets (AF) can help you best if you take it as your doctor has prescribed it.

- Take your medicine every day as prescribed.
- Do not miss doses or take extra doses.
- Call your doctor right away if you feel new fast heartbeats with lightheadedness and fainting. These can be serious and in rare instances can even cause death.
- Do not take sotalol hydrochloride tablets (AF) if you have serious kidney problems, lung disease causing shortness of breath, symptoms of heart failure.
- Tell your doctor and pharmacist the name of all medications (prescription, non-prescription, and natural/herbal remedies) you are taking.
- Do not start taking any other medicines without telling your doctor.
- Go for all your regular checkups.
- Get your refills on time.
- Do not stop taking sotalol hydrochloride tablets (AF) until your doctor tells you to stop.

This leaflet provides a summary of information about sotalol hydrochloride tablets (AF). Your doctor or pharmacist has a longer leaflet written for healthcare professionals that you can ask to read. Sotalol hydrochloride tablets (AF) were prescribed for your particular condition. Do not use it for another condition or give it to others.

Manufactured by:
Epic Pharma, LLC
Laurelton, NY 11413

Manufactured in USA

Rev. 08-2023-00
OE1392