

**PATIENT INFORMATION ABOUT
TIKOSYN[®] (Tee' ko sin)
(generic name: dofetilide)**

This leaflet includes information about Tikosyn[®] that is important for you to know. Read this information carefully before you start taking Tikosyn. Also read it each time you get a refill of Tikosyn to see whether any information regarding your condition has changed. Talk with your doctor or pharmacist if you have any questions. The information in this leaflet cannot take the place of discussions with your health care provider.

What is the most important information I should know about Tikosyn?

Because you have irregular heartbeats (atrial fibrillation) that are troublesome to you, Tikosyn has been prescribed to help your heart to beat in a more normal way. However, in some patients Tikosyn 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 Tikosyn.

Clinical studies using Tikosyn 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 Tikosyn that is 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 Tikosyn in a hospital or another place where your heartbeat can be watched closely by health care professionals for the first few days. They can help you if problems occur. When Tikosyn is started this way, this different type of abnormal heartbeat is rare and the hospital staff are 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 Tikosyn, 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 Tikosyn capsules 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 Tikosyn 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 Tikosyn?”.

Once your doctor finds the right dose for you, always take that exact amount of Tikosyn. Never take an extra dose and never skip a dose of Tikosyn.

What is Tikosyn?

Tikosyn is 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. Tikosyn may help your heart to beat more regularly and stay beating regularly for a longer period of time.

Who should not take Tikosyn?

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

Do not take Tikosyn if you:

- are taking certain other medicines, including
 - cimetidine (TAGAMET, TAGAMET HB)*, used to treat heartburn, upset stomach, and stomach ulcers, available both by prescription and without a prescription
 - verapamil (CALAN, CALAN SR, COVERA-HS, ISOPTIN, ISOPTIN SR, VERELAN, VERELAN PM)*, used to treat high blood pressure and certain heart problems
 - ketoconazole (NIZORAL)*, used to treat certain fungus infections
 - trimethoprim alone (PROLOPRIM, TRIMPEX)* or the combination of trimethoprim and sulfamethoxazole (BACTRIM, SEPTRA)*, used to treat certain bacterial infections
 - prochlorperazine (COMPAZINE)*, used to treat nausea and vomiting
 - megestrol (MEGACE)*, used to treat certain types of cancer or loss of appetite and weight loss associated with AIDS
 - hydrochlorothiazide alone or in combination with other medicines (such as ESIDRIX, EZIDE, HYDRODIURIL, HYDRO-PAR, MICROZIDE, or ORETIC)*
- have serious kidney problems or are on kidney dialysis.

Taking certain other medicines with Tikosyn can increase the chance that you will get the dangerous abnormal heartbeat discussed in “What is the most important information I should know about Tikosyn?”. These include medicines used to treat heart conditions, high blood pressure, depression and other mental problems, asthma, allergies, hay fever, skin problems and

infections. Therefore, you should be sure to tell your health care 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, kidneys or liver.

If you are pregnant, you should know there is no information about the safety of Tikosyn in pregnant women or whether Tikosyn is passed into breast milk. Women who are taking Tikosyn should not breast feed a child.

Tikosyn is not recommended for children.

How should I take Tikosyn?

Your doctor will start you on Tikosyn in the hospital and will check your heart rhythm for the first 3 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 Tikosyn 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 Tikosyn until your doctor tells you to stop. Keep taking it even if you feel fine. However, never take an extra dose of Tikosyn, even if you do not feel well.

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

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

If you take more Tikosyn than you should have, call your doctor right away. If you cannot reach your doctor, go to the nearest hospital emergency room. Take your Tikosyn capsules with you to show to the doctor or nurse.

What should I avoid while taking Tikosyn?

Certain other medicines can increase the amount of Tikosyn in your body (see "Who should not take Tikosyn?"). This can increase your chance of getting the different type of abnormal heartbeat. Do not take Tikosyn with these medicines. Before you start taking Tikosyn tell your doctor about all prescription and non-prescription medicines you are taking (see also "Who should not take Tikosyn?"). Once you begin taking Tikosyn, 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 Tikosyn 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.

What are the possible side effects of Tikosyn?

Tikosyn'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 Tikosyn?".

Dangerous abnormal heartbeats happen rarely. But they can be serious and, in rare instances, can even cause death.

Tikosyn's most common side effects are headache, chest pain, and dizziness. Tikosyn can also cause other side effects. If you are concerned about these or any other side effects, ask your doctor.

Important points about Tikosyn

Tikosyn 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.
- Tell your doctor and pharmacist the names of all medications (prescription, non-prescription, and natural/herbal remedies) you are taking
- Do not start taking any other medicines without telling your doctor
- Do not take cimetidine (TAGAMET, TAGAMET HB)* or verapamil (CALAN, CALAN SR, COVERA-HS, ISOPTIN, ISOPTIN SR or VERELAN, VERELAN PM)* or ketoconazole (NIZORAL)*, trimethoprim alone (PROLOPRIM, TRIMPEX)* or in combination with sulfamethoxazole (BACTRIM, SEPTRA)*, prochlorperazine (COMPAZINE)* or megestrol (MEGACE)*, or hydrochlorothiazide alone or in combination with other medicines (such as ESIDRIX, EZIDE, HYDRODIURIL, HYDROPAR, MICROZIDE, or ORETIC)*
- Go for all your regular checkups
- Get your refills on time
- Do not stop taking Tikosyn until your doctor tells you to stop.

This leaflet provides a summary of information about Tikosyn. Your doctor or pharmacist has a longer leaflet written for healthcare professionals that you can ask to read. Tikosyn was prescribed for your particular condition. Do not use it for another condition or give it to others.

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LAB-0068-5.0

Revised November 2006