TIKOSYN® 500 250 125 mcg capsules
(dofetilide)

TIKOSYN+together™

Supporting you along the way with your TIKOSYN® (dofetilide) treatment

Important resources to help guide you during your TIKOSYN treatment



Please see full Prescribing Information, including BOXED WARNING and Medication Guide, starting on page 19.
Please see full IMPORTANT SAFETY INFORMATION on page 18.

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INDICATION

TIKOSYN® (dofetilide) is a medicine for highly symptomatic atrial fibrillation or atrial flutter (irregular heartbeats). TIKOSYN may help by converting the irregular heartbeats to normal rhythm. It may also help by keeping the normal rhythm for a longer period of time. It has not been shown to work on certain types of irregular heartbeats that may come and go on their own.

BOXED WARNING

To decrease the chance of your getting a different type of dangerous abnormal heartbeat, TIKOSYN treatment must be started or re-started while you are in the hospital. Feeling faint, dizziness/lightheadedness, or having fast heartbeats are symptoms of this abnormal heartbeat. Call your doctor or emergency room as soon as possible if you have any of these symptoms.

While in the hospital, your kidney function and heart rhythm will be monitored for a minimum of 3 days. This helps the doctor to choose the right TIKOSYN dose for you.



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TIKOSYNtogether™: The support you need to get the most from your TIKOSYN® (dofetilide) treatment

Committed to your treatment

The TIKOSYNtogether Support Program is committed to helping you get started with your TIKOSYN treatment. It includes resources to support you as you continue treatment with TIKOSYN. You can join TIKOSYNtogether once your healthcare provider has prescribed you TIKOSYN.

TIKOSYNtogether offers eligible TIKOSYN patients:

- A Medicine Tracker Wallet Card to help you keep track of all the medicines you are taking
- Answers to frequently asked questions about TIKOSYN
- Important information on AF/AFL
- Tips for your hospital stay
- Additional resources, including a Nurse Hotline

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What is TIKOSYN® (dofetilide)?

TIKOSYN is a prescription medicine. It affects the rhythm of your heart. It is used to treat irregular heartbeats such as atrial fibrillation (AF) and atrial flutter (AFL). It's only suited for patients who have lots of symptoms. TIKOSYN can be used to help your heart beat normally again and/or to help keep it beating that way.

TIKOSYN is a medicine that has been used since 2000.

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

TIKOSYN can cause serious side effects, including a type of abnormal heartbeat called Torsade de Pointes. This abnormal heartbeat can lead to death.

To establish the right dose of TIKOSYN, treatment with TIKOSYN must be started in a hospital where your heart rate and kidney function will be checked for the first 3 days of treatment. It is important that when you go home, you take the exact dose of TIKOSYN that your healthcare provider prescribed for you.

While you take TIKOSYN, always watch for signs of abnormal heartbeat.

Call your healthcare provider and go to the hospital **right away** if you:

- Feel faint
- Become dizzy
- Have a fast heartbeat

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Who should not take TIKOSYN® (dofetilide)?

Do not take TIKOSYN if you:

- Have an irregular heartbeat
- Have kidney problems or are on kidney dialysis
- Take any of these medicines:
  - Cimetidine (Tagamet®, Tagamet HB®)
  - Verapamil (Calan®, Calan SR®, Covera-HS®, Isoptin®, Isoptin SR®, Verelan®, Verelan PM®, Tarka®)
  - Ketoconazole (Nizoral®, Xolegel®, Extina®)
  - Trimethoprim alone (Proloprim®, Trimpex®), the combination of trimethoprim and sulfamethoxazole (Bactrim®, Septra®, Sulfatrim®)
  - Prochlorperazine (Compazine®, Compro®)
  - Megestrol (Megace®)
  - Dolutegravir (Tivicay®)
  - Hydrochlorothiazide alone or in combination with other medicines (such as Esidrix®, Ezide®, Hydrodiuril®, Hydro-Par®, Microzide®, or Oretic®)

Ask your healthcare provider if you are not sure if any of your medicines are the kind listed above.

- Are allergic to dofetilide in TIKOSYN

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TIKOSYN® 500 250 125 mcg capsules
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Why am I taking TIKOSYN?

TIKOSYN has been prescribed to you because you have many symptoms from AF/AFL. TIKOSYN may help your heart beat in a normal way. It can be used if you have structural heart disease, congestive heart failure, or have suffered a heart attack.

It is not known if TIKOSYN works and is safe in children younger than 18 years of age.

How should I take TIKOSYN?

You must take TIKOSYN exactly as your healthcare provider tells you to. After your hospital stay, you will know what your personal TIKOSYN dose is. Then, it's important you take that dose every day. Your healthcare provider will tell you more about the best time of day to take TIKOSYN.

- Always listen to all of your healthcare provider's instructions about TIKOSYN. Keep these in mind:
  - Do not change your TIKOSYN dose unless your healthcare provider tells you to
  - **If you miss a dose, just take the next dose at your regular time. Do not take 2 doses of TIKOSYN at the same time**
  - Never take an extra dose of TIKOSYN, no matter how you feel
  - If you take too much TIKOSYN:
    - Call your healthcare provider or go to the nearest hospital emergency room right away
    - Take your TIKOSYN capsules with you to show to the healthcare provider
- Keep all your appointments for tests. Your healthcare provider may need to check your kidney and heart every 3 months to make sure the dose you are taking is still right for you
- Take TIKOSYN with or without food
- Do not stop taking TIKOSYN until your healthcare provider tells you to stop

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What should I tell my healthcare provider before taking TIKOSYN® (dofetilide)?

Tell your healthcare provider about all of your medical conditions, including if you:

- Have heart problems
- Have kidney or liver problems
- Are pregnant or plan to become pregnant. It is not known if TIKOSYN will harm your unborn baby
- Are breast-feeding or plan to breast-feed. It is not known if TIKOSYN passes into your breast milk

Tell your healthcare provider if you take medicines to treat:

- Heart problems
- High blood pressure
- Depression or other mental illnesses
- Asthma
- Allergies or hay fever
- Skin problems
- Infections

TIKOSYN and other medicines may affect each other. This can cause serious side effects.

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Ask your healthcare provider if you are not sure about the medicines you take.
Tell your healthcare provider about all:

- Prescription and nonprescription medicines
- Natural or herbal remedies
- Dietary supplements
- Vitamins

Know the medicines you take. Keep a list of them. Show it to your healthcare provider and pharmacist when you get a new medicine. Tell all of your healthcare providers that you are taking TIKOSYN.



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Are there any side effects from TIKOSYN® (dofetilide)?

Like other medicines, TIKOSYN can cause side effects. In fact, TIKOSYN can cause serious side effects. They include a type of abnormal heartbeat called Torsade de Pointes, which can lead to death. Taking the right dose can reduce the risk. TIKOSYN is started in the hospital. This is to make sure you get the right dose. And if this side effect occurs, healthcare providers will be there to take care of you. If you have concerns, talk to your healthcare provider.

The most common side effects of TIKOSYN include:

- Headache
- Chest pain
- Dizziness

TIKOSYN can cause other side effects. Tell your healthcare provider if you have any side effects that bother you or do not go away. For more information, ask your healthcare provider or pharmacist. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

If I have any questions about TIKOSYN, whom should I call?

If you have any questions about TIKOSYN, there are a number of things you can do:

- Contact the healthcare provider who prescribed you TIKOSYN
- Contact your local pharmacist
- Call our Nurse Hotline at: 1-877-TIKOSYN (1-877-845-6796)



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What is arrhythmia?

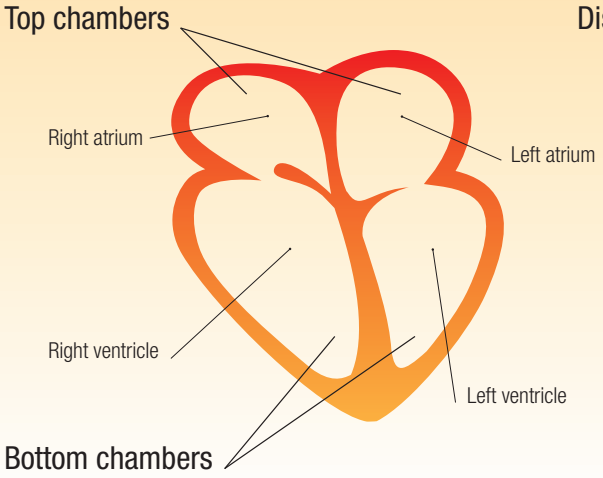
An arrhythmia is a medical term for an abnormal heartbeat. Your heart can beat too slow, too fast, or in an unusual pattern. There are many kinds of arrhythmias. They can happen in any part of the heart. Here, you'll learn about 2 kinds of arrhythmias. They happen in parts of your heart called the atria. The first is called atrial fibrillation (AF). The second is called atrial flutter (AFL).

What are AF and AFL?

AF and AFL are arrhythmias that happen in parts of your heart called the atria. Your heart has 4 parts, or "chambers." The atria are the top 2 chambers. The bottom 2 chambers are called the ventricles. Normally, these chambers tighten and relax on a regular basis.

In AF/AFL, the atria beat very quickly. The beats can be disorganized. The timing of their beat with the ventricles can be off, too.

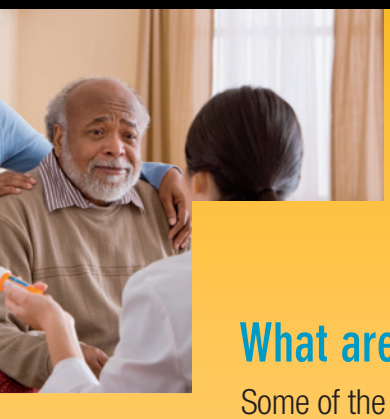
Chambers of your heart



Disorganized and rapid signals in AF



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What are the signs of AF/AFL?

Some of the symptoms you might feel are:

- Irregular and rapid pulse
- Heart palpitations
- Dizziness, sweating, and chest pain or pressure
- Shortness of breath or anxiety
- Tiring more easily, especially when exercising
- Fainting

The symptoms you feel may come and go. Or they may be constant. If you have any of these symptoms, your healthcare provider can check your heartbeat using an electrocardiogram, or ECG, recording.

What are the risks of AF/AFL?

In AF/AFL, your heart doesn't pump blood as well as normal. Blood carries oxygen to your cells. So in AF/AFL, your cells don't get as much oxygen. This can make you feel tired. Also, when your heart doesn't pump normally, you can have low blood pressure. This can make you pass out.

AF/AFL can lead to these and other serious conditions if not treated:

- Chronic fatigue—if you're not getting enough blood, you may feel tired
- Heart failure—prolonged AF/AFL can weaken the heart, making heart failure more likely
- Stroke—when your heart doesn't pump blood normally, blood can pool in your heart. This can cause clots to form. If these clots travel to the brain or lungs, they can stop the flow of blood. This can cause a stroke in the brain. This can also lead to a blood clot stuck in the lungs (pulmonary embolism). Either of these may lead to death

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Types of treatment for AF/AFL

Before your treatment, your healthcare provider might ask you questions about your medical history and lifestyle. There might be a disease or habit causing your AF/AFL. If the disease is treated or the habit changed, the arrhythmia may go away.

There are a number of reasons your healthcare provider may choose one treatment over another. Your healthcare provider will consider:

- Your medical history
- Your type of arrhythmia
- Other conditions you might have

Then your healthcare provider will determine which treatment is right for you.

Cardioversion

With AF/AFL, your healthcare provider may attempt to restore your heartbeat to a regular and controlled rhythm. This is called normal sinus rhythm. The process of restoring rhythm is called cardioversion. Cardioversion can happen in 2 ways:

- Rhythm-control medicines
- Direct-current cardioversion—when electricity is applied directly to the heart

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Types of treatment for AF/AFL (continued)

"Maze" Procedure

AF/AFL can sometimes be treated with certain procedures. One type, done using surgery, is called the "maze" procedure:

- The electrical signals in your heart will be slowed by a "maze"
- This "maze" is created through small cuts. These cuts are stitched up and allowed to scar over
- The scars redirect electrical signals, slowing them down

Catheter Ablation

Your healthcare provider may also consider catheter ablation. There are a few steps in this process:

- A catheter is used to reach the heart to block and correct electrical signals
- Radio waves are sent through the catheter
- These waves create small scars in specific places on heart tissue
- This blocks electrical signals to help ensure they travel the right way

Catheter ablation can be used in 2 ways:

- "Hot spot" ablation—scars are made on areas along the vein that carry blood to your lungs
- Atrioventricular (AV) node ablation—the AV node sends electrical signals from the atria to the ventricles. In AV node ablation, scars are made on the node. A pacemaker, a device used to control your heartbeat, may then be inserted

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Your Hospital Stay

Your TIKOSYN dose is an important factor in your treatment. Your healthcare provider will want to make sure you are getting the dose that's right for you. This will help decrease your chance of getting a type of heartbeat that is potentially dangerous. There are 2 types of tests to find this dose. They are:

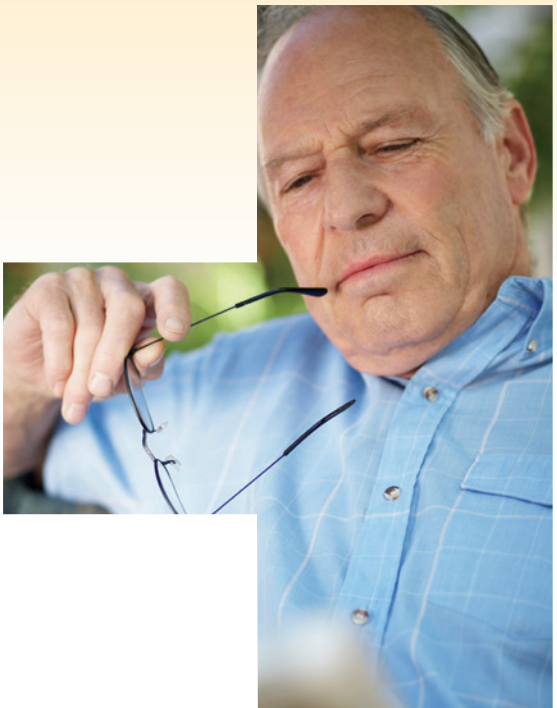
- Blood tests—your healthcare provider will test a small amount of your blood to check your kidney function
- Continuous heart monitoring—a painless test done using an electrocardiogram, or ECG, machine

The hospital is the best place to do these tests and to treat potentially dangerous abnormal heartbeats. For these reasons, a TIKOSYN prescription starts with a 3-day hospital stay. There will be a team of medical staff who will support you while you are there. This will help make sure you get the dose that is right for you.

Preparing for your hospital stay

Before you go to the hospital, ask your healthcare provider about things you may want to bring along. Some suggestions:

- Identification
- Insurance information
- Medications from home
- A notebook for any questions you may have



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During your stay

Think about packing things like clothing, pajamas, and toiletries. Different hospitals have different rules on personal items. Be sure to call ahead to check.

Outside of your blood tests and ECG monitoring, you may want to bring things to stay busy. Consider bringing:

- Journal and/or diary
- Books/tablet/e-reader/laptop
- Portable entertainment devices
- Hobbies, like drawing or sewing

Heading home

Your 3 days will be over before you know it. When you leave, you should be given a 7-day supply of TIKOSYN® (dofetilide). But before you leave, make sure you have everything you need from your healthcare provider. Review the TIKOSYN Medication Guide. Be sure you understand how to take your TIKOSYN. Ask any questions you may have. These may include:

- What is my TIKOSYN dose?
- How do I take TIKOSYN?
- When do I take TIKOSYN?
- What kind of side effects or warnings should I be aware of?

You'll also need to make appointments with your healthcare provider. Your healthcare provider may want to see you every 3 months after your treatment. This is to check your kidney and heart functions. Your healthcare provider will make sure your dose is right.

- Be sure to schedule your first follow-up appointment. You can do it before you leave the hospital
- Ask your healthcare provider about locating a pharmacy where you can fill your TIKOSYN prescription

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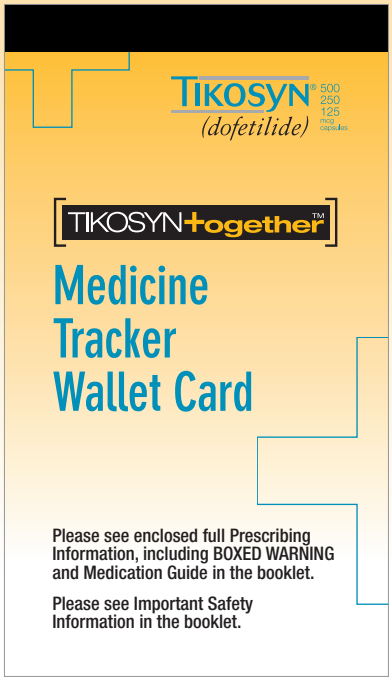
Your Medicine Tracker Wallet Card: An easy way to keep track of all your medicines

It's important to know how TIKOSYN and the other medicines you take affect each other. With this card, you can make a list of all of your medicines, nonprescription medicines, supplements, and vitamins. Its portable size allows you to bring it with you everywhere you go for quick reference. Share it with your healthcare provider whenever you discuss which medications you are prescribed.

This card also has:

- List of medicines you should not take while you are on TIKOSYN
- TIKOSYN dosing tips
- Helpful reminders about what to do if you miss a dose





If you are interested in receiving a printed kit, including this Medicine Tracker Wallet Card, please visit TIKOSYN.com or call 1-877-TIKOSYN (1-877-845-6796) to order.

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REFILLS+

Flexibility and convenience in filling your TIKOSYN prescription

To help you find the right pharmacy that prescribes TIKOSYN:

- Visit www.TIKOSYN.com to search for the pharmacy nearest you



TIKOSYN Home Delivery

With TIKOSYNtogether™, you have the option to sign up to have TIKOSYN delivered directly to your home or office. To sign up, ask your doctor to call **1-844-283-9338**.

SUPPORT+

Nurse Hotline available daily

With TIKOSYNtogether, you can speak to a nurse who can help you with your treatment. Call if you have questions about TIKOSYN. Nurses are available every day at **1-877-TIKOSYN (1-877-845-6796)**.

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To decrease the chance of your getting a different type of dangerous abnormal heartbeat, TIKOSYN treatment must be started or re-started while you are in the hospital. Feeling faint, dizziness/ lightheadedness, or having fast heartbeats are symptoms of this abnormal heartbeat. Call your doctor or emergency room as soon as possible if you have any of these symptoms.

While in the hospital, your kidney function and heart rhythm will be monitored for a minimum of 3 days. This helps the doctor to choose the right TIKOSYN dose for you.

Do not take TIKOSYN if you have congenital or acquired long QT syndrome (a disorder of the heartbeat which may be present from birth, or it may be acquired as a result of certain medical conditions or from taking certain medications. People with long QT syndrome may have symptoms including an unusually rapid heartbeat, fainting, and seizures. Sudden cardiac death may also result from long QT syndrome); have serious kidney problems or are on kidney dialysis; are taking certain other medicines, including cimetidine (Tagamet®, Tagamet HB®), verapamil (Calan®, Calan SR®, Covera-HS®, Isoptin®, Isoptin SR®, Verelan®, Verelan PM®), ketoconazole (Nizoral®), trimethoprim alone (Proloprim®, Trimpex®), the combination of trimethoprim and sulfamethoxazole (Bactrim®, Septra®), prochlorperazine (Compazine®), megestrol (Megace®), dolutegravir (Tivicay®) or hydrochlorothiazide alone or in combination with other medicines (such as Esidrix®, Ezide®, Hydrodiuril®, Hydro-Par®, Microzide®, or Oretic®); or are allergic to dofetilide or other ingredients in TIKOSYN.

The most common side effects of TIKOSYN 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.

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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full Prescribing Information, including BOXED WARNING and Medication Guide, on following pages.

For more information, please visit www.TIKOSYN.com.

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