Risk Evaluation and Mitigation Strategy (REMS)

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

Risks associated with TIKOSYN

In order for Pfizer to communicate certain risks about TIKOSYN, Pfizer has worked with the FDA to develop materials to communicate the risk of induced arrhythmia.

The goals of the REMS for TIKOSYN are to mitigate the risk of TIKOSYN induced arrhythmia by:

- Ensuring that TIKOSYN is prescribed only by certified prescribers, and dispensed only by certified dispensers;

- Educating health care providers about the risks and the need to initiate and re-initiate therapy in a health care facility that can provide calculations of creatinine clearance, continuous electrocardiographic monitoring, and cardiac resuscitation;

- Informing patients about the serious risks associated with TIKOSYN therapy.

TIKOSYN is indicated for the conversion to and maintenance of normal sinus rhythm (delay in the time to recurrence of atrial fibrillation/atrial flutter) in highly symptomatic patients with atrial fibrillation/atrial flutter of greater than 1 week.

To minimize the risk of induced arrhythmia, patients initiated or re-initiated on TIKOSYN should be placed for a minimum of 3 days in a facility that can provide calculations of creatinine clearance, continuous electrocardiographic monitoring, and cardiac resuscitation (for detailed instructions regarding dose selection, see DOSAGE AND ADMINISTRATION). TIKOSYN is available only to hospitals and prescribers who have received appropriate TIKOSYN dosing and treatment initiation education (see DOSAGE AND ADMINISTRATION). For full Prescribing information, please click here.
Prescribers

Per FDA requirements, in order to prescribe TIKOSYN new prescribers are required to complete a one-time certification. Even if you have been certified prior to 2011, you are required to secure a one-time recertification. To become (re)certified you must review the following materials:

TIKOSYN Treatment Guidelines
Prescribing Information
Medication Guide

When you have reviewed all the materials, please print, sign, and mail or fax the Prescriber Certification Form. The fax number is 1-800-788-2637. After we have received your certification form, we will send a written confirmation of receipt.

In addition to your certification, retail pharmacies and institutional pharmacies must also be certified in order to dispense TIKOSYN. Before dispensing a prescription for TIKOSYN, the pharmacist must confirm that you are a health care professional who has been certified and is listed in the Pfizer National TIKOSYN Database.

It is important that you tell your patients to fill their TIKOSYN prescriptions as soon as possible after they are discharged to avoid any disruptions in their treatment. Although patients must be provided with TIKOSYN upon discharge, it may take a few business days for the pharmacy to order TIKOSYN for subsequent prescriptions.

Contact us
Should you have any questions regarding the certification program, please call 1-877-TIKOSYN.

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Institution Pharmacy

Per FDA requirements, in order to order, stock, and dispense TIKOSYN new pharmacies are required to secure a one-time certification. Even if your institution has been certified prior to 2011, you are required to secure a one-time recertification. To become (re)certified you must review the following materials:

TIKOSYN Treatment Guidelines
Prescribing Information
Medication Guide

And sign the Institution Certification Form:

NOTE: A designated representative must complete and sign this form as part of the TIKOSYN REMS requirement.

Institution Certification Form

When you have reviewed all the materials, please print, sign, and mail or fax back the Certification Form. The fax number is 1-800-788-2637. After the Certification Form is received, you will receive written confirmation of receipt. In addition, before dispensing TIKOSYN, you are required to confirm that the prescriber has been certified.

Before dispensing TIKOSYN, the pharmacist is required to confirm that the prescriber has been certified. In addition, the institution must agree to stock and provide patients prior to discharge a free 7-day (14 count) supply of TIKOSYN and the Medication Guide. As a contingency, if the initiating/re-initiating institution does not have outpatient licensing privileges to dispense the free 7-day supply of TIKOSYN, the institution will ensure the patient’s take home prescription is ordered and filled at a retail pharmacy prior to patient discharge.

Contact us
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Pharmacy

Per FDA requirements, to order and dispense TIKOSYN retail pharmacies are required to secure a one-time certification. Even if you have been certified prior to 2011, you are required to secure a one-time recertification.

To become (re)certified you must review and follow the TIKOSYN In Pharmacy System (T.I.P.S.™) certification procedures below and (re)enroll in the T.I.P.S. Program:

- Review the Prescribing Information, including the Medication Guide and Treatment Guidelines
- Complete the TIKOSYN Pharmacy Certification Form
- Sign and fax the form to 1-800-788-2637
- After 1 to 2 business days, confirm your certification by calling 1-877-TIKOSYN (1-877-845-6796) or visit www.tikosynlist.com. You will need to enter your pharmacy DEA number
- Your signature on the TIKOSYN certification form acknowledges that the appropriate staff members in your pharmacy are aware of the procedures for dispensing TIKOSYN
- The T.I.P.S. Kit (Procedure Booklet and Display Piece) is available here. Please post the T.I.P.S. program procedures, and TIKOSYN contraindications in your pharmacy.

Corporate Pharmacy Enrollment (certifying multiple pharmacies)
For corporate pharmacy enrollment you must print out a copy of the blank Pharmacy Certification Form and complete the required fields.
A list of pharmacy sites that have been trained should be included as a separate attachment: this list must include the same required Pharmacy Information detailed on the enrollment form for EACH pharmacy.
Both the completed form and the attached list of pharmacy site information should be emailed to TIKOSYNREMS@UBC.com

Through pharmacy certification the pharmacy acknowledges that:

- The pharmacist will verify that a prescriber has participated in the TIKOSYN REMS and is confirmed in the Pfizer National TIKOSYN Database before dispensing.
- The pharmacist will dispense a Medication Guide with each prescription.

Contact us
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Reference ID: 3789274
instructions regarding dose selection, see **DOSAGE AND ADMINISTRATION**. TIKOSYN is available only to hospitals and prescribers who have received appropriate TIKOSYN dosing and treatment initiation education (see **DOSAGE AND ADMINISTRATION**). For full Prescribing information, please [click here](http://pftikosynremdev.prod.acquia-sites.com/pharmacies/).
This Web site allows pharmacies that have completed the TIKOSYN Risk Evaluation and Mitigation Strategy (REMS) Program to verify the status of TIKOSYN prescribers affiliated with your hospital.

**PHARMACY DEA/NABP LOOKUP**

To access this system, please enter your Pharmacy DEA or NABP number.

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**Important Safety Information**

To minimize the risk of induced arrhythmia, patients initiated or re-initiated on TIKOSYN should be placed for a minimum of 3 days in a facility that can provide calculations of creatinine clearance, continuous electrocardiographic monitoring, and cardiac resuscitation. TIKOSYN is available only to hospitals and prescribers who have received appropriate TIKOSYN dosing and treatment initiation education.

TIKOSYN is contraindicated in patients with congenital or acquired long QT syndromes, a baseline QT interval or QTc >440 msec (500 msec in patients with ventricular conduction abnormalities), severe renal impairment (calculated creatinine clearance <20 mL/min), or known hypersensitivity to TIKOSYN.

TIKOSYN is also contraindicated with verapamil, hydrochlorothiazide (alone or in combination, such as with triamterene), and cation transport system inhibitors such as cimeide, ketoconazole, trimethoprim (alone or in combination with sulfamethoxazole), prochlorperazine, dolutedegravir and megestrol because these drugs may cause an increase in dofetilide plasma concentration.

TIKOSYN can cause serious ventricular arrhythmias, primarily torsade de pointes type ventricular tachycardia, a polymorphic ventricular tachycardia associated with QT interval prolongation. QT interval prolongation is directly related to dofetilide plasma concentrations. Factors such as reduced creatinine clearance or certain doxilide drug interactions will increase dofetilide plasma concentrations. The risk of TdP can be reduced by controlling the plasma concentration through adjustment of the initial dofetilide dose according to creatinine clearance and by monitoring the ECG for excessive increases in the QT interval. Calculation of creatinine clearance and QTc for all patients must precede administration of the first dose of TIKOSYN. Renal function and QTc should be re-evaluated every 3 months or as medically warranted.

The most common adverse events reported were headache, chest pain, dizziness, respiratory tract infection, dyspnea, and nausea.

**Indication**

TIKOSYN is indicated for the maintenance of normal sinus rhythm (delay in time to recurrence of atrial fibrillation/atrial flutter [AF/AFi]) in patients with atrial fibrillation/atrial flutter of greater than one week duration who have been converted to normal sinus rhythm. Because TIKOSYN can cause life-threatening ventricular arrhythmias, it should be reserved for patients in whom atrial fibrillation/atrial flutter is highly symptomatic. In general, antiarrhythmic therapy for atrial fibrillation/atrial flutter aims to prolong the time in normal sinus rhythm. Recurrence is expected in some patients.

TIKOSYN is indicated for the conversion of atrial fibrillation and atrial flutter to normal sinus rhythm.

TIKOSYN has not been shown to be effective in patients with paroxysmal atrial fibrillation.