Available in Retail Pharmacy

T.I.P.S.™
Procedures Booklet

Welcome to the TIKOSYN In Pharmacy System (T.I.P.S.) program

Boxed Warning

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.

Please see accompanying full Prescribing Information, including Boxed Warning, and Medication Guide.
The T.I.P.S. procedures booklet will guide you through the program's 3 steps: Enroll, Order, and Dispense TIKOSYN® (dofetilide). If you have any questions about TIKOSYN or any of the T.I.P.S. program procedures, or if you need additional program supplies, please call 1-877-TIKOSYN or visit www.TIKOSYNREMS.com.

TIKOSYN® (dofetilide) is indicated for the maintenance of normal sinus rhythm (delay in time to recurrence of atrial fibrillation/atrial flutter [AF/AFL]) 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® (dofetilide) 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.

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Selected Safety Information

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.

Please see accompanying full Prescribing Information, including Boxed Warning, and Medication Guide.
Enrolling in T.I.P.S

You must enroll in the T.I.P.S. program to order and dispense TIKOSYN® (dofetilide).

To enroll in the T.I.P.S. program

- Complete the enclosed TIKOSYN Pharmacy Certification Form
- Sign and fax the form to 1-800-788-2637
- After 1 to 2 business days, confirm your enrollment by calling 1-866-249-7261 or visiting www.TIKOSYNLIST.com. You will need to enter your pharmacy DEA number
- Your signature on the enclosed TIKOSYN certification form acknowledges that the appropriate staff members in your pharmacy are aware of the procedures for dispensing TIKOSYN

Ordering TIKOSYN

Enrollment in the T.I.P.S. program must be completed before you place an order for TIKOSYN® (dofetilide).

To order

- NOTE: TIKOSYN can only be prescribed by Prescribers who are certified in the TIKOSYN Risk Evaluation and Mitigation Strategy (REMS) program. Please provide the Certified Prescriber’s DEA number associated with each order for TIKOSYN
- Order TIKOSYN through your wholesaler
- TIKOSYN® (dofetilide) is available only in bottles of 60 capsules in 3 dosage strengths: 125, 250, and 500 mcg
- All TIKOSYN orders will be drop-shipped directly to your pharmacy

Selected Safety Information

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

Please see accompanying full Prescribing Information, including Boxed Warning, and Medication Guide.
Dispensing TIKOSYN® (dofetilide)

Prescriber must be a confirmed registrant in the TIKOSYN REMS program before TIKOSYN is ordered through your wholesaler or dispensed by the pharmacy.

Before ordering or dispensing a prescription for TIKOSYN, you must confirm that the prescriber is a healthcare professional who has registered for the TIKOSYN REMS program and is listed in the TIKOSYN confirmed registrant database.

To verify that a prescriber is a registrant in the program, access the program database by calling 1-866-249-7261 or visiting www.TIKOSYNLIST.com and entering your pharmacy DEA number.

- **DO NOT** order or dispense TIKOSYN® (dofetilide) if prescriber participation in the TIKOSYN REMS program cannot be verified. Refer these prescribers to 1-866-249-7261 to speak to a TIKOSYN Customer Service Representative.

- Dispense TIKOSYN as prescribed in accordance with standard pharmacy practice (TIKOSYN must be ordered directly from Pfizer per individual prescription).

- Prescriptions filled according to standard pharmacy practice are subject to standard periodic review processes to ensure compliance with these conditions.

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**Selected Safety Information**

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

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We thank you for your interest in Pfizer and hope this information is helpful. If you would like additional information about TIKOSYN or the T.I.P.S. program, please call 1-877-TIKOSYN or visit www.TIKOSYNREMS.com.

Please see accompanying full Prescribing Information, including Boxed Warning, and Medication Guide.
Indication

TIKOSYN (dofetilide) is indicated for the maintenance of normal sinus rhythm (delay in time to recurrence of atrial fibrillation/atrial flutter [AF/ATL]) 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.

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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 thiazides), and calcium transport system inhibitors such as triamterene, hydrochlorothiazide, spironolactone (alone or in combination with amiloride), propranolol, megestrol, and dolasetron 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 dofetilide drug interactions will increase dofetilide plasma concentration. 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.

Please see accompanying full Prescribing Information, including Boxed Warning, and Medication Guide.