Dofetilide Capsules 125mcg, 250mcg and 500mcg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	**Maintenance of Normal Sinus Rhythm (Delay in AF/AFl Recurrence)** Dofetilide capsules are 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 dofetilide capsules 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. **Conversion of Atrial Fibrillation/Flutter** Dofetilide capsules are indicated for the conversion of atrial fibrillation and atrial flutter to normal sinus rhythm. Dofetilide capsules have not been shown to be effective in patients with paroxysmal atrial fibrillation.
2	Dosage	What is the recommended dosage?	The dose of dofetilide capsules must be individualized according to calculated creatinine clearance and QTc. (QT interval should be used if the heart rate is <60 beats per minute. There is no data on use of dofetilide capsules when the heart rate is <50 beats per minute.) The usual recommended dose of dofetilide capsules are 500 mcg twice a day (BID), as modified by the dosing algorithm. For consideration of a lower dose, see Prescribing Information.
3	Administration	How to administer?	• Take dofetilide capsules exactly as your doctor tells you. • Do not change your dofetilide capsules dose unless your doctor tells you to. • Your doctor will do tests before you start and while you take dofetilide capsules. • Do not stop taking dofetilide capsules until your doctor tells you to stop. If you miss a dose, just take the next dose at your regular time. Do not take 2 doses of dofetilide capsules at the same time. • Dofetilide capsules can be taken with or without food. • If you take too much dofetilide capsules, call your doctor or go to the nearest hospital

			emergency room right away. Take your dofetilide capsules with you to show to the doctor.
4	Administration	Can tablet be chewed?	Take dofetilide capsules exactly as your doctor tells you.
5	Administration	Use in Pediatric Population	The safety and effectiveness of dofetilide in children (<18 years old) has not been established.
6	Administration	Use in Geriatric Population	No overall differences in safety, effect on QTc, or effectiveness were observed between elderly and younger patients. Because elderly patients are more likely to have decreased renal function with a reduced creatinine clearance, care must be taken in dose selection
7	Mechanism	Mechanism of Action	Dofetilide shows Vaughan Williams Class III antiarrhythmic activity. The mechanism of action is blockade of the cardiac ion channel carrying the rapid component of the delayed rectifier potassium current, I_{Kr}. At concentrations covering several orders of magnitude, dofetilide blocks only I_{Kr} with no relevant block of the other repolarizing potassium currents (e.g., I_{Ks}, I_{K1}). At clinically relevant concentrations, dofetilide has no effect on sodium channels (associated with Class I effect), adrenergic alpha-receptors, or adrenergic beta-receptors.
8	Warning	Black Box Warning	To minimize the risk of induced arrhythmia, patients initiated or re-initiated on dofetilide capsules 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 Prescribing Information.
9	Lactation	Use in Lactation	There is no information on the presence of dofetilide in breast milk. Patients should be advised not to breast-feed an infant if they are taking dofetilide. Before taking dofetilide capsules, tell your doctor about breast-feeding or plan to breast-feed.
10	Pregnancy	Use in Pregnancy	There are no adequate and well controlled studies in pregnant women. Therefore, dofetilide should only be administered to pregnant women where the benefit to the patient justifies the potential risk to the fetus. Before taking dofetilide capsules, tell your doctor if you are pregnant or plan to become pregnant.
12	Storage	What are the storage conditions?	Store at 15° to 30° C (59° to 86° F). **Protect from moisture and humidity.**
13	Dispensing	How to Dispense?	Dispense in tight, child-resistant containers.
14	Contraindication	What are the contraindications of (medication).	Dofetilide is contraindicated in patients with congenital or acquired long QT syndromes. Dofetilide should not be used in patients with a baseline QT interval or QTc >440 msec (500 msec in patients with ventricular conduction abnormalities). Dofetilide is also contraindicated in patients with severe renal impairment (calculated creatinine clearance <20 mL/min).

			The concomitant use of verapamil or the cation transport system inhibitors cimetidine, trimethoprim (alone or in combination with sulfamethoxazole), or ketoconazole with dofetilide is contraindicated, as each of these drugs cause a substantial increase in dofetilide plasma concentrations. In addition, other known inhibitors of the renal cation transport system such as prochlorperazine, dolutegravir and megestrol should not be used in patients on dofetilide. The concomitant use of hydrochlorothiazide (alone or in combinations such as with triamterene) with dofetilide is contraindicated because this has been shown to significantly increase dofetilide plasma concentrations and QT interval prolongation. Dofetilide is also contraindicated in patients with a known hypersensitivity to the drug.
15	Drug Interactions	Any Drug Interactions?	**Drug-Drug Interactions** • Concomitant use Cimetidine, Verapamil, Ketoconazole, Trimethoprim Alone or in Combination with Sulfamethoxazole and Hydrochlorothiazide (HCTZ) Alone or in Combination with Triamterene were contraindicated. • Dofetilide is eliminated in the kidney by cationic secretion. Inhibitors of renal cationic secretion are contraindicated with dofetilide. • For complete Drug interactions, please refer to Prescribing information.
Pharmaceutical Particulars			
16	Pharmaceutical Form	How is it supplied?	Dofetilide capsules are supplied for oral administration in three dosage strengths: 125 mcg (0.125 mg) light orange and white capsules, 250 mcg (0.25 mg) peach capsules, and 500 mcg (0.5 mg) peach and white capsules.
17	Ingredients	Active and Inactive	Active ingredient: Dofetilide Inactive ingredients: magnesium stearate, pregelatinized starch, silicified microcrystalline cellulose. The capsule shell contains titanium dioxide, FD&C yellow 6 and gelatin, additionally 125 mcg capsule shell contains D&C yellow 10 and FD&C red 40. The printing ink contains iron oxide black, shellac, propylene glycol and potassium hydroxide.
Allergens			
18	Ingredients	Does it contain Gluten?	No
19	Ingredients	Does it contain alcohol?	Dofetilide API contains Methonal NMT 3000 PPM
20	Ingredients	Does it contain dyes?	FD&C Yellow 6, FD&C Red 4 & D&C Yellow 10, Colorant used in EHF Capsule shells
21	Ingredients	Does it contain Lactose?	No
22	Ingredients	Does it contain Nuts?	No
23	Ingredients	Does it contain Preservatives?	No
25	Ingredients	Does it contain Soy products?	No

26	Ingredients	Are all excipients are free from human or animal origin?	Yes
27	Ingredients	Other Substances	Dofetilide Capsules 125mcg, 250mcg and 500mcg were free from Latex, Casein, Whey, Rye, Corn, Sugar, Oats, Wheat, Spelt, Barley and Rennet.
Miscellaneous			
28	Miscellaneous	May I know the product availability?	Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products
29	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
30	Miscellaneous	Do you have any patient's assistance program?	Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company.
31	Miscellaneous	How do I report an adverse drug effect or reaction to Novadoz medication?	To report SUSPECTED ADVERSE REACTIONS, contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
32	Miscellaneous	Why does my pharmacy that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products
33	Miscellaneous	May I know where is this product manufactured?	**Manufactured by:** MSN Laboratories Private Limited Telangana – 509 228, INDIA **Distributed by:** Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714