DABIGATRAN ETEXILATE Capsules USP 75 mg, 110 mg and 150 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1.	Use/Indication	What is the product indicated for?	Dabigatran etexilate capsules are a direct thrombin inhibitor indicated • To reduce the risk of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation. • For the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in adult patients who have been treated with a parenteral anticoagulant for 5-10 days. • To reduce the risk of recurrence of DVT and PE in adult patients who have been previously treated. • For the prophylaxis of DVT and PE in adult patients who have undergone hip replacement surgery.
2.	Dosage	What is the recommended dosage?	Dabigatran Etexilate Dosing Recommendations: 1. ***Non-Valvular Atrial Fibrillation (NVAF) in Adult Patients:*** o CrCl > 30 mL/min: 150 mg orally twice daily. o CrCl 15-30 mL/min: 75 mg orally twice daily. 2. ***Treatment of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE) in Adult Patients:*** o CrCl > 30 mL/min: 150 mg orally twice daily, following 5-10 days of parenteral anticoagulation. 3. ***Reduction in the Risk of Recurrence of DVT and PE in Adult Patients:*** o CrCl > 30 mL/min: 150 mg orally twice daily, following previous treatment. 4. ***Prophylaxis of DVT and PE Following Hip Replacement Surgery in Adult Patients:*** o CrCl > 30 mL/min: 110 mg orally on the first day, followed by 220 mg orally once daily. 5. ***Important Notes:*** o Dabigatran etexilate capsules are not interchangeable on a milligram-to-milligram basis with other dosage forms of dabigatran etexilate. o Carefully review guidelines for converting to or from other oral or parenteral anticoagulants to ensure proper management.

3.	Administration	How do I take it?	• Take the capsules with a full glass of water. • If gastrointestinal distress occurs, consider taking the capsule with food to help minimize discomfort. • Temporarily discontinue dabigatran etexilate capsules before invasive or surgical procedures when possible, then restart promptly
4.	Formulation	Can capsule be crushed?	Dabigatran etexilate capsules should be swallowed whole. Do not break, chew, or empty the contents of the capsule, as this may increase drug exposure.
5.	Administration	What do I do if I miss a dose?	• If a dose is missed, take it as soon as possible on the same day. • If it is less than 6 hours before the next scheduled dose, skip the missed dose. • Do not double the dose to make up for a missed dose.
6.	Administration	Use in Pediatric Population	The safety and efficacy of dabigatran etexilate capsules have not been established in pediatric patients with non-valvular atrial fibrillation or those who have undergone hip replacement surgery.
7.	Administration	Use in Geriatric Population	The risk of bleeding increases with age, but the risk-benefit profile is favorable in all age groups.
8.	Mechanism	Mechanism of Action	Dabigatran and its acyl glucuronides are competitive, direct thrombin inhibitors. Because thrombin (serine protease) enables the conversion of fibrinogen into fibrin during the coagulation cascade, its inhibition prevents the development of a thrombus. Both free and clot-bound thrombin, and thrombin-induced platelet aggregation are inhibited by the active moieties.
9.	Warning	Black Box Warning	**(A)** ***Risk of Thrombotic Events Due to Premature Discontinuation of Dabigatran*** Premature discontinuation of dabigatran, or any oral anticoagulant, significantly increases the risk of thrombotic events. To mitigate this risk, consider transitioning to another anticoagulant if dabigatran is stopped for reasons other than active pathological bleeding or the completion of a prescribed course of therapy. **(B)** ***Risk of Spinal/Epidural Hematoma*** Epidural or spinal hematomas may occur in patients receiving dabigatran who are undergoing neuraxial anesthesia or spinal puncture. These hematomas have the potential to cause long-term or permanent paralysis. Patients should be closely monitored for neurological impairment, and any signs of such impairment should be treated as a medical emergency. Careful consideration of the risks and benefits is essential before proceeding with neuraxial interventions in patients who are currently anticoagulated or require anticoagulation therapy.
10.	Lactation	Use in Lactation	Breastfeeding is not recommended during treatment with dabigatran.

11.	Pregnancy	Use in Pregnancy	Inform healthcare provider immediately if became pregnant or intend to become pregnant during treatment with dabigatran
12.	Interaction	Is there any interaction between medication and other drugs?	Avoid coadministration with dabigatran If using P-gp inhibitors in adult patients with CrCl 30 to 50 mL/min: Reduce dose or avoid If P-gp inhibitors in adult patients with CrCl <30 mL/min: Not recommended
13.	Storage	What are the storage conditions?	***Bottles*** Store at 25°C (77°F); excursions allowed between 15°C to 30°C (59°F to 86°F). Once opened, use within 4 months. Keep the bottle tightly closed and store in the original package to protect from moisture. ***Blisters*** Store at 25°C (77°F); excursions allowed between 15°C to 30°C (59°F to 86°F). Keep in the original package to protect from moisture.
14.	Dispensing	How to Dispense?	As prescribed by the Physician
15.	Contraindication	What are the contraindications of (medication).	• Active pathological bleeding • History of serious hypersensitivity reaction to dabigatran • Mechanical prosthetic heart valve
Pharmaceutical Particulars			

16.	Pharmaceutical Form	How is it supplied?	• ***Dabigatran Etexilate 75 mg Capsules:*** The 75 mg capsules contain a white to light yellow blend of granular powder and pellets, in size "2" capsules. The capsule has a white opaque cap imprinted with "MD" and a white opaque body imprinted with "75" in black ink. The capsules are available in the following packages:
			  • NDC 72205-202-60: Unit-of-use bottle containing 60 capsules
			  • NDC 72205-202-34: Blister pack containing 60 capsules (6 x 10 capsule blister cards) – For institutional use only
			
			• ***Dabigatran Etexilate 110 mg Capsules:*** The 110 mg capsules contain a white to light yellow blend of granular powder and pellets, in size "1" capsules. The capsule has a white opaque cap imprinted with "MD" and a white opaque body imprinted with "110" in black ink. The capsules are available in the following packages:
			  • NDC 72205-203-60: Unit-of-use bottle containing 60 capsules
			  • NDC 72205-203-34: Blister pack containing 60 capsules (6 x 10 capsule blister cards) – For institutional use only

			• ***Dabigatran Etexilate 150 mg Capsules:*** The 150 mg capsules contain a white to light yellow blend of granular powder and pellets, in size "0" capsules. The capsule has a white opaque cap imprinted with "MD" and a white opaque body imprinted with "150" in black ink. The capsules are available in the following packages: • NDC 72205-204-60: Unit-of-use bottle containing 60 capsules • NDC 72205-204-34: Blister pack containing 60 capsules (6 x 10 capsule blister cards) – For institutional use only.
17.	Ingredients	Active and Inactive Ingredients	**Active:** Dabigatran etexilate mesylate. **Inactive ingredients**: • Croscarmellose Sodium • Hydroxypropyl Cellulose (90,000 WAMW) • Hypromellose 2910 (3 mPa.s) • Magnesium Stearate • Talc • Tartaric Acid • Titanium Dioxide • Ferrosoferric Oxide • Propylene Glycol • Potassium Hydroxide • Shellac The capsule shell is composed of hypromellose, titanium dioxide. The imprinting ink contains black iron oxide, propylene glycol, potassium hydroxide and shellac.
Allergens			
18.	Ingredients	Is it Vegetarian?	Yes
19.	Ingredients	Does it contain Gluten?	No
20.	Ingredients	Does it contain Dairy Products?	No
21.	Ingredients	Does it contain Casein	No
22.	Ingredients	Does it contain Whey?	No
23.	Ingredients	Does it contain corn?	No
24.	Ingredients	Does it contain rye?	No
25.	Ingredients	Does it contain sugar?	No
26.	Ingredients	Does it contain Oats?	No
27.	Ingredients	Does it contain wheat?	No

28.	Ingredients	Does it contain spelt?	No
29.	Ingredients	Does it contain barley?	No
30.	Ingredients	Does it contain rennet?	No
31.	Ingredients	Does it contain starch?	No
32.	Ingredients	Does it contain Iodine?	No
33.	Ingredients	Does it contain latex?	No
34.	Ingredients	Does it contain alcohol?	Yes; API contains solvents within the limits as per ICH
35.	Ingredients	Does it contain dyes?	No
36.	Ingredients	Does it contain flavor?	No
37.	Ingredients	Does it contain Lactose?	No
38.	Ingredients	Does it contain Nuts?	No
39.	Ingredients	Does it contain Preservatives?	No
40.	Ingredients	Does it contain Soy products?	No
41.	Ingredients	Does it contain peanut?	No
Miscellaneous			
42.	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.
43.	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
44.	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.
45.	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.
46.	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.
47.	Miscellaneous	Manufacturer and Distributor	**Manufactured by:** MSN Laboratories Private Limited Telangana – 509 228, INDIA .