

Ivabradine tablet, film coated 5mg,7.5mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	<i>Ivabradine tablets are a prescription medicine used:</i> To treat adults who have chronic (lasting a long time) heart failure, with symptoms, to reduce their risk of hospitalization for worsening heart failure.
2	Dosage	What is the recommended dosage?	- Starting dose is 2.5 (vulnerable adults) or 5 mg twice daily with food. After 2 weeks of treatment, adjust dose based on heart rate. The maximum dose is 7.5 mg twice daily. Heart rate >60 bpm: Increase the dose by 2.5 mg twice daily, up to a maximum of 7.5 mg twice daily. Heart rate 50–60 bpm: Maintain the current dose. Heart rate <50 bpm or signs/symptoms of bradycardia: Decrease the dose by 2.5 mg twice daily. If the current dose is 2.5 mg twice daily, discontinue therapy.
3	Administration	How do I take it?	✓ Take ivabradine tablets exactly as your doctor tells you ✓ Do not stop taking ivabradine tablets without talking with your doctor. ✓ Ivabradine tablets comes as a tablet. ✓ Tell your doctor if you have trouble swallowing tablets. ✓ Your doctor may change your dose of ivabradine tablets during treatment ✓ Take ivabradine tablets 2 times each day with food. ✓ If you miss a dose of ivabradine tablets, do not give another dose. Give the next dose at the usual time. ✓ If you take too much ivabradine tablets, call your doctor or go to the nearest emergency room right away. ✓ Avoid drinking grapefruit juice and taking St. John's wort during treatment with ivabradine tablets. These can affect the way ivabradine tablets works and may cause serious side effects.

4	Formulation	Can tablet be crushed?	Do not crush or chew the tablets
5	Administration	What do I do if I miss a dose?	✓ If you miss a dose of ivabradine tablets, do not give another dose. Give the next dose at the usual time.
6	Administration	Use in Pediatric Population	The safety and efficacy of ivabradine have not been established in patients less than 6 months of age.
7	Administration	Use in Geriatric Population	• This medicine works the same in older people as in younger adults. • No dose change is needed for 65 or 75 years and above patients.
8	Mechanism	Mechanism of Action	Ivabradine works by blocking specific channels hyperpolarization-activated cyclic nucleotide-gated (HCN) channels in the heart that control the natural pacemaker current responsible for regulating heart rate. Its effects are mainly seen at the sinoatrial (SA) node, which slows the heart rate. It may slightly prolong some electrical conduction times in the heart, but it does not affect the heart's pumping strength or the recovery of the heart chambers. Ivabradine can also affect similar channels in the eye that respond to bright light. Because of this, some patients may experience brief episodes of increased brightness or light flashes in part of their vision, especially when moving quickly from dark to bright light. These visual effects are temporary and usually harmless.
9	Warnings and Precautions	Warnings	• Fetal toxicity: Females should use effective contraception. • Monitor patients for atrial fibrillation. • Monitor heart rate decreases and bradycardia symptoms during treatment. • Not recommended in patients with 2 degree AV block.
10	Lactation	Use in Lactation	Ivabradine may pass into breast milk and could harm a breastfed baby, so breastfeeding is not recommended while taking this medicine.
11	Pregnancy	Use in Pregnancy	Ivabradine may harm an unborn baby and should be avoided during pregnancy; if used, pregnant women especially those with heart failure must be closely monitored, as slowing the heart rate can worsen their condition and increase the risk of complications such as preterm birth.
12	Precautions	Is there any interaction between medication and alcohol?	No
13	Interaction	Is there any interaction with food/Medications?	• Do not drink grapefruit juice or take St. John's wort while using ivabradine, as they can change how the medicine works and cause serious side effects.

			• Avoid CYP3A4 inhibitors or inducers. (7.1) • Negative chronotropes increase risk of bradycardia, monitor heart rate.
14	Storage	What are the storage conditions?	Store ivabradine tablets at room temperature (around 25°C), and keep them between 15°C and 30°C.
15	Dispensing	How to Dispense?	As prescribed by the Physician
16	Contraindication	What are the contraindications of (medication).	• Acute decompensated heart failure. • Clinically significant hypotension • Sick sinus syndrome, sinoatrial block or 3-degree AV block, unless a functioning demand pacemaker is present • Clinically significant bradycardia • Severe hepatic impairment • Heart rate maintained exclusively by the pacemaker • In combination with strong cytochrome CYP3A4 inhibitors
Pharmaceutical Particulars			
17	Pharmaceutical Form	How is it supplied?	<i>Ivabradine tablet, film coated USP are supplied as follows:</i> 5 mg of Ivabradine: Orange colored, capsule shaped, film-coated tablets, functionally scored with debossing "M" & "I" on one side and "2" on other side. • Bottles of 60 tablets: NDC 72205-336-60 • Bottles of 180 tablets: NDC 72205-336-18 7.5 mg of Ivabradine: Orange colored, round shaped, film-coated tablets debossed with "MI" on one side and "1" on the other side. • Bottles of 60: NDC 72205-337-60 • Bottles of 180: NDC 72205-337-18.
18	Ingredients	Active and Inactive Ingredients	Active: Ivabradine Inactive: colloidal silicon dioxide, lactose monohydrate, magnesium stearate, maize starch, maltodextrin, FD&C yellow#6, glycerin, Hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, polyethylene glycol and titanium dioxide.

19	Coating	What is the type of coating?	Film-coated tablets
Allergens			
21	Ingredients	Is it Vegetarian?	No
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain Dairy Products?	Yes (Lactose used as diluent in the FP products and sourced from Cow's milk)
24	Ingredients	Does it contain Casein	No
25	Ingredients	Does it contain Whey?	No
26	Ingredients	Does it contain corn?	Yes
27	Ingredients	Does it contain rye?	Yes
28	Ingredients	Does it contain sugar?	No
29	Ingredients	Does it contain Oats?	No
30	Ingredients	Does it contain wheat?	No
31	Ingredients	Does it contain spelt?	No
32	Ingredients	Does it contain barley?	No
33	Ingredients	Does it contain rennet?	No
34	Ingredients	Does it contain starch?	Yes
36	Ingredients	Does it contain Iodine?	No
37	Ingredients	Does it contain latex?	No
38	Ingredients	Does it contain alcohol?	Yes (API contains solvents within the limits as per ICH)
39	Ingredients	Does it contain dyes?	Yes
40	Ingredients	Does it contain flavor?	No
41	Ingredients	Does it contain Lactose?	Yes
42	Ingredients	Does it contain Nuts?	No
43	Ingredients	Does it contain Preservatives?	No
44	Ingredients	Does it contain Soy products?	No
45	Ingredients	Does it contain peanut?	No
46	Ingredients	Does it contain nickel?	No
Miscellaneous			
47	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.

48	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
49	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.
50	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 .
51	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.
52	Miscellaneous	Manufacturer and Distributor	MSN Laboratories Private Limited Telangana – 509 228, INDIA Distributed by: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714