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Dispense with Medication Guide available at: www.ingenus.com/medguide/ivabradine-tablets.pdf

MEDICATION GUIDE Ivabradine (eye VAB ra deen) Tablets
What is the most important information I should know about ivabradine tablets? Ivabradine tablets may cause serious side effects in adults and children, including: • Harm to an unborn baby. Females who are able to get pregnant: ○ Must use effective birth control during treatment with ivabradine tablets. ○ Tell your doctor right away if you become pregnant during treatment with ivabradine tablets. • Increased risk of irregular or rapid heartbeat (atrial fibrillation or heart rhythm problems). Tell your doctor if you feel any of the following symptoms of an irregular or rapid heartbeat: ○ heart is pounding or racing (palpitations). ○ chest pressure. ○ worsened shortness of breath. ○ near fainting or fainting. • Slower than normal heart rate (bradycardia). Tell your doctor if you have: ○ a slowing of heart rate, or ○ symptoms of a slow heart rate such as dizziness, fatigue, lack of energy. In young children signs and symptoms of slow heart rate may include: poor feeding, difficulty breathing or turning blue.
What is ivabradine tablets? Ivabradine tablets is a prescription medicine used: • to treat adults who have chronic (lasting a long time) heart failure, with symptoms, to reduce their risk of hospitalization for worsening heart failure.
Who should not take ivabradine tablets? Do not take ivabradine tablets if you have: • symptoms of heart failure that recently worsened • very low blood pressure (hypotension) • certain heart conditions: sick sinus syndrome, sinoatrial block, or 3rd degree atrioventricular block • a slow resting heart rate before treatment with ivabradine tablets. Ask your doctor what a slow resting heart rate is for you. • certain liver problems • been prescribed any medicines that can increase the effects of ivabradine tablets. Ask your doctor if you are not sure if you have any of the medical conditions listed above.
What should I tell my doctor before taking ivabradine tablets? Before you take ivabradine tablets, tell your doctor about all of your medical conditions, Including if you: • have any other heart problems, including heart rhythm problems, a slow heart rate, or a heart conduction problem. • are breastfeeding or planning to breastfeed. It is not known if ivabradine passes into breast milk. You and your doctor should decide if you will take ivabradine tablets or breastfeed; do not do both. • are pregnant or planning to become pregnant. See “What is the most important information I should know about ivabradine tablets? - Harm to an unborn baby” section. Tell your doctor about all the medicines you take, including prescription and over the counter medicines, vitamins, and herbal supplements. Ivabradine tablets may affect the way other medicines work, and other medicines may affect how ivabradine tablets works. This could cause serious side effects.
How should you take ivabradine tablets? • 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 or your child take too much ivabradine tablets, call your doctor or go to the nearest emergency room right away.
What should you avoid while taking ivabradine tablets? • 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.

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What are the possible side effects of ivabradine tablets?
Ivabradine tablets may cause serious side effects. See “What is the most important information I should know about ivabradine tablets?”
The most common side effects of ivabradine tablets are:

- increased blood pressure
- temporary brightness in part of your field of vision. This is usually caused by sudden changes in light (luminous phenomena). This brightness usually happens within the first 2 months of treatment with ivabradine tablets and may go away during or after treatment with ivabradine tablets. Be careful when driving or operating machinery where sudden changes in light can happen, especially when driving at night.

These are not all the side effects of ivabradine tablets. Ask your doctor or pharmacist for more information. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ivabradine tablets?

- Store ivabradine tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Keep ivabradine tablets and all medicines out of the reach of children.

General information about the safe and effective use of ivabradine tablets.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ivabradine tablets for a condition for which it was not prescribed. Do not give ivabradine tablets to other people, even if they have the same symptoms that you have. It may harm them. You can ask your doctor or pharmacist for information about ivabradine tablets that is written for health professionals.

What are the ingredients in ivabradine tablets?
Active ingredient: ivabradine
Inactive ingredients:
Tablet: lactose monohydrate, maltodextrin, maize starch b, colloidal silicon dioxide, magnesium stearate, hypromellose, titanium dioxide, polyethylene glycol 4000, yellow iron oxide and red iron oxide.
Manufactured for:
Ingenus Pharmaceuticals, LLC
Orlando, FL 32811-7193
Made in India

For more information contact Ingenus Pharmaceuticals, LLC at 1-877-748-1970

This Medication Guide has been approved by the U.S. Food and Drug Administration.



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