

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

Pr **LANCORA™**

ivabradine (as ivabradine hydrochloride) tablets

Read this carefully before you start taking **LANCORA™** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LANCORA™**.

What is LANCORA™ used for?

LANCORA™ is a medication used to treat stable chronic heart failure. **LANCORA™** should be used in adults who have a heart rate that is equal to or above 77 beats per minute. **LANCORA™** will be used in combination with standard heart failure therapy. **LANCORA™** will only be prescribed by doctors who are experienced in treating heart failure.

How does LANCORA™ work?

LANCORA™ works on specific cells in the heart to slow down your heart rate.

What are the ingredients in LANCORA™?

Medicinal ingredients: ivabradine



Non-medicinal ingredients:

Core tablet: colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, maltodextrin.

Tablet coating: hypromellose, macrogol 6000, glycerol, magnesium stearate, red iron oxide (E172), titanium dioxide (E171), yellow iron oxide (E172).

LANCORA™ comes in the following dosage forms:

5 mg and 7.5 mg film-coated tablets.

- **5mg:**
 - tablets are salmon-coloured and are rod shaped.
 - engraved with “5” on one face and * on the other.
 - The 5 mg tablet can be broken in half to make two halves of 2.5 mg each.
- **7.5mg:**
 - tablets are salmon-coloured and triangular.
 - engraved with “7.5” on one face and * on the other.

Do not use LANCORA™ if:

- you are allergic (hypersensitive) to ivabradine or any of the other ingredients of LANCORA™
- your resting heart rate before treatment is too slow (below 70 beats per minute)
- you have a heart condition or heart disease such as:
 - a recent heart attack
 - your heart suddenly can't pump enough blood (cardiogenic shock)
 - severe heart failure that requires you to be in the hospital for treatment
 - problems with the rhythm of your heart or the electrical system in your heart (congenital long QT syndrome, sick sinus syndrome, sino-atrial block, third degree atrioventricular block)
 - very low blood pressure (<90/50 mmHg)
 - you need a pacemaker to beat your heart for you
- you have severe liver problems
- you are taking the following medications:
 - ketoconazole, itraconazole (to treat fungal infections)
 - clarithromycin, josamycin (antibiotics)
 - nelfinavir, ritonavir, atazanavir (to treat HIV infections)
 - nefazodone (to treat depression)
 - diltiazem, verapamil (used for high blood pressure or angina)
- you are a woman able to have children and not using reliable contraception; you are pregnant or trying to become pregnant or breast-feeding
- you are lactose intolerant or have a rare hereditary disease that means you should not have milk. LANCORA™ contains lactose, a natural ingredient in milk. These diseases include:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption.

LANCORA™ is not intended for use in children younger than 18 years old.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LANCORA™. Talk about any health conditions or problems you may have, including if you:

- have heart problems such as:
 - irregular heartbeat or heart rhythm
 - an abnormally rapid heart rate
 - unexpected fainting
 - heart palpitations (feeling like your heart has skipped a beat or added an extra beat)
 - increase in chest pain
 - lower than normal level of potassium in your blood
 - one of the valves in your heart is more narrow (aortic stenosis)
 - a heart device such as a pacemaker, cardioverter defibrillator or cardiac resynchronizer
 - high or low blood pressure
 - a reduced heart rate with shortness of breath or tiredness. This could mean that your heart slowed down too much.

- severe heart failure or heart failure with an electrocardiogram (ECG) abnormality called ‘bundle branch block’
- have a family history of problems of electrocardiogram (ECG) abnormality called “Long QT syndrome”
- have had a recent stroke
- have moderate liver problems
- have severe kidney problems.

Other warnings you should know about:

Risk of harm to fetus

If you are a woman of child-bearing potential, you should use appropriate birth control measures to avoid getting pregnant while taking LANCORA™. If you get pregnant while taking LANCORA™, your fetus could be harmed or could die.

Monitoring before taking LANCORA™ and when your dose is changed

Your doctor will monitor your heart rate on at least three separate visits before you start treatment with LANCORA™ and whenever your dose is changed. Your doctor may also monitor your heart rate and rhythm at other times during your treatment.

Blood pressuring monitoring

If you have high blood pressure and need treatment with LANCORA™, your doctor:

- will regularly monitor your blood pressure.
- may need to change your blood pressure medication.

Irregular heart rhythm

LANCORA™ may cause an irregular heart rhythm. This has happened more in patients taking certain medications like amiodarone. Your doctor will monitor your heart rhythm and the electrical system of your heart with an electrocardiogram (ECG).

Tell your doctor if you have any of the following symptoms of an irregular heart rhythm:

- fast or irregular heartbeat
- feeling like your heart is skipping a beat
- thumping in your chest
- discomfort, pain or pressure in your chest
- shortness of breath
- less ability to exercise
- feeling tired, weak, dizzy or light-headed
- confusion

Abnormally slow heart rate

LANCORA™ may lower your heart rate too much. This may happen more in patients:

- taking other heart rate lowering drugs
- who are elderly (75 years of age or older).

Your doctor will monitor your heart rate. Tell your doctor if you have any of the following symptoms of a heart rate that is too low:

- nearly fainting or fainting
- weakness or fatigue
- dizziness
- shortness of breath
- chest pain
- feeling confused or having memory problems

Effects on Vision

LANCORA™ may cause temporary visual symptoms. You may:

- have blurry vision
- see halos or stars of light
- see rapid pulses light
- see colored bright lights
- see moving and twisting colours of light
- find that you have moments of brightness that come and go in only certain portions of what you see with your eyes

You may notice that these symptoms happen when there are sudden changes in light intensity in your environment. For example, you may have symptoms if you walk into a bright room from a dark room. These symptoms usually go away on their own. These symptoms typically happen in the first two months of treatment.

Driving and Using Machines:

LANCORA™ may make you:

- feel dizzy, tired or weak
- have blurry vision
- see spots or stars of light in your eyes
- have other problems with your vision because of halos, patches of brightness in your vision or pulses of light.

Be careful when driving or using machines. Know how you feel while taking LANCORA™ before you drive or use machines.

Tell your healthcare professional about all the medications you take, including any drugs, vitamins, minerals, natural supplements or alternative medications. The following may interact with LANCORA™:

- diltiazem, verapamil (for high blood pressure or angina)
- ketoconazole, itraconazole, fluconazole (to treat fungal infections)
- rifampicin, clarithromycin, josamycin (antibiotics)
- nelfinavir, atazanavir, ritonavir (to treat HIV infections)
- nefazodone (to treat depression)
- barbiturates (for difficult sleeping or epilepsy)
- phenytoin (for epilepsy)
- St John's Wort (herbal treatment for depression)
- Medications that may affect the heart rate or the electrical system of the heart, such as:
 - quinidine, disopyramide, ibutilide, sotalol, amiodarone (to treat heart rhythm disorders)
 - pimozone, ziprasidone, imipramine (to treat anxiety, depression, schizophrenia)
 - mefloquine (malarial medication)
 - erythromycin IV (an antibiotic)
 - pentamidine (an antiparasitic medication)
- furosemide, hydrochlorothiazide, indapamide (to treat edema, high blood pressure).
- simvastatin (used to lower cholesterol).

Do not consume grapefruit juice during treatment with LANCORA™.

How to take LANCORA™:

- You should take LANCORA™ two times per day:
 - Once in the morning with food, and
 - 12 hours later in the evening with food.
- Always take LANCORA™ exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.
- Only stop taking LANCORA™ if your doctor tells you to.
- If you think that the effect of LANCORA™ is too strong or too weak, talk to your doctor or pharmacist.

Usual dose:

- Your doctor will decide the right dose for you. Your doctor will adjust your dose based on your heart rate.
- The usual recommended starting dose is one 5mg tablet of LANCORA™ twice a day. Your doctor may increase your dose to one 7.5mg tablet twice a day.
- In some cases, you may start your treatment with a lower dose of 2.5mg twice a day. Your doctor may recommend this dose if you are elderly (≥ 75 years old) or are taking some specific medications. To take this dose, you will need to break one 5mg tablet into two, and take one half in the morning with food and the other half in the evening with food.

If you received LANCORA™ in blister packaging:

Each blister card contains 14 tablets, with two in each row and seven rows in total. Each row has the day of the week on it to help you keep track of your daily doses.

Overdose:

Your heart rate could be very lowered by a large dose of LANCORA™. You may feel breathless or tired.

If you think you have taken too much LANCORA™, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a dose of LANCORA™, take the next dose at the usual time. Do not take a double dose to make up for the forgotten dose.

What are possible side effects from using LANCORA™?

- Dizziness
- Visual symptoms (blurred vision, seeing light spots and flashes, etc.)
- Fatigue, malaise, feeling tired and weak
- Nausea, diarrhea
- Constipation, abdominal pain
- Feeling cold in extremities (fingers and toes)
- Joint pain
- Headache, generally during the first month of treatment
- Red and itchy skin
- Muscle spasms

These are not all the possible side effects you may feel when taking LANCORA™. If you experience any side effects not listed here, contact your healthcare professional.

Like all medications, LANCORA™ may have side effects, although not everybody gets them.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Abnormally slow heart beat (heart rate below 50 beats per minute): nearly fainting or fainting, weakness or fatigue, dizziness, shortness of breath, chest pain		✓	
Abnormally fast heart beat (fast heart rate)		✓	
UNCOMMON			
Angioedema: swelling of the face, eyelids, lips, tongue or			✓

throat, difficulty swallowing or breathing			
Blood pressure increase : severe headache, fatigue, confusion, vision problems, chest pain, difficulty breathing		✓	
Cramping in the lower leg(s)		✓	
Fainting : temporary loss of consciousness due to sudden drop in blood flow to the brain		✓	
Heart attack : chest pain that feels like a tight ache, pressure or squeezing, upper body pain, shortness of breath, feeling dizzy or like you will pass out			✓
Mini-stroke : numbness or muscle weakness - usually on one side of the body, trouble speaking or understanding words, dizziness or loss of balance, double vision or loss of vision			✓
Problem with the electrical system of the heart : rapid, slow or irregular heartbeat or increased fatigue, swelling of legs and feet and shortness of breath		✓	
Sudden drop in blood pressure : feeling of lightheadedness or dizziness		✓	
VERY RARE			
Irregular heart rhythm : fast or slow heartbeat, irregular heartbeat, discomfort, pain or pressure in the chest, shortness of breath		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (<http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
 - By calling 1-866-234-2345 (toll-free);
 - By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9
- Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- LANCORA™ should be stored at room temperature (15 to 30°C).
- Keep out of reach and sight of children.
- Use LANCORA™ before the expiry date stated on the bottle, carton and blister strip. The expiry date refers to the last day of that month.
- Do not throw any medication into the garbage, or down the toilet or sink. Ask your pharmacist how to throw away medications you no longer use. This can help protect the environment.

If you want more information about LANCORA™:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://www.hc-sc.gc.ca>); the manufacturer's website (www.servier.ca), or by calling 1-800-363-6093.

This leaflet was prepared by Servier Canada Inc.

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