

PRODUCT MONOGRAPH

Pr INHIBACE®

cilazapril tablets

2.5 mg and 5.0 mg

angiotensin converting enzyme inhibitor

Hoffmann-La Roche Limited
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Date of Preparation:
March 22, 1993

Date of Revision:
July 24, 2018

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Submission Control No: 214793

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Pr **INHIBACE**[®]
cilazapril tablets

Read this carefully before you start taking INHIBACE[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about INHIBACE[®]. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about INHIBACE[®].

ABOUT THIS MEDICATION**What the medication is used for:**

INHIBACE is used to treat the following:

- Mild to moderate essential high blood pressure (hypertension). The cause of essential high blood pressure is unknown.
- Heart failure. This is a condition where the heart cannot pump adequate amounts of blood to satisfy the needs of the body.

What it does:

INHIBACE is an angiotensin converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because their medicinal ingredient ends in ‘-PRIL’.

It works by making your blood vessels relax and widen. This helps to lower your blood pressure. It also makes it easier for your heart to pump blood around your body if you have chronic heart failure.

This medicine does not cure your disease. It helps to control it. Therefore, it is important to continue taking INHIBACE regularly even if you feel fine.

When it should not be used:

Do not take INHIBACE if you:

- Are allergic to cilazapril or to any non-medicinal ingredient in the formulation.
- Are allergic (hypersensitive) to other ACE inhibitor medicines. These include captopril, enalapril, lisinopril and ramipril.
- Have experienced an allergic reaction (angioedema) with swelling of the hands, feet, or ankles, face, lips, tongue, throat, or sudden difficulty breathing or swallowing, to any ACE inhibitor or without a known cause. Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.
- Have been diagnosed with hereditary angioedema: an increased risk of getting an allergic reaction that is passed down through families. This can be triggered by different factors, such as surgery, flu, or dental procedures.
- Are pregnant or intend to become pregnant. Taking INHIBACE during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. INHIBACE passes into breast milk.
- Have a build up of fluid in your abdomen (ascites).

- Are already taking a blood pressure-lowering medicine that contains aliskiren (such as Rasilez) and you have diabetes or kidney disease.
- Are lactose intolerant or have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption
 as lactose is a non-medicinal ingredient in INHIBACE[®]

What the medicinal ingredient is:

cilazapril

What the non-medicinal ingredients are:

lactose monohydrate, cornstarch, hydroxypropyl methylcellulose, talc, sodium stearyl fumarate and titanium dioxide. Iron oxide is present as the colouring agent in the tablet.

What dosage forms it comes in:

Tablets; 2.5 mg and 5.0 mg

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions - Pregnancy
INHIBACE should not be used during pregnancy. If you discover that you are pregnant while taking INHIBACE, stop the medication and contact your doctor, nurse, or pharmacist as soon as possible.

BEFORE you use INHIBACE talk to your doctor, nurse or pharmacist if you:

- Are allergic to any drug used to lower blood pressure.
- Have narrowing of an artery or a heart valve.
- Have/had a heart attack or a stroke.
- Have heart failure.
- Have diabetes, liver or kidney disease.
- Are on dialysis.
- Are on LDL apheresis (a treatment to lower the LDL cholesterol in the blood).
- Are dehydrated or recently suffered from excessive vomiting, diarrhea or sweating.
- Are on a low salt diet.
- Are receiving gold (sodium aurothiomalate) injections.
- Have recently received or are planning to have allergy shots for bee or wasp stings.
- Have a collagen disease (skin disease) such as lupus (systemic lupus erythematosus) or scleroderma (a skin condition leading to hardening or thickening of the skin).
- Are less than 18 years old. INHIBACE is not recommended for use in children.
- Are taking a medicine that contains aliskiren, such as Rasilez, used to lower high blood pressure. The combination with INHIBACE is not recommended.
- Are taking a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”) or other drugs that may increase serum potassium (e.g., trimethoprim-containing products).

- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take INHIBACE.

You may become sensitive to the sun while taking INHIBACE®. Exposure to sunlight should be minimized until you know how you respond.

If you are going to have surgery and will be given an anesthetic, be sure to tell your doctor or dentist that you are taking INHIBACE®.

Driving and using machines

You may feel dizzy while taking INHIBACE. This is more likely to happen when you first start treatment or when the dose is increased. If you feel dizzy, do not drive or use any tools or machines.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with INHIBACE:

- Agents increasing serum potassium, such as a salt substitute that contains potassium, potassium supplements, potassium-sparing diuretics (a specific kind of “water pill,” e.g. spiro lactone, triamterene, amiloride, eplerenone) or other drugs that may increase serum potassium (e.g. trimethoprim-containing products).
- Allopurinol used to treat gout.
- Anesthetics and narcotics (for pain relief)
- Antipsychotics (for treatment of schizophrenia or bipolar disorder)
- Anti-diabetic drugs including insulin and oral medicines (e.g. metformin, gliptins, sulfonylureas).
- Digoxin, a heart medication
- Gold salts (for the treatment of rheumatoid arthritis).
- Lithium (used to treat bipolar disorder).
- Non-steroidal anti-inflammatory drugs’ (NSAIDs), used to reduce pain and swelling. Examples include aspirin, indometacin, naproxen, ibuprofen and celecoxib.
- Other blood pressure lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. RASILEZ), angiotensin receptor blockers (ARBs) or other ACE inhibitors (in addition to INHIBACE).
- Steroid medicines (such as hydrocortisone, prednisolone and dexamethasone) or other medications which suppress the immune system.
- Tricyclic antidepressants (e.g. amitriptyline, clomipramine, imipramine)
- mTOR inhibitors (e.g. sirolimus, everolimus)
- DPP-IV inhibitors (e.g. vildagliptin)

Taking INHIBACE with food and drink

Tell your doctor or pharmacist if you are taking food supplements that contain potassium.

PROPER USE OF THIS MEDICATION

Take INHIBACE exactly as prescribed. It is recommended to take your dose at about the same time every day.

Usual Adult Dose:

Follow your doctor’s instructions about how much medicine you should take. If you have any questions, you should consult your doctor or pharmacist.

Overdose:

If you think you have taken too much INHIBACE contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you take more INHIBACE than you should, the following effects may happen: feeling dizzy or light-headed, shallow breathing, cold clammy skin, being unable to move or speak and a slow heart beat.

Missed Dose:

If you forget to take a dose, skip the missed dose. Then take the next dose when it is due.

Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- Dizziness, headache, trouble sleeping
- Drowsiness, feeling tired, weakness
- Runny or blocked nose, sneezing
- Rash, itching
- Abdominal pain, upset stomach, decreased appetite
- Diarrhea, constipation, nausea, vomiting
- Muscle cramps and/or joint pain, pins and needles sensation
- Sweating more than usual, flushing

If any of these affects you severely, tell your doctor, nurse or pharmacist.

INHIBACE can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical help
		Only if severe	In all cases	
Common (affects less than 1 in 10 people)	Low Blood Pressure: Dizziness, fainting, lightheadedness. May occur when you go from sitting to standing up.		✓	✓ (if actual fainting occurs)
	Increased levels of potassium in the blood: Irregular heartbeat, muscle weakness and generally feeling unwell.		✓	
Uncommon (affects less than 1 in 100 people)	Angioedema and Severe Allergic Reactions (anaphylaxis): Swelling of the face, eyes, lips, tongue or throat, difficulty swallowing or breathing, rash (including skin rash which may be severe), hives, itching, fever, abdominal cramps, chest discomfort or tightness.			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical help
	Only if severe	In all cases	
Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		✓	
	Increased heart rate		✓
	Chest pain (Angina)		✓
	Breathing problems, including shortness of breath and tightness in the chest.		✓
	Rare (affects less than 1 in 1000 people)		
Decreased platelets: bruising, bleeding, fatigue and weakness.		✓	
Decreased white blood cells: Infections (e.g., sore throat, fever), fatigue, aches, pains, and flu-like symptoms.		✓	
Stroke: weakness, blurred vision slurred speech, trouble speaking, face drooping, dizziness, headache.			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical help
	Only if severe	In all cases	
Heart attack: chest pain and pressure (can be radiating from the left arm), heart palpitations, nausea, vomiting, trouble breathing, sweating, anxiety.		✓	
Irregular heartbeat		✓	
Lupus-like Syndrome: fever, fatigue, joint and muscle pain, generally feeling unwell.		✓	
Liver Disorder: Yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.		✓	
Inflammation of the Pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting.		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical help
	Only if severe	In all cases	
Kidney Disorder: Change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue.		✓	
Serious skin reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis): Any combination of itchy skin rash, redness, blistering and severe peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands, joint pain, yellowing of the skin or eyes, dark urine.			✓

This is not a complete list of side effects. For any unexpected effects while taking INHIBACE, contact your doctor or

pharmacist.



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If you have any further questions, ask your doctor or pharmacist.

HOW TO STORE IT

Store 15-30 °C. Keep container tightly closed.

Keep out of reach and sight of children.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.rochecanada.com>

or by contacting the sponsor, Hoffmann-La Roche Limited, at: 1-888-762-4388 (Drug Information).

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Last revised: July 24, 2018

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