

PRODUCT MONOGRAPH

^{Pr} **INHIBACE PLUS**[®]

cilazapril and hydrochlorothiazide

tablets 5 mg/12.5 mg

angiotensin converting enzyme inhibitor / diuretic

Hoffmann-La Roche Limited
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**Pr INHIBACE PLUS®
cilazapril and hydrochlorothiazide
tablets**

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

ABOUT THIS MEDICATION

What the medication is used for:

INHIBACE PLUS lowers high blood pressure.

What it does:

INHIBACE PLUS contains a combination of 2 drugs: cilazapril and hydrochlorothiazide.

- Cilazapril is an angiotensin converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because their medicinal ingredient ends in ‘-PRIL’. It lowers blood pressure.
- Hydrochlorothiazide is a diuretic or “water pill” that increases urination. This lowers blood pressure.

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

When it should not be used:

Do not take INHIBACE PLUS if you:

- Are allergic to cilazapril or hydrochlorothiazide or to any non-medicinal ingredient in the formulation.
- Are allergic to any other blood pressure medicines of the same class (called ACE inhibitors).
- Are allergic to any sulfonamide-derived drugs (sulfa drugs); most of them have a medicinal ingredient that ends in “-MIDE”.
- 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.
- Have difficulty urinating or produce no urine.
- Have a build up of fluid in your abdomen (ascites).
- Are pregnant or intend to become pregnant. Taking INHIBACE PLUS during pregnancy can cause injury

- and even death to your baby.
- Are breastfeeding. INHIBACE PLUS passes into breast milk.
- Are lactose intolerant or have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption

because lactose is a non-medicinal ingredient in INHIBACE PLUS.

- Are already taking a blood pressure-lowering medicine that contains aliskiren (such as Rasilez) and you have diabetes or kidney disease.

What the medicinal ingredients are:

cilazapril and hydrochlorothiazide

What the non-medicinal ingredients are:

cornstarch, hydroxypropyl methylcellulose, lactose, red iron oxide, sodium stearyl fumarate, talc, and titanium dioxide.

What dosage forms it comes in:

Tablets; 5 mg cilazapril and 12.5 mg hydrochlorothiazide

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions - Pregnancy

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

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

- Are allergic to any drug used to lower blood pressure
- Are allergic to penicillin
- Have recently received or are planning to get allergy shots for bee or wasp stings.
- Have narrowing of an artery or a heart valve.
- Have had a heart attack or stroke.
- Have heart failure.
- Have diabetes, liver or kidney disease.
- Are on dialysis.
- Have lupus or gout.
- 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 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 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 on a low-salt diet.
- Are receiving gold (sodium aurothiomalate) injections.
- Are less than 18 years old. INHIBACE PLUS 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 PLUS is not recommended.
- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”.

Hydrochlorothiazide in INHIBACE PLUS can cause Sudden Eye Disorders:

- **Myopia:** sudden nearsightedness or blurred vision.
- **Glaucoma:** an increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss.

These eye disorders are related and can develop within hours to weeks of starting INHIBACE PLUS.

You may become sensitive to the sun while taking INHIBACE PLUS. 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 PLUS.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to INHIBACE PLUS. Dizziness, lightheadedness, or fainting can especially occur after the first dose and when the dose is increased.

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 PLUS:

- Adrenocorticotrophic hormone (ACTH) used to treat West Syndrome.
- 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 and eplerenone) or other drugs that may increase serum potassium (e.g., trimethoprim-containing products).
- Alcohol, barbiturates (sleeping pills), or narcotics (strong pain medications). They may cause low blood pressure and dizziness when you go from lying or sitting to standing up.
- Amphotericin B, an antifungal drug.
- Anticancer drugs, including cyclophosphamide and

- methotrexate.
- Antidepressants, in particular selective serotonin reuptake inhibitors (SSRIs), including citalopram, escitalopram, sertraline, and tricyclic antidepressants (e.g. amitriptyline, clomipramine, imipramine).
- Antipsychotics.
- Antidiabetic drugs, including insulin and oral medicines.
- Bile acid resins used to lower cholesterol.
- Calcium or vitamin D supplements.
- Corticosteroids used to treat joint pain and swelling.
- Digoxin, a heart medication.
- Drugs that slow down or speed up bowel function, including atropine, metoclopramide, and domperidone.
- Drugs used to treat epilepsy, including carbamazepine and topiramate.
- Drugs used to treat irregular heart beat
- Gout medications, including allopurinol and probenecid.
- Lithium used to treat bipolar disease.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Other blood pressure lowering drugs. When taken in combination with INHIBACE PLUS, they may cause excessively low blood pressure.
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurane.
- Gold salts for the treatment of rheumatoid arthritis.
- Tetracycline, an antibiotic
- Amantadine, an antiviral
- Cyclosporine, an immunosuppressant medication
- Iodine containing contrast media
- Blood pressure-lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. RASILEZ), or angiotensin receptor blockers (ARBs).
- mTOR inhibitors (e.g. sirolimus, everolimus)
- DPP-IV inhibitors (e.g. vildagliptin)

PROPER USE OF THIS MEDICATION

INHIBACE PLUS is not for initial therapy. You must first be stabilized on the individual components (cilazapril and hydrochlorothiazide) of INHIBACE PLUS. If your dosage matches the dosages in INHIBACE PLUS, your doctor may prescribe INHIBACE PLUS taken once a day (instead of each component as a separate pill).

Take INHIBACE PLUS exactly as prescribed. It is recommended to take your dose at about the same time every day. INHIBACE PLUS tablets must not be chewed or crushed and should always be taken with a full glass of water.

INHIBACE PLUS can be taken with or without food. If INHIBACE PLUS causes upset stomach, take it with food or milk.

Overdose:

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

Missed Dose:

If you have forgotten to take your dose during the day, carry on with the next one at the usual time. Do not double 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

Side effects may include:

- Dizziness, headache, trouble sleeping
- Drowsiness, feeling tired, weakness
- Dry cough, dry or swollen mouth
- Runny or blocked nose, sneezing
- Rash, itching
- Abdominal pain, upset stomach, decreased appetite
- Diarrhea, constipation, nausea, vomiting
- Change in the way things taste
- 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 PLUS 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, nurse, or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Low Blood Pressure: dizziness, fainting, lightheadedness May occur when you go from lying or sitting to standing up.	✓		

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

Symptom / effect	Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Decreased or increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell.		✓	
Uncommon Angioedema and Severe Allergic Reaction (anaphylaxis): Swelling of the face, eyes, lips, tongue or throat, difficulty swallowing or breathing, wheezing, rash, hives, itching, fever, abdominal cramps, chest discomfort or tightness.			✓
Heart Attack: chest pain and pressure (can be radiating from the left arm), heart palpitations, nausea, vomiting, trouble breathing, sweating, anxiety.			✓

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

Symptom / effect	Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Kidney Disorder: Change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue.		✓	
Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.		✓	
Increased blood sugar: frequent urination, thirst, and hunger.	✓		
Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat.		✓	
Fast or irregular heart beat		✓	
Chest pain (Angina)		✓	
Lupus-Like Syndrome: fever, fatigue, joint and muscle pain, generally feeling unwell		✓	

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

Symptom / effect	Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Breathing problems, including shortness of breath, trouble breathing, tightness in the chest, cough, wheezing			✓
Rare Decreased Platelets: bruising, bleeding, fatigue and weakness		✓	
Decreased White Blood Cells: infections (e.g. sore throat, fever), fatigue, aches, pains, and flu-like symptoms		✓	

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

Symptom / effect		Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Very rare	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.			✓
Unknown	Eye disorders: - Myopia: sudden near sightedness or blurred vision - Glaucoma: increased pressure in your eyes, eye pain			✓

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

Symptom / effect		Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
	Stroke: weakness, blurred vision, trouble speaking, slurred speech, face drooping, dizziness, headache			✓
	Anemia: fatigue, loss of energy, weakness, shortness of breath		✓	
	Inflammation of the Pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		✓	

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

HOW TO STORE IT

Store between 15-30°C.

Keep container tightly closed.

Keep out of reach and sight of children.

Return all unused or expired tablets to your doctor, nurse or pharmacist for safe disposal. Do not throw them away with your household waste.

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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