

Consumer Medicine Information

INHIBACE®

cilazapril tablets 0.5 mg, 2.5 mg, 5 mg

What is in this leaflet

This leaflet answers some common questions about INHIBACE.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of your taking INHIBACE against the benefits expected for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What INHIBACE is used for

INHIBACE contains the active ingredient cilazapril, which belongs to a group of medicines known as ACE (Angiotensin Converting Enzyme) inhibitors. Cilazapril is used to treat raised blood pressure and chronic heart failure.

Cilazapril works by inhibiting (blocking) natural chemicals produced by the body which increase blood pressure. This inhibition leads to a reduction of blood pressure. When given together with digitalis (a medicine which increases the strength of the heart) and/or diuretics (water tablets) this will also reduce the strain on your heart and enable it to work more efficiently, thus easing the symptoms of chronic heart failure.

Before you take INHIBACE

When you must not take it

Do not take INHIBACE if:

- 1. you are allergic to cilazapril or other medicines of the same class (called ACE-Inhibitors).**
- 2. you are allergic to any of the ingredients listed at the end of this leaflet.**
- 3. you are pregnant or breast feeding**
Your baby may absorb this medicine in the womb and therefore there is a possibility of harm to the baby.
- 4. you have previously suffered from angioedema (swelling of the skin, particularly of the face and around the lips), when taking other ACE-Inhibitors.**
- 5. the package is torn or shows signs of tampering**
- 6. the expiry date printed on the pack has passed**

If you take this medicine after the expiry date has passed it may not work as well.

Use in children

Children should not be given INHIBACE.

Before you start to take it

Tell your doctor if:

- 1. you are pregnant or plan to become pregnant**
You must not take INHIBACE if you are pregnant.
- 2. you are breastfeeding or wish to breastfeed**
You must not take INHIBACE if you are breast feeding or plan to breast feed.
- 3. you have any other health problems, especially the following:**
 - recently suffered from vomiting or diarrhoea
 - have a heart, liver or kidney condition
 - you are galactose intolerant, or suffer from Lapp lactase deficiency or glucose-galactose malabsorption syndrome
- 4. you are on a restricted salt diet**
- 5. you are currently on haemodialysis or haemofiltration**
- 6. you are allergic to any other medicines, foods, dyes or preservatives**
- 7. you plan to have surgery (including dental surgery)**
Tell your doctor if you are about to have any form of operation that requires an anaesthetic.

If you have not told your doctor about any of the above, tell them before you start taking INHIBACE.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

Some medicines may interfere with INHIBACE. These medicines include, but are not limited to:

- non-steroidal anti-inflammatory medicines used for relief of pain e.g. aspirin, ibuprofen (Nurofen[®]), diclofenac (Voltaren[®]), naproxen (Naprosyn[®])
- potassium-sparing diuretics e.g. amiloride (Midamor[®]), amiloride/hydrochlorothiazide (Amizide[®]), amiloride/frusemide (Frumil[®]), triamterene/hydrochlorothiazide (Triamizide[®]), spironolactone (Aldactone[®], Spirotone[®])
- angiotensin receptor antagonists, used to reduce blood pressure e.g. losartan (Cozaar[®]), candesartan (Atacand[®])
- potassium supplements or potassium-containing salt substitutes
- lithium (Lithicarb[®], Priadel[®])
- antidiabetic medicines (for lowering blood sugar in diabetes)
- desensitization therapy with wasp or bee venom
- immunosuppressive therapy

These medicines may be affected by INHIBACE, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while taking INHIBACE.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take INHIBACE

- Always take your medicine exactly as your doctor tells you to and do not stop treatment unless he/she tells you to do so:
- If you have high blood pressure, your normal starting dose will be between 0.5 mg and 1.25 mg per day. Your doctor may change the dose to suit your needs throughout your treatment. The full effect of your medicine is not usually seen until after two to four weeks of treatment and the effect then remains constant.
If your blood pressure is not adequately controlled by INHIBACE, your doctor may prescribe a diuretic (water tablet) which will work together with your medicine to further control your blood pressure.
- If you are elderly, your doctor will probably start you on 0.5 mg a day if you are suffering from hypertension and 0.5 mg if you suffer from chronic heart failure. After starting therapy your doctor may adjust your dose, depending on your response.
- If you have kidney or liver problems, your doctor may start you on a lower dose than normal before adjusting your dose depending on your response.
- If you have chronic heart failure, treatment usually starts with a daily dose of 0.5 mg in addition to digitalis and/or diuretics. Depending on your individual response to the treatment your doctor may decide to increase the daily dose. If you are already taking diuretics your doctor may reduce the dose of the diuretic, or even stop you taking the diuretic at all before you start taking INHIBACE.
- Take your medicine before or after meals, and swallow the tablets whole with water or another non-alcoholic drink. The medicine should be taken at around the same time each day, ideally in the morning.
- If you miss a dose, you should never make it up by doubling the next dose. Instead, you should simply continue with the next dose when it is due.
- Do not change the prescribed dose of your medicine yourself. If you think the effect of your medicine is too weak or too strong, talk to your doctor.

In case of an overdose

Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much INHIBACE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking INHIBACE

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking INHIBACE.

Tell your doctor if you become pregnant while taking INHIBACE.

Tell your doctor that you are taking INHIBACE if you are going to have any laboratory tests.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel that the tablets are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Things you must not do

Do not stop taking INHIBACE tablets or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give INHIBACE tablets to anyone else even if they have the same condition as you.

Do not use INHIBACE to treat other complaints unless your doctor says to.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how INHIBACE affects you.

As with many other medicines used to treat high blood pressure, INHIBACE may cause dizziness, drowsiness or light-headedness in **some** people. Make sure you know how you react to INHIBACE before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy, drowsy or light-headed. If you drink alcohol, dizziness, drowsiness or light-headedness may be worse.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking INHIBACE.

INHIBACE helps most people with high blood pressure but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- headache
- dizziness, faintness
- tiredness
- cough
- indigestion
- skin rashes
- hair loss
- increased sensitivity to light

These are the more common side effects of INHIBACE. Mostly these are mild and some may decrease as you get used to your medicine.

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:

- your face, lips, tongue and/or throat become swollen
- you develop a persistent pain in the abdomen

- symptoms of serious kidney failure, which may include passing little or no urine, drowsiness, nausea, vomiting and/or breathlessness
- chest pains, rapid or irregular heart beat
- difficulty breathing or coughing up blood
- symptoms of a stroke which may include weakness/numbness in the face, arms, legs or either side of your body, difficulty speaking, understanding or swallowing, loss of vision, severe and abrupt headache

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything on this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking INHIBACE

- Keep the pack away from sources of heat (store below 25 °C).
- Keep this medicine out of the reach and sight of children.
- This medicine must not be used after the expiry date printed on the pack.
If the pharmacist has repacked the medicine for you, there may not be an expiry date on the pack. Return any left over medicine to your pharmacist. Only keep it if your doctor tells you to.
- REMEMBER this medicine is for you. Only a doctor can prescribe it for you. Never give it to others. It may harm them even if their symptoms are the same as yours.

Further information

You can get more information on INHIBACE from your doctor or pharmacist.

What can you do to reduce your high blood pressure?

If you are overweight try to maintain a lower body weight.

Take more exercise; ask your doctor for advice.

If you drink alcohol, try to reduce your daily consumption.

If you are a smoker, try to give up smoking.

Product Description

What INHIBACE looks like

The white tablets contain 0.5 mg of cilazapril and have "CIL 0.5" imprinted on one side.

The pink tablets contain 2.5 mg of cilazapril and have "CIL 2.5" imprinted on one side.

The reddish-brown tablets contain 5 mg of cilazapril and have "CIL 5.0" imprinted on one side.

Ingredients

All the tablets contain the additional ingredients lactose monohydrate, maize starch, sodium stearyl fumarate, hypromellose, purified talc, and the colorants titanium dioxide (E171). In addition the 2.5 mg and 5 mg tablets also contain red iron oxide (E172) and the 2.5 mg tablets also contain yellow iron oxide (E172).

All the tablets are scored so that they can easily be broken into halves.

Distributor

INHIBACE is distributed by:

Roche Products (New Zealand) Ltd
P O Box 12492 Penrose
AUCKLAND 1642

Customer Enquiries: 0800 656 464

This leaflet was prepared on 24 January 2011.