

Package Leaflet: Information for the user
Cibacen 10mg
Film coated tablets
Benazepril hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Cibacen is and what it is used for
2. What you need to know before you take Cibacen
3. How to take Cibacen
4. Possible side effects
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1. What Cibacen is and what it is used for

Cibacen film-coated tablets contain 10mg benazepril hydrochloride. This is one of a group of medicines called ACE inhibitors. Cibacen is used to treat high blood pressure. It can also be used to treat some types of heart or kidney disease.

2. What you need to know before you taken Cibacen

Do not take Cibacen

- If you are allergic to benazepril or any other ACE inhibitor or to any of the ingredients in the tablets (listed in section 6)
- If you previously had a reaction to an ACE inhibitor involving hoarseness, swelling of the face, mouth, hands or feet, or sudden breathing problems
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- If you are more than 3 months pregnant. (it is also better to avoid Cibacen in early pregnancy – see pregnancy section).
- If you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.
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Warnings and Precautions

Talk to your doctor or pharmacist before taking Cibacen

- If you are taking any of the following medicines used to treat high blood pressure:
 - An angiotensin II receptor blocker (ARBs) (also known as sartans – for example, valsartan,

telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
– aliskiren

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading “Do not take Cibacen”.

Take special care with Cibacen

- If you suffer from any kidney disease
- If you are a child with previous kidney problems
- If you suffer from liver disease
- If you have suffered from any heart or blood vessel disorders (including heart attack, stroke, heart valve disorder or aortic valve disorder)
- If you are about to have an operation (including dental surgery)
- If you are suffering from diarrhoea or vomiting
- If you have low blood pressure (symptoms include faintness or dizziness, especially when standing)
- If you are about to have or are having dialysis
- If you have collagen vascular disease (disease of the connective tissue) such as lupus erythematosus rheumatoid arthritis or scleroderma
- If you are about to receive Hymenoptera venom treatment (a venom used to test or treat allergy to insect stings)
- If you are of black origin; you might be more likely to suffer side effects such as serious allergic reaction which causes swelling of the face or throat
- If you have high levels of potassium in your blood (hyperkalaemia)
- If you are on a salt-restricted diet
- If you are a child with heart problems

If any of the above applies to you, or if you are not sure, tell your doctor who will decide what to do.

Your doctor will monitor your white blood cell count if you have collagen vascular disease and kidney problems. This is because you may be at risk of developing agranulocytosis. Symptoms of which include sore throat, fever and getting infections more often. Tell your doctor if you develop any of these symptoms.

You must tell your doctor if you think you are (or might become) pregnant. Cibacen is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Children and adolescents

Cibacen can be used to treat high blood pressure in children and adolescents from 7 years of age.

Cibacen should not be used to treat children or adolescents with heart failure or kidney disease.

Cibacen tablets are not suitable for children under 7 years of age or for older children who cannot swallow tablets. Safety and effectiveness of this medicine in children younger than 7 years old have not been established. The long term effect of this medicine on growth, puberty and general development of children has not been studied.

Other medicines and Cibacen

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Your doctor may need to change your dose and/or take other precautions:

If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Cibacen” and “Warnings and precautions”).

You especially need to tell your doctor or pharmacist if you are using:

- Medicines used to lower blood pressure, especially diuretics (water tablets) such as spironolactone
- Medicines for depression (e.g. Lithium)
- Medicines for diabetes
- Medicines containing potassium, potassium supplements or salt substitutes containing potassium
- Indomethacin, a medicine which is used to treat inflammation and pain
- Gold to treat symptoms of rheumatoid arthritis
- Non-steroidal anti-inflammatory drugs used for pain relief and inflammation (e.g. ibuprofen, indomethacin)
- Aspirin (acetylsalicylic acid) when used for pain relief and inflammation (benazepril may be used with aspirin when aspirin is used to prevent heart attacks and strokes)
- Ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection;
- Heparin, a medicine used to thin blood;
- Medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus)
- Potassium supplements (including salt substitutes), potassium-sparing diuretics and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots)

If you are taking any of the following medicines, the risk of angioedema may be increased:

- Racecadotril, a medicine used to treat diarrhoea;
- Medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus).
- Vildagliptin, a medicine used to treat diabetes.

In rare cases benazepril can increase the blood sugar lowering effects of antidiabetic tablets and insulin. This may happen in the first few weeks of treatment. If this happens you should contact your doctor.

Cibacen with food and drink

Do not drink alcohol whilst taking this medicine without first asking your doctor. Alcohol may make blood pressure fall more and/or increase the possibility of dizziness or fainting.

Pregnancy and breastfeeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Cibacen before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Cibacen. Cibacen is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant as it may cause serious harm to your baby if used after the third month of pregnancy.

Breastfeeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Breast-feeding new-born babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking Cibacen. In the case of an older baby your doctor should advise you on the benefits and risks of taking Cibacen whilst breast-feeding compared with other treatments.

Driving and using machines

If you feel dizzy or sleepy do not drive or use machinery until these effects wear off.

Cibacen contains lactose

The tablets may not be suitable for you if you cannot take lactose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

3. How to take Cibacen

It is important to take your medicine as directed by your doctor and to keep appointments with the doctor even if you are feeling well. Read the label on the tablets carefully, it will tell you when to take them. In general, treatment is started with the smallest appropriate dose and this can be increased by your doctor as necessary. Your doctor will prescribe the lowest possible dose to suit your needs, to be taken once or in two doses each day.

Adults:

Adults with high blood pressure:

The usual daily dose is in the range 2.5 – 20 mg/day. If you are not sure how many tablets to take, ask your doctor or pharmacist. Maximum recommended daily dose is 40mg given as a single dose or two doses. Patients with high blood pressure and impaired kidney function:

Your doctor may reduce your dose under certain conditions (creatinine clearance is below 30 ml/min). The starting dose is 10mg. Dosage may be increased to up to 10mg daily.

Progressive chronic kidney insufficiency

Long term use to slow the progression of kidney disease, the recommended dose is 10mg daily. Patients with congestive heart failure: Recommended initial dose is 2.5mg once daily. Dose may be increased to 10mg and eventually to 20mg once daily at appropriate intervals

Patients with high blood pressure and heart failure A lower initial dose (e.g. 5mg) is recommended

Older patients:

Usual initial dose is 5mg once daily which may be titrated to 10mg

Children and adolescents from 7 years of age with high blood pressure:

The usual recommended starting dose is 0.2mg/kg. The maximum daily dose for children is 10mg.

Take your tablets at the same time each day in the morning. They can be taken before, during or after breakfast. If your doctor has prescribed a larger dose, he may wish you to take a tablet twice daily. Swallow your tablets whole with a drink of water.

It is important for your doctor to check your progress at regular visits to make sure that this medicine is working properly.

Check with your doctor immediately if you have a stomach upset, especially if nausea, vomiting or diarrhoea is severe or does not go away. These conditions may cause you to lose too much water and lead to low blood pressure.

Dizziness (light-headedness) or fainting may also occur when you take exercise or if the weather is hot. Heavy sweating can make you lose too much water and cause low blood pressure. Be very careful during exercise or hot weather.

If you take more Cibacen than you should

If you accidentally take too many tablets, tell your doctor once or contact your nearest hospital casualty department.

If you forgot to take Cibacen

If you forget to take a dose, take the next dose at the usual time. Do NOT take a double dose.

If you stop taking Cibacen

Do not stop taking your tablets suddenly. Ask your doctor first.

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

4. Possible side effects

Like all medicines, Cibacen can cause side effects although not everybody gets them.

If you get any of the following tell your doctor immediately:

- Swelling of the face, eyes, lips or tongue
- Sudden problems with swallowing or breathing

Check with your doctor as soon as possible if any of the following effects occur:

- Dizziness, light-headedness (especially during the first few days of treatment) or fainting
- Sore throat, fever or chills

- Yellowing of your skin or the whites of your eyes
- Stomach upset, nausea with vomiting or diarrhoea
- Constipation
- Abdominal pain
- Numbness or tingling in the hands feet or lips
- Skin rash or itching
- Chest pain
- Frequent passing of water or pain on passing water
- Feeling of pressure and pain in the back
- Ringing in the ears
- Impairment or loss of taste
- Sensitivity of the skin to light (photosensitivity)
- Pollakiuria: passing small quantities of urine more frequently than normal

Many side effects will clear up without you having to stop the treatment. Check with your doctor if any of the following are severe or last for more than a few days.

- Headache, unusual tiredness or sleepiness, sleep problems
- Persistent cough
- Fast heartbeat or palpitations
- Flushing of the face
- Nervousness
- Joint or muscle pain

Very rarely the following side effects may be observed:

- Heart problems including heart attack, irregular heart beat
- Severe pain in the back and abdomen possibly indicating inflammation of the pancreas
- Very severe hypersensitivity reactions e.g. Stevens-johnson syndrome a serious illness with blistering of the skin mouth eyes and genitals
- Liver disorder, typically with jaundice, fatigue, anorexia, abdominal pain
- Kidney disorder manifesting with lower output of urine
- Decrease in blood platelets count
- Hemolytic anemia: blood disorder, symptoms include tiredness and shortness of breath.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cibacen

Keep out of the sight and reach of children.

Do not use Cibacen after the expiry date which is stated on the carton and the blister after the expiry date. The expiry date refers to the last day of that month.

Do not store above 25°C

Store in the original package to protect from moisture.

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.

6. Contents of the pack and other information

What Cibacen contains

The active substance is benazepril hydrochloride 10 mg

The other ingredients are:

Core – colloidal anhydrous silica, microcrystalline cellulose, hydrogenated castor oil, lactose monohydrate, pregelatinised maize starch, crospovidone

Coat – hypromellose, yellow iron oxide (E172) titanium dioxide (E171), macrogol 8000 and talc.

What Cibacen looks like and contents of the pack

The tablets are light yellow, ovaloid biconvex, film coated and scored on both sides.

The tablets come in calendar packs of 28 tablets. Each tablet pocket is marked with the day of the week.

Marketing Authorisation Holder and Manufacturer

Manufactured by:

MADAUS GmbH,
51101 Cologne,
Germany

Marketing Authorisation Holder

Mylan IRE Healthcare Limited,
Unit 35/36, Grange Parade,
Baldoyle Industrial Estate,
Dublin 13,
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