

Package leaflet: Information for the user

Captor-HCT 25mg/12.5mg & 50mg/25mg Tablets

captopril & hydrochlorothiazide

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 only. Do not pass it on to others. It may harm them even if their signs of illness 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.

What is in this leaflet:

1. What Captor-HCT is and what it is used for
2. What you need to know before you take Captor-HCT
3. How to take Captor-HCT
4. Possible side effects
5. How to store Captor-HCT
6. Contents of the pack and other information

1 What Captor-HCT is and what it is used for

Captor-HCT is used to treat:

- **high blood pressure**

This medication is made up of two different active substances: captopril and hydrochlorothiazide.

Captopril belongs to the ACE inhibitors medicine group (angiotensin-converting enzyme inhibitors). Captopril expands your blood vessels. This reduces your blood pressure and makes it easier for your heart to pump blood to all body parts.

Hydrochlorothiazide is a water pill (diuretic). It increases the amount of salt and water you lose in your urine. This also results in a fall in blood pressure.

2 What you need to know before you take Captor-HCT

Do not take Captor-HCT:

- if you are **allergic** to
 - captopril, hydrochlorothiazide or
 - any of the other ingredients of this medicine (listed in section 6) or
 - other ACE inhibitors or to any other sulphonamide derivatives
- if during earlier ACE inhibitor use you had **swelling of the face, lips, tongue** and/or **throat** with difficulty swallowing or breathing

Do not take Captor-HCT if you had any of these reactions

- without a known cause or
- if it has been confirmed that you have a hereditary or
- other form of fluid accumulation (angioedema)
- if you have severely reduced **kidney** function
- if you have severely reduced **liver** function
- 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 Captor-HCT 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.

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before taking Captor-HCT if you:

- suffer from **dehydration** due to treatment with ‘water tablets’ (diuretics), dialysis, a low salt diet, vomiting or diarrhoea. After starting medication, a large drop in blood pressure may frequently occur and feeling faint or light-headed.
- suffer from **heart disorders** such as heart failure, narrowing of the aortic or mitral valves (aortic or mitral stenosis) or an increase in the thickness of the heart muscle (hypertrophic cardiomyopathy or ‘HOCM’) or if you have a condition involving the blood vessels in the brain
- have **kidney problems**
- are undergoing **dialysis treatment**
 - with high flux membranes
 - blood separation treatment to remove cholesterol from your blood by machine with dextran sulphate or **desensitisation treatment** to reduce the effects of an allergy to a **bee or wasp sting**.

In these cases tell your doctor that you are taking Captor-HCT. He/She may wish to interrupt your treatment to prevent a possible allergic reaction.

- have **liver problems**. If you develop jaundice during use of Captor-HCT stop taking it and consult your doctor.
- have **blood vessel disease**, known as collagen vascular disease
- **black people of afro-Caribbean origin** have a higher risk of the effect of Captor-HCT being reduced
- have a **cough** inform your doctor if this becomes worse
- have **symptoms of intestinal angioedema** such as abdominal pain, nausea, vomiting and bloating
- have **systemic lupus erythematosus**
- are undergoing an **operation with a general anaesthetic**, inform your doctor about Captor-HCT
- are taking **other medicines**, such as potassium supplements, lithium (for mental disorders) or medicines against diabetes
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- **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.
- are taking any of the following medicines used to treat high blood pressure:
 - an angiotensin II receptor blocker (ARB) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems
 - aliskiren.

In particular, talk to your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines:

- 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)
- 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 Captor-HCT’.

- if you experience an **infection** with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately.
- if you have changes in your vision or pain in one or both of your eyes while taking this medicine. This could be a sign that you are developing glaucoma, increased pressure in your eye(s). You should discontinue this medicine and seek medical attention.

- if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Captor-HCT.

You must tell your doctor if you think you are (or might become) pregnant. Captor-HCT 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).

While taking this medicine you should be aware of the following:

- If you have to undergo an **anti-doping test** hydrochlorothiazide can produce a positive result
- If you undergo a so called **bentiromide test** for your thyroid gland, hydrochlorothiazide can produce a false result.

If you are unsure if any of the above apply to you, please discuss this with your doctor.

Other medicines and Captor-HCT

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

This applies in particular if you are also taking:

- **diuretics** ('water tablets') which are used to treat high blood pressure including potassium-sparing diuretics such as spironolactone, triamterene or amiloride
- other **medicines** used to **treat high blood pressure**
Your doctor may need to change your dose and/or to take other precautions:
if you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings 'Do not take Captor-HCT' and 'Warnings and precautions')
- medicines to treat arthritis or muscle pain, such as **ibuprofen** or **indomethacin**
- medicines for mental disorders or depressions such as
 - **lithium**
 - **medicines to treat psychoses**
 - **tricyclic antidepressants**, such as amitriptyline
- medicines which are most often used to avoid rejection of transplanted organs (sirolimus, temsirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors).
See section 'Warnings and precautions'.
- **potassium** supplements or salt substitutes containing potassium, diuretics (water tablets, in particular those so called potassium sparing), other drugs which can increase potassium in your body (such as heparin, ciclosporin and co-trimoxazole also known as trimethoprim/sulfamethoxazole)
- **blood sugar lowering medicines**, such as insulin or those taken orally.
The antidiabetic medicine dose may need adjusting.
- central nervous system stimulative medicines, such as
 - **ephedrine** or **pseudoephedrine**, which could be included in decongestants or cough/cold remedies or
 - **salbutamol**, a medicine for treating asthma
- **medicines to suppress the body's immune system**
- **allopurinol**, a medicine to treat gout
- **procainamide**, used to treat abnormal heartbeats
- medicines used in cancer (**cytostatics**)
- medicines against **high cholesterol** (colestyramine, colestipol resins). These medicines should be taken 1 hour before or 4-6 hours after Captor-HCT.
- **amphotericin B** (medicine for fungal infections)
- **carbenoxolone** (medicine for gastrointestinal diseases)
- **corticosteroids** (anti-inflammatory hormone
 - like substances from the adrenal gland)

- **ACTH** (to test whether your adrenal glands are working properly)
- medicines to promote defaecation (**laxatives**)
- the concentration of **calcium** in the blood can be increased by calcium salts
- medicines that promote the pumping power of the **heart** (cardiac glycosides)
- tubocurarine chloride, **muscle-relaxants** that are used in operations
- drugs associated with **torsades de pointes**
- **carbamazepine** (medicine to treat seizures)
- **sacubitril/valsartan**, a medicine used to treat a type of long-term (chronic) heart failure in adults (see section 2 'Do not take Captor-HCT')
- **vildagliptin**, a medicine used to treat diabetes
- **racecadotril**, a medicine used to treat diarrhoea.

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Captor-HCT before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Captor-HCT. Captor-HCT 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.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding.

Captor-HCT is not recommended for mothers who are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines

Captor-HCT can affect your ability to drive, usually when you first start taking your medicine, if your doctor changes your dose or in combination with alcohol. If you feel light-headed or dizzy, you should not drive or operate machinery.

Captor-HCT contains lactose monohydrate.

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 Captor-HCT

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Take the tablets before, during or after meals with a glass of water.

The tablets can be divided into equal halves.

The recommended dose is:

• Adults

The usual dosage is 50mg/25mg once a day in the morning. The maximum daily dose is 50mg/25mg.

• Diabetic patients

The usual starting dose is 25mg/12.5mg once a day.

• Patients with reduced kidney function

If you suffer from a kidney disorder your doctor may reduce the dose. Captor-HCT should not be used if you have severely impaired kidney function.

• Elderly

The usual starting dose is 25mg/12.5mg once a day.

• **Children**

Not recommended.

If you take more Captor-HCT than you should

Contact your doctor or the nearest hospital casualty department immediately.

Take this leaflet or some tablets with you so that people will know what you have taken.

If you forget to take Captor-HCT

Take the missed dose as soon as you remember but never take two doses in one day.

If you stop taking Captor-HCT

Do not stop treatment before talking to your doctor, as this will reduce the treatment's effect.

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

4 Possible side effects

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

Allergic reaction signs and symptoms are:

- difficulties in breathing
- swelling of the face, hands, feet, lips, tongue and/or throat
- severe skin itch with raised lumps.

Stop taking Captor-HCT and seek medical advice immediately, if you develop any of the allergic reaction signs.

Other possible side effects of captopril:

Common: may affect up to 1 in 10 people

- sleep problems
- taste abnormalities
- dizziness
- dry, irritating cough
- shortness of breath
- feeling sick (nausea)
- vomiting
- upset stomach
- abdominal pain
- diarrhoea
- constipation
- dry mouth
- peptic ulcer
- itching
- rash
- hair loss.

Uncommon: may affect up to 1 in 100 people

- headache
- the sensation of pins and needles
- loss of appetite
- increased heart rate
- angina
- heart palpitations
- low blood pressure
- numbness or tingling in the fingers and toes

- flushing
- looking pale
- swelling of the eyes and lips (angioedema)
- chest pain
- tiredness
- general weakness.

Rare: may affect up to 1 in 1,000 people

- drowsiness
- mouth ulcers
- kidney disorders or failure
- changes in frequency of passing urine
- symptoms of intestinal angiodema such as abdominal pain, nausea, vomiting and bloating.

Very Rare: may affect up to 1 in 10,000 people

- deficiency of red blood cells with signs such as looking pale or feeling tired
- unexpected bruising
- blood abnormality and abnormalities of the lymph glands
- high levels of potassium in the blood
- low blood sugar levels
- confusion
- depression
- cerebrovascular incidents, including stroke, cerebrovascular insufficiency and lapse of consciousness
- blurred vision
- heart problems, including heart attack
- difficulty in breathing, stuffy nose, certain forms of pneumonia
- swollen tongue
- inflammation of the pancreas
- impaired liver function and raised liver enzymes
- liver damage, inflammation of the liver or jaundice (yellowing of the skin and/or the whites of the eyes)
- severe skin disorders including Stevens-Johnson syndrome
- sensitivity of the skin to light
- muscle pain
- joint pain
- an abnormal condition of the kidney known as nephrotic syndrome
- inability to maintain an erection (impotence)
- enlargement of one or both breasts in men
- fever
- proteinuria
- eosinophilia
- increase of serum potassium
- decrease of serum sodium
- elevation of BUN, serum creatinine and serum bilirubin
- decreases in haemoglobin, haematocrit, leucocytes, thrombocytes
- positive ANA titre
- elevated ESR.

Other possible side effects of hydrochlorothiazide:

- inflammation of a salivary gland
- blood abnormality
- high blood levels of: sugar, uric acid (as in the case of gout), cholesterol, triglycerides
- low blood level of potassium which can cause muscle weakness, twitching or abnormal heart rhythm
- low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits or coma

- restlessness
- depression
- sleep disturbances
- temporary blurred vision and visual changes which can make a colourless object look tinged with yellow, near sightedness, glaucoma (increased eye pressure)
- vertigo
- dizziness and fainting on standing up, irregular heart beat
- loss of appetite
- the sensation of pins and needles
- feeling of light-headedness
- inflammation of blood vessels, often with skin rash
- difficulty breathing, wheezing caused by inflammation of the lungs, fluid in the lungs
- gastric irritation, diarrhoea, constipation
- inflammation of the pancreas
- jaundice (yellowing of the skin and/or the whites of the eyes)
- hypersensitivity to light, rash, hives, a skin condition with red scaly patches over the nose and cheeks (lupus erythematosus) this condition may be worsened in patients who already have it, a skin disease known as toxic epidermal necrolysis
- muscle spasm
- kidney problems
- fever
- weakness.

Frequency ‘not known’:

- skin and lip cancer (Non-melanoma skin cancer)

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 HPR

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Captor-HCT

Do not store above 25°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and on the carton after ‘Exp’. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Captor-HCT contains

- The active substances are captopril and hydrochlorothiazide.
One Captor-HCT 25mg/12.5mg tablet contains 25mg captopril and 12.5mg hydrochlorothiazide.
One Captor-HCT 50mg/25mg tablet contains 50mg captopril and 25mg hydrochlorothiazide.
- The other ingredients are microcrystalline cellulose, lactose monohydrate, pregelatinised maize starch, stearic acid and magnesium stearate.

What Captor-HCT looks like and contents of the pack

Captor-HCT 25mg/12.5mg is a white, round tablet with a score notch on one side. The opposite convex side is engraved with 'Cc'. It is available in the following pack size: 30 tablets.

Captor-HCT 50mg/25mg is a white, octagonal tablet with a crossed score notch on one side. The opposite convex side is engraved with 'Cc'. It is available in the following pack size: 30 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers:

Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.

Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.

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