

PACKAGE LEAFLET : INFORMATION FOR THE USER

Accupro® 5mg, 10 mg & 20mg Film-coated Tablets

Quinapril Hydrochloride

Important things that you SHOULD know about your medicine:

- Accupro is a treatment for high blood pressure and to help treat heart failure.
- 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.
- You should take Accupro regularly to get the maximum benefit, even if you are feeling well.
- Most people do not have serious problems when taking Accupro but side effects can occur – see Section 4 for details. If you experience swelling of the face, tongue or throat, see your doctor immediately. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- Taking other medicines may sometimes cause problems. Check with your doctor or pharmacist before taking this or any other medicines.
- If you think you are (or might become) pregnant, you must tell your doctor. Do not take Accupro if you are more than 3 months pregnant.

What is in this leaflet:

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

1. What Accupro is and what it is used for

Accupro is one of a group of medicines called angiotensin converting enzyme (ACE) inhibitors. ACE inhibitors work by widening blood vessels in the body, which can reduce the pressure in the vessels. It is used to treat high blood pressure, or to help treat heart failure.

2. What you need to know before you take Accupro

⚠ Do not take Accupro:

- If you have had an allergic reaction in the past to Accupro, the active ingredient quinapril hydrochloride, or any of the other ingredients listed in Section 6. This may have been itching, a rash on the skin or difficulty in breathing.
- If you are more than 3 months pregnant (It is also better to avoid Accupro in early pregnancy – see pregnancy section).
- If you have a condition called angioedema (a swelling of the face, tongue or throat which causes difficulty breathing).
- If you have a history of angioedema (a swelling of the face, tongue or throat which causes difficulty breathing) relating to previous treatment with an ACE inhibitor
- If you have obstruction of the blood flow from the left ventricle of the heart. This can result in loss of consciousness, pain in the chest, breathlessness or a rapid heartbeat.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- If you are taking sacubitril/valsartan, a medicine for heart failure.

⚠ Warnings and Precautions

Talk to your doctor or pharmacist before taking Accupro.

If any of the following statements applies to you, and you have not already discussed the matter with your doctor, you must contact your doctor before taking ACCUPRO, as this medicine may not be suitable for you if:

- You have aortic stenosis (narrowing of the main blood vessel from the heart)
- You have kidney disease or use a haemodialysis machine (an artificial kidney). Your doctor will monitor your kidney function.
- You have liver disease
- You have heart disease, heart failure or ischaemic heart (reduced blood supply of heart muscle) or cerebrovascular disease (disease of the blood vessels supplying the brain). Your doctor will monitor your blood pressure for the first 2 weeks of treatment due to a risk of low blood pressure.
- You have collagen vascular disease (deposits of collagen in your blood vessels) and/or kidney disease. Your doctor will monitor your white blood cell count.
- You are having, or about to have, low density lipoprotein apheresis treatment (removal of cholesterol from your blood by machine).
- You suffer from allergies or obstructive airway disease such as asthma.
- You are having, or about to have, desensitisation treatment, i.e. to reduce the effects of an allergy to a bee or wasp sting.
- You are a black patient, this medicine might not work as well for you or you might be more likely to suffer serious side effects (e.g. angioedema, swelling of the face, eyes, tongue or throat)
- You suffer from severe kidney problems
- You have diabetes and are taking insulin or oral hypoglycaemic (sugar, glucose, lowering) agents.
- You are experiencing any fluid inadequacies due to diarrhoea, vomiting, diuretic therapy (water tablets), dietary salt restriction or dialysis.
- You are also taking other medicines (please see taking other medicines section below).
- You have intestinal angioedema (a swelling of the stomach or intestine leading to stomach pain)
- You are or will be undergoing major surgery or during anaesthesia with medicines that lower blood pressure
- You suffer from a sugar intolerance (galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption)
- You must tell your doctor if you think you are (or might become) pregnant. Accupro 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).
- 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
- You are simultaneously receiving an mTOR (mammalian target of Rapamycin) inhibitor (e.g. temsirolimus) or a DPP-4 (dipeptidyl-peptidase-4) inhibitor (e.g. vildagliptin) or a neutral endopeptidase inhibitor (e.g. racecadotril), may have an increased risk for angioedema (swelling of the face, eyes, tongue or throat). Special caution is advised if treatment with an mTOR inhibitor or DPP-4 inhibitor or a neutral endopeptidase inhibitor is initiated in patients who are already receiving an ACE inhibitor.
- You are taking medicines or have conditions which may decrease sodium levels in your blood.

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 Accupro'.

Other medicines and Accupro

Tell your doctor if you are taking, have recently taken or might take any other medicines. There are some medicines that may interact with Accupro. Your doctor may need to change your dose and/or to take other precautions if you are taking:

- Angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings 'Do not take Accupro' and 'Warnings and precautions').
- Other blood pressure treatments and diuretics (water tablets).
- Medicines to treat infections called tetracyclines.
- Antibiotics like sulfamethoxazole and trimethoprim.
- Potassium supplements (this includes salt substitutes which often contain potassium).
- Lithium (used to treat depression, mania and aggressive or self-mutilating behaviour).
- Drugs to treat diabetes. Anti-diabetic medicines such as insulin and oral hypoglycaemic agents) may cause an increased blood glucose lowering effect with the risk of much lower levels of glucose in the blood

Mammalian target of rapamycin (mTOR) inhibitors used to treat kidney cancer (including temsirolimus), certain antidiabetic drugs (DPP-4 inhibitors e.g. vildagliptin) or certain drugs against heart insufficiency and high blood pressure (neutral endopeptidase inhibitor, e.g. racecadotril): the risk of an angioedema (swelling of the face, eyes, tongue or throat) can be elevated.

- Anti-inflammatory drugs known as non-steroidal anti-inflammatory drugs
- Injectable gold treatments
- Allopurinol (used to treat chronic gout), cytostatic (used to treat cancer) and immunosuppressive agents, steroids or procainamide (used to treat irregular heartbeats)
- Alcohol, barbiturates (used to treat depression), narcotics (mood altering substance)
- Antacids (used to treat heartburn)
- Beta-blockers (used to treat angina and high blood pressure)
- Methyl dopa (used to treat angina and high blood pressure)

You should always tell your doctor if you are taking or have recently taken any other medicine, even those not prescribed, because they might interact with Accupro.

Surgery

Remember to tell any medical staff that you are taking Accupro. This is important if you go into hospital for an operation as your anaesthetist will want to know.

Laboratory Tests

Accupro may affect the results of some laboratory tests. Tell your doctor or hospital staff that you are taking Accupro if you need to have any tests carried out by your doctor or in hospital.

⚠ Accupro with food and drink

Accupro can be taken with or without food.

⚠ Pregnancy, breast-feeding and fertility

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Accupro before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Accupro. Accupro 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. Breast-feeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking Accupro.

In the case of an older baby your doctor should advise you on the benefits and risks of taking Accupro whilst breast-feeding, compared with other treatments.

⚠ Driving and using machines

Your tablets may affect your ability to drive or operate machinery safely, especially when initiating Accupro therapy. They may make you feel dizzy or weary. If affected, do not drive or operate machinery and contact your doctor immediately.

Important information about some of the ingredients in Accupro

Accupro contains lactose (a type of sugar), 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 Accupro

For treatment of hypertension (high blood pressure) the starting dose is usually 10 mg a day, which may be increased gradually up to a maximum of 80 mg a day.

For the treatment of heart failure or if you are also taking water tablets (diuretics) to treat your high blood pressure, or you have kidney disease, the starting dose is usually 5 mg, which may be increased up to a maximum of 40 mg a day.

Accupro should not be used in children under 12 years of age.

For elderly patients, the recommended starting dose to treat high blood pressure is 10 mg given once a day.

Accupro tablets should be taken either once or twice a day. Whatever dose you have been prescribed, follow your doctor's instructions exactly and never change the dose yourself.

Swallow the tablets whole with water. **Do not chew, divide or crush** the tablets.

If you are still not sure, ask your doctor or pharmacist.

It is important to keep taking your tablets. They help to control your blood pressure.

Don't wait until your tablets are finished before seeing your doctor.

If you take more Accupro than you should

Taking too many tablets at once may make you unwell. Tell your doctor or go to your nearest hospital casualty department immediately. Take along any tablets that are left, the packaging and the label so that the hospital staff can easily tell what medicine you have taken.

If you forget to take Accupro

Do not worry. If you forget to take a dose, miss out the forgotten dose completely and take the next dose at the normal time. **Do not take a double dose to make up for a missed dose.**

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

4. Possible side effects

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

STOP taking Accupro and call an ambulance immediately if you experience any of the following symptoms. Although they are very rare, they can be serious.

- Severe allergic (anaphylactoid) reactions such as swelling of the face, tongue, lips or throat (angioedema), which may cause great difficulty breathing; swelling of the extremities (hands or feet).
- Severe abdominal pain and/or back pain causing you to feel or be sick (this may be a sign of swelling in the intestine or an inflamed pancreas).
- Intense skin rash including hives, severe itching, blistering, peeling and swelling of the skin (Stevens Johnson Syndrome), inflammation of mucous membranes (pemphigus).

Tell your doctor **immediately** if you experience any of the following symptoms after taking this medicine. Although they are very rare, these symptoms can be serious.

- Feeling faint, particularly when standing. This may mean your blood pressure is too low (hypotension). This is more likely to occur if you have been taking diuretics (water tablets), other blood pressure medication in addition to Accupro, alcohol or if you are dehydrated or on dialysis. If you feel light headed or faint, lie down until this feeling passes.
- Severe sore throat or severe mouth ulcers, particularly if you suffer from kidney problems or collagen vascular disease. This may mean you do not have enough of certain white blood cells (neutropenia/agranulocytosis), which may lead to increased risk of infection or fever.
- Chest pain, tightness of the chest, shortness of breath, wheezing or trouble breathing, irregular, fast or strong heartbeat (palpitations).
- Yellowing of the skin or the eyes (jaundice) which may be a sign of liver inflammation (hepatitis)

The following side-effects have also been reported in patients with high blood pressure being treated with Accupro. If any of these side-effects gets serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor:

Very common: may affect more than 1 in 10 people

- painful muscles; back pain
- feeling weak; sleeplessness
- numbness or tingling sensation in your limbs
- raised levels of potassium in your blood
- sore throat
- headache; dizziness
- low blood pressure
- shortness of breath; coughing
- vomiting
- diarrhoea
- upset stomach
- feeling sick
- stomach pain
- tiredness
- increased creatinine and blood urea in blood
- nasal stuffiness and/or runny nose (rhinitis)
- chest pain

Uncommon: may affect up to 1 in 100 people

- angioedema (swelling of the deeper layer of the skin caused by a build up of fluid)
- vertigo, feeling sleepy
- fluid retention in the body
- kidney and urinary problems
- joint pain
- inflammation of your sinuses (sinusitis)
- itching; rash; sweating
- dry mouth or throat
- lazy eye
- depression; nervousness, confusion
- failure/ inability to achieve erection in males
- ministroke
- drowsiness
- ringing in the ears
- heart attack
- rapid heart beat (tachycardia)
- palpitations
- widening of the blood vessels
- wind
- protein in urine
- fever
- chest infection
- bronchitis

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

- disorders of balance
- fainting or collapse
- hair loss
- skin sensitivity to sunlight causing burning or redness
- loss of consciousness
- white blood cells accumulating in lungs (eosinophilic pneumonitis)
- swollen tongue
- constipation
- taste changes
- skin rash (erythema multiforme)
- hives
- skin disease characterized by group of itching blisters (pemphigus)

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

- bowel obstruction
- swelling of the intestine
- blurred vision
- inflammation of the skin characterised by inflamed scaly skin like lesions (dermatitis psoriasiform)

Not known: frequency cannot be estimated from the available data

- decreased numbers of white blood cells or decrease in blood platelets which may result in bruising or easy bleeding; low numbers of red blood cells (anaemia).
- decreased sodium concentrations in the blood
- swelling of the face, tongue and throat with difficulty breathing, dizziness, itchy skin, which is a sign of an anaphylactic reaction.
- low blood pressure when getting up from a lying or sitting position
- stroke
- difficulty breathing
- inflammation of the pancreas
- hepatitis (liver inflammation), jaundice
- sensitivity of the skin to sun light
- hair loss
- change in red blood cells in blood

Skin changes may be associated with fever, muscle and joint pain (myalgias, arthralgias, arthritis), vascular inflammation (vasculitis), inflammations of tissues and certain changes in laboratory values.

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

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

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

Not known: frequency cannot be estimated from the available data

Accupro may cause certain changes in your blood and your doctor may do blood tests to monitor this. If you notice bruising, feeling very tired or if you are diabetic and notice changes in your sugar levels, let your doctor know so blood tests can be arranged if necessary.

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 HPRAs 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 Accupro

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

Do not use Accupro after the expiry date (Exp, Verwendbar bis or ΛΗΞΗ) which is stated on the carton and blister. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

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 protect the environment.

6. Further information

What Accupro contains and its package:

Accupro 5mg Tablets contain 5mg quinapril (as hydrochloride)

Accupro 10mg Tablets contain 10mg quinapril (as hydrochloride)

Accupro 20mg Tablets contain 20mg quinapril (as hydrochloride).

Product imported from The Netherlands, Greece and the UK contain the following excipients: Heavy magnesium carbonate, lactose monohydrate, gelatine, crospovidone, magnesium stearate, candelilla wax, hypromellose, hypromellose, titanium dioxide (E171), macrogol 400 and red iron oxide (E172).

Product imported from Germany and Romania contains the following excipients:

Heavy magnesium carbonate, lactose monohydrate, gelatine, crospovidone, magnesium stearate, candelilla wax, hypromellose, hypromellose, titanium dioxide (E171) and macrogol 400.

Accupro 5mg Tablets

Product imported from Greece:

Brown, elliptical film-coated tablets with a breakline and '5' on both sides.

Product imported from Romania:

White, elliptical film-coated tablets with a breakline and '5' on both sides.

Accupro 10mg Tablets

Product imported from the Netherlands and the UK.

Brown, film-coated triangular tablets with a breakline and '10' on one side and a breakline only on the other side.

Product imported from Germany and Romania:

White, film-coated triangular tablets with a breakline and '10' on one side and a breakline only on the other side.

Accupro 20mg Tablets

Product imported from Greece and The Netherlands:

Brown, film-coated, round tablets with a breakline on one side and '20' on the other side.

Product imported from Germany:

White, film-coated, round tablets with a breakline on one side and '20' on the other side.

Product imported from Romania:

White, film-coated, round tablets with a breakline on one side and '20' on the other side or.

White, film-coated, round tablets with a breakline on one side and a breakline and '20' on the other side

Pack size:

Accupro 5mg Tablets are available in blister packs of 28 and 30 tablets, contained in an outer cardboard carton.

Accupro 10mg Tablets are available in blister packs of 28 and 30 tablets, contained in an outer cardboard carton.

Accupro 20mg Tablets are available in blister packs of 14, 28 and 30 tablets, contained in an outer cardboard carton.

Not all pack sizes may be marketed.

The name of Accupro in the Netherlands is Acupril.

The name of Accupro in Greece is Accupron.

The name of Accupro in the UK and Germany is Accupro.

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

MANUFACTURER

Accupro 5mg and 20mg tablets, sourced in Greece, are manufactured by: Cosmo SpA, Italy or Goedecke GmbH, Freiburg, Germany

Accupro 10mg tablets, sourced in the UK, are manufactured by: Goedecke AG, Freiburg, Germany

Accupro 10mg and 20mg tablets, sourced in the Netherlands, are manufactured by: Pfizer B.V., Capelle a/d IJssel, The Netherlands.

Accupro 10mg and 20mg tablets, sourced in Germany, are manufactured by: Pfizer Manufacturing Deutschland GmbH, Heinrich-Mack-Straße 35, 89257 Illertissen, Betriebsstätte Freiburg, Mooswaldallee 1, Freiburg, Germany

Accupro 5mg, 10mg and 20mg tablets, sourced in Romania, are manufactured by: Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg, Mooswaldallee 1, 79090 Freiburg, Germany

Parallel Product Authorisation number:

Accupro 5mg film coated Tablets – PPA 465/135/1

Accupro 10mg film coated Tablets – PPA 465/135/2

Accupro 20mg film coated Tablets – PPA 465/135/3

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