

Package leaflet: Information for the user

Pfizer **Accupro**[®]

**5 mg, 10 mg, 20 mg & 40 mg film-coated tablets
quinapril**

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 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 contains quinapril, which 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.

Accupro is used to treat high blood pressure, or to help treat heart failure.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Accupro

Do not take Accupro

- if you are allergic to quinapril or any of the other ingredients of this medicine (listed in section 6). Signs of allergic reaction include 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 below)
- 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, as this medicine may not be suitable for you:

- if you have aortic stenosis (narrowing of the main blood vessel from the heart)
- if you have kidney disease or use a haemodialysis machine (an artificial kidney). Your doctor will monitor your kidney function
- if you have liver disease
- if 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
- if 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.
- if you are having, or about to have, low density lipoprotein apheresis treatment (removal of cholesterol from your blood by machine)
- if you suffer from allergies or obstructive airway disease such as asthma
- if you are having, or about to have, desensitisation treatment, i.e. to reduce the effects of an allergy to a bee or wasp sting
- if 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)
- if you suffer from severe kidney problems
- if you have diabetes and are taking insulin or oral hypoglycaemic (sugar, glucose, lowering) agents
- if you are experiencing any fluid inadequacies due to diarrhoea, vomiting, diuretic therapy (water tablets), dietary salt restriction or dialysis
- if you are also taking other medicines (see **Other medicines and Accupro** section below)
- if you have intestinal angioedema (a swelling of the stomach or intestine leading to stomach pain)
- if you are or will be undergoing major surgery or during anaesthesia with medicines that lower blood pressure
- if you suffer from a sugar intolerance (galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption)
- 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 below).
- 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
- if 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

- if 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 or pharmacist 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 advise you 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).

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

Please see section 3 **How to take Accupro**.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. 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

If you are breast-feeding, or about to start breast-feeding, ask your doctor or pharmacist for advice before taking this medicine. Breast-feeding new born 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.

Accupro contains lactose

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

Always take this medicine exactly as your doctor or pharmacist has told you. Check

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**YOU WILL FIND MORE
ABOUT ACCUPRO ON
THE BACK OF THIS LEAFLET**

with your doctor or pharmacist if you are not sure.

The recommended dose of Accupro is:

Adults

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 elderly patients, the recommended starting dose to treat high blood pressure is 10 mg given once 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 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. The tablets can be taken with or without food.

Swallow the tablets whole with water. **Do not chew, divide or crush** the tablets. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Use in children and adolescents

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

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

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 forgotten dose.**

If you stop taking Accupro

Do not stop taking your tablets or alter the dose you are currently taking without seeing your doctor first. It is important to keep taking your tablets as they help to control your blood pressure. Do not wait until your tablets are finished before seeing your doctor.

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

4. Possible side effects

Like all medicines, this medicine 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, (Steven 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:

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
- mini-stroke
- drowsiness
- ringing in the ears
- heart attack
- rapid heartbeat (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 psoriasisiform)

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

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 HPRA 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 this medicine after the expiry date which is stated on the carton and blister strip after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from moisture.

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 protect the environment.

6. Contents of the pack and other information

What Accupro contains

The active substance in Accupro is quinapril. Each tablet contains 5 mg of quinapril (present as 5.416 mg quinapril hydrochloride), 10mg of quinapril (present as 10.832 mg quinapril hydrochloride), 20 mg of quinapril (present as 21.664 mg quinapril hydrochloride) or 40 mg of quinapril (present as 43.328 mg quinapril hydrochloride).

The other ingredients (excipient(s)) are magnesium carbonate, lactose monohydrate (see section 2 **Accupro contains lactose**), gelatin, crospovidone and magnesium stearate. The tablet coating contains candellilla wax and Opadry Y-5-9020G (containing hypromellose, hydroxypropyl cellulose, polyethylene glycol, red iron oxide (E172) and titanium dioxide (E171)).

What Accupro looks like and contents of the pack

Each 5 mg tablet is reddish brown and oval in shape. They are embossed with "5" on both sides and have a score line on both sides.

Each 10 mg tablets is reddish brown and triangular in shape. They are embossed with "10" on one side only and have a score line on both sides.

Each 20 mg tablet is reddish brown and round in shape. They are embossed with "20" on one side only and have a score line on both sides.

Each 40 mg tablet is reddish brown and oval in shape. They are embossed with "40" on one side and "PD 535" on the other side.

Each strength of Accupro is supplied in blister packs of 28, 30, 50, 60 and 100 tablets and tampereiners (with desiccant) of 50, 56, 60 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Pfizer Healthcare Ireland
9 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24

Manufacturer:
Pfizer Manufacturing Deutschland GmbH
Betriebsstätte Freiburg
Mooswaldallee 1
79090 Freiburg
Germany

Company contact address:

For further information on this medicine, please contact Medical Information at the following address:
Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland.
Tel: 1800 633 363.

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