

## Package leaflet: Information for the user

Accupro® 5 mg, 10 mg, 20 mg and 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 condition called angioneurotic oedema (a swelling of the face, tongue or throat which causes difficulty breathing)
- if you have aortic stenosis (narrowing of the main blood vessel from the heart).
- if you have kidney disease
- 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 you have kidney disease or use a haemodialysis machine (an artificial kidney)
- if you experience jaundice or any other symptoms of liver disease, then contact your doctor immediately
- if you have heart disease or heart failure
- if you have previously had a sudden drop in blood pressure after taking medicines to treat high blood pressure
- if you have collagen vascular disease (deposits of collagen in your blood vessels)

- 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 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 have diabetes
- if you are also taking other medicines (see **Other medicines and Accupro** section below)
- if you are of child bearing potential (see **Pregnancy** section below)
- if you are undergoing major surgery or being given anaesthesia in any treatment
- if you have intolerance to sugars such as lactose or galactose
- 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), as you 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 (including aliskiren and 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)
- non-steroidal anti-inflammatory pain killers (including aspirin or ibuprofen)
- steroids (including hydrocortisone, dexamethasone or prednisolone)
- procainamide (used to correct irregular heartbeats), cytostatic drugs (cancer therapy), immunosuppressants (for the treatment of autoimmune diseases e.g. Crohn's disease and rheumatoid arthritis) or allopurinol (for the treatment of chronic gout)
- indigestion and heartburn medicines (antacids)
- medicines that have a sedative effect. This includes alcoholic drinks and sleeping pills
- ACTH (tetracosactrin) (used to treat adrenal disorders)
- sympathomimetics (used to treat heart failure and shock)
- 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
- injectable gold treatments.

### **Laboratory Tests**

Accupro may affect the results of some laboratory tests. Tell your doctor or hospital 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 machines safely. 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 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 the treatment of heart failure, if you are also taking water tablets (diuretics) to treat your high blood pressure, you are aged 65 or over, or you have kidney disease, the starting dose is usually 2.5 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. The 5 mg, 10 mg and 20 mg tablets can be divided into equal doses.

#### **Use in children and adolescents**

Accupro should not be used in children and adolescents under 18 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 tell your doctor immediately** if you experience any of the following symptoms after taking this medicine. These symptoms can be serious.

- Severe allergic (anaphylactoid) reaction to this medicine. The symptoms include swelling of the face, tongue and throat which cause great difficulty breathing and angioedema (swelling of the deeper layer of the skin caused by a build-up of fluid).
- Severe abdominal pain causing you to be sick, resulting from inflammation of the wall of the bowel (intestinal angioedema).
- Severe abdominal pain that may spread to the back accompanied with feeling very unwell which may be a symptom of pancreatitis.
- Chest pain, tightness of the chest, shortness of breath, wheezing or trouble breathing, which may be a symptom of angina or a heart attack and an irregular or rapid heartbeat (palpitations).
- Weakness of arms, legs or face or problems speaking and visual disturbance which may be symptoms of a possible stroke.
- Sudden severe headache, seizures, loss of coordination, loss of balance (cerebrovascular accident).
- Skin rash, rawness, irritation, itching, hives, blistering, peeling and scaling.
- Red or purple skin rash, skin pain, hives, blistering of the skin and mouth, nose, eyes, genitals, facial and tongue swelling developing after a fever, flu like symptoms (Stevens Johnson Syndrome).
- Feeling faint, particularly when suddenly standing up. 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.
- Tightness of the chest, shortness of breath, wheezing or trouble breathing.
- Yellowing of the skin or the whites of the eyes (jaundice).

The following side-effects have also been reported in patients with high blood pressure being treated with Accupro:

#### **Common: may affect up to 1 in 10 people**

- increased potassium levels in the blood
- sleeplessness
- coughing; throat infection
- nasal stuffiness and/or runny nose (rhinitis)
- diarrhoea
- indigestion
- feeling or being sick
- tiredness; weakness; lack of energy
- headache
- dizziness

- sensation of tickling, pricking or burning on the skin
- back pain
- low blood pressure
- pain in the muscle
- increased creatinine and urea nitrogen in the blood
- decreased sodium concentrations in the blood

**Uncommon: may affect up to 1 in 100 people**

- depression; nervousness; confusion
- widening of the blood vessels
- fluid retention in the body
- rapid heartbeat (tachycardia)
- drowsiness
- reduced vision (not correctable by glasses or contact lenses)
- ringing or noises in the ears
- spinning of the head or dizziness due to problems with the inner ear
- dry mouth or throat
- wind
- excessive sweating
- rash on the skin
- failure/inability to achieve erection in males
- protein in urine, urinary tract infection, reduced kidney function
- inflammation of your sinuses (sinusitis), bronchitis, upper respiratory tract infection
- fever

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

- taste disturbances
- constipation
- soreness of the tongue
- disorders of balance
- swelling of the lungs from an increase in eosinophils, a type of white blood cell (eosinophilic pneumonitis)

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

- blurring of vision
- swelling of the walls of the bowels (intestines). Symptoms include abdominal pain, nausea, vomiting and intestinal cramps (intestinal angioedema)

**Not known: frequency cannot be estimated from the available data**

- abnormal breakdown of red blood cells
- bruising or a purple or red rash (purpura)
- abdominal pain caused by inflammation of the liver or blocked bile ducts
- decreased numbers of white blood cells or decrease in blood platelets (thrombocytopenia) which may result in bruising or easy bleeding; low numbers of red blood cells (anaemia)
- hair loss
- sensitivity of the skin to light
- dark urine, nausea, vomiting, muscle cramps, confusion and seizures. These may be symptoms of a condition called SIADH (inappropriate antidiuretic hormone secretion)
- psoriasis or worsening of existing psoriasis (skin disease characterised by reddened patches covered with silvery scales)

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 sugar levels rising 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. 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), 10 mg of quinapril (present as 10.832 mg quinapril hydrochloride), 20 mg quinapril (present as 21.66 mg quinapril hydrochloride) or 40 mg quinapril (present as 43.328 mg quinapril hydrochloride).

The other ingredients (excipients(s)) are magnesium carbonate, lactose (see section 2 **Accupro contains lactose**), gelatin, crospovidone and magnesium stearate. The tablet coating contains candelilla 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 tablet 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 7, 28, 56 and 100 tablets and tampereiners (with desiccant) of 56 and 100 tablets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Pfizer Limited  
Sandwich  
Kent  
CT13 9NJ  
United Kingdom

Manufacturer:

Pfizer Manufacturing Deutschland GmbH  
Betriebsstätte Freiburg  
Mooswaldallee 1  
79090 Freiburg

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**Company Contact address:**

For further information on this medicine, please contact Medical Information at the following address:  
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