

ACCUPRO 10 MG AND 20 MG FILM-COATED TABLETS

QUINAPRIL HYDROCHLORIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

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

1. WHAT ACCUPRO IS AND WHAT IT IS USED FOR

This medicine 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.

It 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 hydrochloride or any of the other ingredients of this medicine. 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).
- 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.

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).
- You experience jaundice or any other symptoms of liver disease, then contact your doctor immediately.
- You have heart disease or heart failure.
- You have previously had a sudden drop in blood pressure after taking medicines to treat high blood pressure.
- You have collagen vascular disease (deposits of collagen in your blood vessels).
- 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 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 have diabetes.
- You are also taking other medicines.
- You are of child bearing potential (see pregnancy section).
- 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

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 including medicines obtained without a prescription. There are some medicines that may interact with Accupro. Your doctor may need to change your dose and/or to take other precautions:

- 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), 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.
- Medicines to treat diabetes (including vildagliptin).
- ACTH (tetracosactrin) (used to treat adrenal disorders).
- Sympathomimetics (used to treat heart failure and shock).
- mTOR inhibitors used to treat kidney cancer (including temsirolimus).
- 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

Accupro can be taken with or without food.

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 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 machines safely. They may make you feel dizzy or weary. If affected, do not drive or operate machines and contact your doctor immediately.

Accupro contains lactose

Lactose is 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.

Do not wait until your tablets are finished before seeing your doctor.

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.

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

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.

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 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. They help to control your blood pressure.

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. If any of these side-effects gets serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor:

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

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

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. 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 your medicine after the expiry date which is stated on carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

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.

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