

PATIENT INFORMATION LEAFLET
ACCUPRO™ 5mg FILM-COATED TABLETS
(quinapril)

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
- Keep this leaflet. You may need to read it again.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms 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.

Please read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important to you. If you have any further questions, ask your doctor or pharmacist.

The name of your medicine is Accupro 5mg film-coated tablets but it will be referred as Accupro throughout the leaflet.

In this leaflet:

1. What Accupro is and what it is used for
2. Before you take Accupro
3. How to take Accupro
4. Possible side effects
5. How to store Accupro
6. Further 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. 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 aortic stenosis (narrowing of the main blood vessel from the heart).

Take special care with 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:

- You have kidney disease or use a haemodialysis machine (an artificial kidney)
- You have liver disease
- You have heart disease
- 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.
- 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.
- You have diabetes.
- You are also taking other medicines.
- 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).

Taking other medicines

There are some medicines that may interact with Accupro:

- Other blood pressure treatments and diuretics (water tablets).
- Medicines to treat infections called tetracyclines.
- Potassium supplements (this includes salt substitutes which often contain potassium).
- Lithium (used to treat depression).
- Drugs to treat diabetes.

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.

Taking Accupro with food and drink

Accupro can be taken with or without food.

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 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 machinery

Your tablets may affect your ability to drive or operate machinery safely. 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 10mg a day, which may be increased gradually up to a maximum of 80mg 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 5mg, which may be increased up to a maximum of 40mg a day. Accupro should not be used in children under 12 years of age.

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 miss a dose of 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, 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:

The most common side effects are:

- feeling or being sick
- headache; dizziness
- tiredness
- coughing; chest infection
- nasal stuffiness and/or runny nose (rhinitis)

Common side effects occurring in less than 1 in 10 people taking Accupro:

- mild stomach pain; wind
- painful muscles; back pain;
- feeling weak; sleeplessness
- numbness or tingling sensation in your limbs
- raised levels of potassium in your blood
- sore throat.

Uncommon side effects occurring in less than 1 in 100 people taking Accupro:

- disorders of balance (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
- failure/ inability to achieve erection in males

Rare side effects occurring in less than 1 in 1000 people taking Accupro:

- fainting or collapse
- increased 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).
- hair loss
- skin sensitivity to sunlight causing burning or redness. 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. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. How to store Accupro

Do not use the tablets after the expiry date on the blister and the carton. For example "Exp 02-2012" means you should not take your tablets after February 2012. Return any out-of-date tablets to your pharmacist for safe disposal.

Do not store above 25°C.

Keep out of the reach and sight of children.

If your doctor decides to end your treatment, return any unused tablets to your pharmacist for safe disposal. Only keep them if your doctor tells you to.

If your tablets become discoloured or show other signs of deterioration, you should seek the advice of your pharmacist.

6. Further information

What Accupro contains and its package:

Each tablet contains 5mg quinapril base (equivalent to 5.416 quinapril hydrochloride) as the active ingredient. The other ingredients are heavy magnesium carbonate, lactose, gelatin, crospovidone and magnesium stearate. The coating of Accupro tablets contains candelilla wax, hypromellose, hydroxypropylcellulose, macrogol, red iron oxide (E172) and titanium dioxide (E171). The tablets are brown film-coated elliptical tablets, imprinted with a scoreline on both sides and marking '5' on one side of the scoreline on both sides of the tablet. Accupro is available in blister packs of 28 film-coated tablets.

Manufactured by: Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg, Mooswaldallee, 1 – D-79090 Freiburg Germany.

Procured from within the EU and repackaged by PPA Holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 ONU, UK.

Accupro 5mg film-coated tablets

POM

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