

Package leaflet: Information for the user

Accuretic® 20 mg/12.5 mg film-coated tablets quinapril and hydrochlorothiazide

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

1. What Accuretic is and what it is used for

Accuretic contains the active substances quinapril and hydrochlorothiazide. Quinapril belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors. ACE inhibitors work by widening blood vessels in the body, which can help to reduce the pressure in the vessels. Hydrochlorothiazide belongs to a group of medicines called diuretics. Diuretics help the body to get rid of extra fluid and are used in patients with high blood pressure. Because they get rid of fluid, diuretics are sometimes called 'water tablets'.

Accuretic is used to treat high blood pressure.

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 Accuretic

Do not take Accuretic

- if you have hereditary (inherited)/idiopathic (unknown cause) angioedema (a swelling of the face, tongue or throat which causes difficulty breathing)
- if you are allergic to quinapril or hydrochlorothiazide or any of the other ingredients of this medicine (listed in section 6), similar medicines or to a group of antibiotics called sulfonamides
- if you have a history of angioedema relating to previous treatment with an ACE inhibitor
- if you are in your second or third trimester of pregnancy
- if you have an obstruction in your heart that slows blood in the heart
- if you have severe kidney disease or are experiencing problems passing water (anuria)
- if you have been told after a blood test that you have high levels of potassium in your blood
- if you have diabetes or impaired kidney function and you are being 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 Accuretic, as this medicine may not be suitable for you:

- if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Accuretic
- if you have aortic stenosis (narrowing of the main blood vessel from the heart), low blood pressure, heart disease or other problems with your heart (e.g. heart failure)
- if you have kidney disease, a transplanted kidney or use a haemodialysis machine (an artificial kidney), are being treated with diuretics, or have a salt-restrictive diet. This is because Accuretic may lower your blood pressure and cause you to feel faint
- if you have liver disease
- if you are elderly
- if you have collagen vascular disease (deposits of collagen in your blood vessels)
- if you have both kidney disease and collagen vascular disease. This is because Accuretic decreases the number of neutrophils and white blood cells in the blood. Tell your doctor if you get symptoms such as sore throat or fever after taking Accuretic
- if you are having, or about to have, low density lipoprotein apheresis treatment (removal of cholesterol from your blood by machine)
- if you have parathyroid disease, this is a disease associated with increased calcium, decreased phosphate, development of kidney stones and stomach ulcers and reduction in bone strength
- if you suffer from allergies or asthma
- if you have suffered from angioedema in the past (red rash followed by facial swelling which can be severe enough to cause breathing difficulties)
- if you have a history of severe allergic reactions such as swelling of the face, lips, tongue or throat or swelling of the hands or feet. This is because the taking of Accuretic may also cause severe swelling
- 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)
- if you have a salt or electrolyte imbalance in your blood (e.g. sodium or potassium), your doctor may want to monitor you more closely
- if you suffer from hypokalaemia (low levels of potassium in your blood) symptoms of this are dryness of mouth, thirst, weakness, lethargy or muscle pain
- 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 planning to become pregnant, or you just became aware of being pregnant
- if you have diabetes or gout
- if you have systemic lupus erythematosus (SLE) an allergic condition which causes joint pain, skin rashes and fever
- if you are about to have major surgery which requires an anaesthetic
- if you develop visual problems such as eye pain, a decrease in vision or blurred vision while on Accuretic. The active ingredient, hydrochlorothiazide can cause you to develop visual problems. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion), an increase of pressure in your eye and can happen within hours to a week of taking Accuretic. If this is not treated, it can lead to loss of vision. If you experience such symptoms, you should seek medical attention. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- if you are also taking other medicines
- if you have lost a lot of body salts or fluids through being sick (vomiting), having diarrhoea, being on a low salt diet, taking diuretics (water tablets) for a long time or having had dialysis
- a rapid swelling of the wall of the bowels (intestines) can occur when taking Accuretic. Patients can experience abdominal pain with or without vomiting
- 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.

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 Accuretic**.

Other medicines and Accuretic

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 Accuretic. Your doctor may need to change your dose and/or take other precautions if you are taking:

- angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings **Do not take Accuretic** and **Warnings and precautions**)
- other blood pressure treatments and diuretics (including aliskiren and water tablets)
- antibiotics like sulfamethoxazole, trimethoprim and tetracycline antibiotics
- potassium supplements (this includes salt substitutes which often contain potassium)
- anaesthetics
- lithium (used to treat depression, mania or self-harming behaviour)
- non-steroidal anti-inflammatory pain killers (for example aspirin or ibuprofen)
- corticosteroids (for example hydrocortisone, dexamethasone or prednisolone) and ACTH (tetracosactide) or medicines known to reduce the amount of potassium in the blood
- procainamide (used to correct irregular heartbeats)
- cytostatic medicines (cancer therapy)
- immunosuppressants (for the treatment of autoimmune diseases such as Crohn's disease and rheumatoid arthritis)
- allopurinol, uricosurics and xanthine oxidase inhibitors (for the treatment of chronic gout)
- indigestion and heartburn medicines (antacids)
- 'pressor amines' such as norepinephrine or other medicines from the same group
- medicines that have a sedative effect. This includes alcoholic drinks and sleeping pills
- medicine for an irregular heart rhythm e.g. digoxin, amiodarone or sotalol
- medicines that can be used to reduce cholesterol or bile salts (cholestyramine and colestipol)
- medicines to treat diabetes such as insulin or tablets. You may need to alter your dose of insulin while taking Accuretic
- medicines such as digitalis glycosides (digoxin) or any medicines used for the treatment of ventricular tachycardia. Tachycardia is a condition where the heart rate beats faster than normal. Care should be taken when Accuretic is taken together because of the potential risk of low concentrations of potassium in the blood
- 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.

Surgery

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

Laboratory Tests

Accuretic may affect the results of some laboratory tests. Tell your doctor or hospital staff that you are

taking Accuretic if you need to have any tests carried out by your doctor or in hospital.

Accuretic with food and drink

See section 3 **How to take Accuretic**.

Pregnancy, breast-feeding and fertility

Do not start taking Accuretic if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby. Ask your doctor for advice before taking this medicine.

Your doctor will normally advise you to stop taking Accuretic before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Accuretic. Accuretic is not recommended during 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. Accuretic is not recommended for mothers who are breast-feeding.

Driving and using machines

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.

Accuretic contains lactose

Accuretic 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 Accuretic

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 Accuretic is one tablet each day. Try to take the tablet at about the same time every day. Accuretic can be taken with or without food.

Accuretic should not be used in children and adolescents under 18 years of age.

Accuretic is not recommended for use in patients who suffer with kidney disease with a creatinine clearance of less than 40 ml/min.

In the elderly, adequate blood pressure control should be achieved with the lowest possible dose.

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.

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 Accuretic than you should

Taking too many tablets at once may make you unwell. If you take too many Accuretic tablets, 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 Accuretic

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 forgotten dose.

If you stop taking Accuretic

Do not stop taking your medicine or alter the dose you are currently taking without seeing your doctor first.

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 Accuretic 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, lips, tongue or throat (angioedema) which may cause great difficulty breathing; swelling of the extremities (hands and feet).
- Severe abdominal pain and/or back pain causing you to feel or be sick (this may be a sign of an inflamed intestine or an inflamed pancreas).
- Chest pain or tightness, shortness of breath or racing of the heart. These could be symptoms of a heart attack or other heart problem.
- Weakness of arms, legs or problems speaking which may be symptoms of a possible stroke.
- Serious, potentially life threatening skin rashes including hives, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome), toxic epidermal necrolysis (TEN) and pemphigus.

Tell your doctor **immediately** if you experience any of the following symptoms after taking Accuretic. 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 Accuretic, alcohol, or if you are dehydrated or are 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. You may not have enough of certain white blood cells (neutropenia/agranulocytosis) which may lead to increased risk of infection or fever.
- Chest pain, angina, tightness of the chest, shortness of breath, wheezing or trouble breathing, irregular or strong heartbeat (palpitations).
- Yellowing of the skin or the eyes (jaundice) which may be a sign of liver inflammation (hepatitis).
- Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma).

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

Common side effects: may affect up to 1 in 10 people

- diarrhoea, indigestion, mild stomach pain, feeling or being sick
- dizziness, headache, feeling weak, tiredness, sleepiness or sleeplessness
- painful muscles, muscle weakness, back pain
- high levels of uric acid in your blood causing swollen, painful joints (gout)
- coughing, bronchitis
- nose or throat infections, nasal stuffiness and/or runny nose (rhinitis)
- widening of blood vessels
- chest pain
- inflammation of the throat
- increased levels of creatinine in the serum. This is a waste molecule that is produced from muscle

metabolism

- increased levels of nitrogen in the blood, that comes from the waste product urea
- increased potassium in the blood
- awareness of the heart beat
- increased heart rate

Uncommon side effects: may affect up to 1 in 100 people

- kidney and urinary problems, urinary tract infection
- numbness or tingling sensation in your limbs
- aching joints
- depression, nervousness, confusion
- ringing or noise in the ears
- wind
- lazy eye
- feeling of spinning or rotation of surroundings (vertigo)
- fainting, low blood pressure
- dry mouth or throat, taste disturbances
- fluid retention in the body
- angioedema (a swelling of the face, tongue or throat which causes difficulty breathing)
- inflammation of your sinuses (sinusitis)
- feeling hot (fever), increased sweating
- hair loss, itching, sensitivity of skin to light
- failure/inability to achieve penile erection
- viral infection
- shortness of breath
- mild form of diabetes
- rash
- protein in urine
- mini-stroke
- heart attack

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

- problems with balance
- inflammation of the lungs which can cause breathlessness, cough and raised temperature
- constipation
- inflammation of the tongue
- inflammation of blood vessels
- skin blisters
- psoriasis
- skin disorders associated with fever, muscle and joint pain

Very Rare side effects: may affect up to 1 in 10,000

- obstruction of the digestive system (bowel), swelling or fluid in the small bowel
- blurred vision
- hives

Not known: frequency cannot be established from the available data

- skin and lip cancer (Non-melanoma skin cancer)
- allergic condition which can cause joint, skin and organ problems (systemic lupus erythematosus)
- skin discolouration
- itching and scaling of the skin
- skin peeling and lesions
- damage to the skin tissue
- changes in 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)
- bleeding or blockage of the blood vessels in the brain (stroke)
- narrowing of the airways in the lungs (bronchospasm)
- effects results of blood or other laboratory tests
- increased numbers of blood cells involved in allergic diseases
- serious allergic reaction
- inflammation of the liver
- yellowing of the skin or the eyes
- inflammation of the pancreas
- immune system condition affecting the skin and mucous membranes
- inflammation of the kidneys
- inflammation of the lining of the lungs, heart or abdomen
- irregular heart beat
- reduced blood pressure when standing
- short-sightedness
- acute closure glaucoma (increased pressure in the eyes)

Accuretic 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 or pharmacist. 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 Accuretic

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 Accuretic contains

The active substances in Accuretic are quinapril and hydrochlorothiazide. Each tablet contains 20 mg of quinapril (present as 21.70 mg quinapril hydrochloride) and 12.5 mg of hydrochlorothiazide.

The other ingredients (excipient(s)) are heavy magnesium carbonate, lactose (see section 2 **Accuretic contains lactose**), povidone, crospovidone and magnesium stearate.

The coating of the tablets contains candelilla wax and Opadry pink OY-S-6937 which contains iron oxide (E172), titanium dioxide (E171), hypromellose, hydroxypropyl cellulose and polyethylene glycol.

What Accuretic looks like and contents of the pack

Each Accuretic tablet is pink, film-coated and triangular in shape.

The tablets are available in blister packs of 7, 28, 30, 56 or 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
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Manufacturer:

Pfizer Manufacturing Deutschland GmbH
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