

Package leaflet: Information for the user

Accuretic® 10/12.5 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 are in your second or third trimester of pregnancy. It is also better to avoid Accuretic in early pregnancy. See section 2 **Pregnancy, breast-feeding and fertility**
- if you are allergic to quinapril, hydrochlorothiazide, or any of the other ingredients of this medicine (listed in section 6), similar drugs 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 have kidney disease or are experiencing problems passing water (anuria)
- if you have an obstruction in your heart that slows blood in the heart
- if you have hereditary (inherited)/idiopathic (unknown cause) angioneurotic oedema (a swelling of the face, tongue or throat which causes difficulty breathing)
- 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 Accuretic:

- 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)
- if you have kidney disease, a transplanted kidney, or use a haemodialysis machine (an artificial kidney)
- if you have liver disease
- if you have heart disease or heart failure
- if you are elderly
- if you have low blood pressure (hypotension), likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy (water tablets), low-salt diet, diarrhoea, vomiting, or haemodialysis
- if you have a dry cough
- if you are of African-Caribbean ethnic origin
- 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 have a history of severe allergic reactions, asthma or angioedema (such as swelling of the eyes, face, lips, tongue or throat)
- 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 (see section 2 **Pregnancy, breast-feeding and fertility**)
- if you are breast-feeding or about to start breast-feeding (see section 2 **Pregnancy, breast-feeding and fertility**)
- if you are taking medicines containing lithium
- 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 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 experience visual disturbances and increased pressure in the eye. Symptoms of increased pressure in the eye are intense pain, redness of the eye, headaches, tender eye area, misty vision and loss of vision
- if you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to a week of taking Accuretic. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this
- if you are about to have surgery or receive anaesthetics (even at the dentist), remember to tell any medical staff that you are taking Accuretic
- if you have a fever, sore throat, mouth ulcers, tiredness, unexplained bruising or bleeding, or a blood problem such as low or lack of white blood cells (neutropenia or agranulocytosis)
- 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 section 2 **Do not take Accuretic**.

Children and adolescents

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

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 to take other precautions if you are taking:

- angiotensin II receptor blocker (ARB) or aliskiren (see section 2 **Do not take Accuretic and Warnings and precautions**)
- other blood pressure treatments and diuretics (including aliskiren and water tablets)
- medicines called tetracyclines used to treat infections
- cholestyramine and colestipol (medicines used to treat high levels of fats in the blood)
- medicines called ‘pressor amines’ such as norepinephrine and epinephrine
- antibiotics like sulfamethoxazole and trimethoprim
- potassium supplements (this includes salt substitutes which often contain potassium)
- anaesthetics
- lithium (used to treat depression)
- non-steroidal anti-inflammatory pain killers (including aspirin or ibuprofen)
- corticosteroids (including hydrocortisone, dexamethasone or prednisolone) and ACTH (tetracosactide) or drugs known to reduce the amount of potassium in the blood
- procainamide (used to correct irregular heartbeats), cytostatic drugs (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)
- medicines that have a sedative effect. This includes alcoholic drinks and sleeping pills
- digitalis glycosides (e.g. digoxin, for the treatment of heart problems)
- 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.

Laboratory Tests

Accuretic may affect the results of some laboratory tests. Tell your doctor or hospital 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 planning to become pregnant.

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.

Tell your doctor if you are breast-feeding or about to start breast-feeding. Accuretic is not recommended for mothers who are breast-feeding.

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.

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.

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

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

Your doctor may increase the dose to two tablets which may be taken together once a day or may be taken separately, one tablet in the morning and one in the evening.

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

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.

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 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 Accuretic and seek immediate medical attention if you experience any of the following symptoms as they can be serious:

Common: may affect up to 1 in 10 people

- severe chest pain, tightness of the chest, shortness of breath, wheezing or trouble breathing, irregular or strong heartbeat (palpitations). These symptoms may be due to heart attack or angina

Uncommon: may affect up to 1 in 100 people

- ringing or noise in the ears

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

- severe abdominal pain causing you to be sick (intestinal angioedema)

Not known: frequency cannot be estimated from the available data

- severe allergic (anaphylactoid) reaction to this medicine such as swelling of the face, tongue and throat which cause great difficulty breathing (angioedema)
- weakness of arms, legs or problems speaking which may be symptoms of a possible stroke
- fever, cough, and other nonspecific symptoms, followed by redness and sloughing of the skin and mucous membranes (Toxic Epidermal Necrolysis). A skin rash with irregular red spots or 'target' lesions (erythema multiforme). Intense skin rash including hives, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome)
- 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
- neutropenia/agranulocytosis resulting in decreased numbers of white blood cells or decrease in blood platelets which may result in bruising or easy bleeding

- severe abdominal and back pain accompanied with feeling very unwell (pancreatitis)
- liver inflammation (hepatitis), abdominal pain, nausea, dark brown urine, yellowing of the skin or the eyes (jaundice)
- inflammation of the kidneys (tubulointerstitial nephritis) symptoms include fever and a rash but occasionally patients might notice blood in urine as well
- 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. If any of these side effects get 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

- diarrhoea, indigestion, mild stomach pain, feeling or being sick
- dizziness, headache, tiredness, feeling weak, 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
- increased levels of creatinine in the blood
- increased levels of blood urea
- chest pain
- increased levels of Potassium in serum
- rapid heart rate

Uncommon: 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
- 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
- inflammation of your sinuses (sinusitis)
- increased sweating, feeling hot (fever)
- hair loss, itching, sensitivity of skin to light
- failure/inability to achieve penile erection
- viral infection
- heart attack (myocardial infarction)
- increased glucose levels in blood
- painful joints
- shortness of breath
- swelling under the skin
- protein in urine

Rare: 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
- psoriasis
- swelling of the hands, face and tongue (angioedema)
- skin disorders

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

- obstruction of the digestive system (bowel)
- blurred vision
- hives

Not known: frequency cannot be estimated from the available data

- skin and lip cancer (Non-melanoma skin cancer)
- allergic condition which causes joint pain, skin rashes and fever (systemic lupus erythematosus)
- inflammation of the lining of the lungs, heart or abdomen (serositis)
- erythema and scaling of the skin (dermatitis exfoliative)
- bruising or a purple or red rash (purpura)
- small fluid-filled blisters on the skin (pemphigus)
- skin discolouration
- low numbers of red blood cells (anaemia)
- bleeding from blood vessels in the brain
- narrowing of the airways in the lungs (bronchospasm)
- short-sightedness

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 your 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 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 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 10 mg of quinapril (present as 10.85 mg quinapril hydrochloride) and 12.5 mg of hydrochlorothiazide.

The other ingredients (excipient(s)) are 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), hydroxypropylmethyl cellulose, hydroxypropyl cellulose and polyethylene glycol.

What Accuretic looks like and contents of the pack

Accuretic tablets are oval, pink, film-coated tablets scored on both sides. The tablets are available in blister packs of 7, 28, 30, 100 and 156 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Pfizer Limited

Ramsgate Road

Sandwich

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CT13 9NJ

United Kingdom

Manufacturer:

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

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