

Version 4, 02/2016

PACKAGE LEAFLET

Package leaflet: Information for the user
Quinapril 5mg, 10mg, 20mg and 40mg Tablets

Quinapril Hydrochloride

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

1. What Quinapril tablets is and what it is used for

The active ingredient in Quinapril Tablets is quinapril (present as quinapril hydrochloride). This belongs to 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.

For the other ingredients in Quinapril Tablets, (see section 6.)

Quinapril is an ACE inhibitor used to treat high blood pressure (hypertension) and to help treat heart failure. Quinapril is effective alone or together with water tablets (diuretics) in patients with hypertension. Quinapril can also be used for the treatment of heart failure when given together with a diuretic and/or cardiac glycoside such as digoxin.

Treatment of heart failure with quinapril should always be started under close medical supervision.

2. What you need to know before you take Quinapril tablets

Do not take Quinapril tablets if:

- you are allergic to quinapril, any other ACE inhibitor or any of the other ingredients (listed in section 6).
- you are more than 3 months pregnant. (It is also better to avoid quinapril tablets in early pregnancy – see pregnancy section.)
- you have taken an ACE inhibitor before and had an allergic reaction to it resulting in swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing or you or any member of your blood relatives have suffered a similar allergic reaction for any reason in the past.
- you suffer from a severe allergic skin reaction called hereditary/ idiopathic angioneurotic oedema where itchy swellings erupt on your face, hands, genital areas and mouth.
- If you suffer from a heart condition called dynamic left ventricular outflow obstruction.

- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If you think any of these apply to you, **do not use** any of these tablets.

Talk to your doctor first and follow the advice given to you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Quinapril tablets

- you think you are (or might become) pregnant. Quinapril tablets are 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)
- you have aortic stenosis (narrowing of the main blood vessel from the heart)
- you have kidney disease
- you are using a haemodialysis machine (an artificial kidney)
- you are taking diuretics (water tablets)
- you have collagen vascular disease such as dermatomyositis, (connective-tissue disease that is characterized by inflammation of the muscles and the skin) lupus erythematosus (SLE condition which causes joint pain, skin rashes, and fever) or polyarteritis nodosa (inflammation of the arteries)
- you are having, or about to have, low density lipoprotein apheresis treatment (removal of cholesterol from your blood by machine)
- 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 had a recent bout of diarrhoea and/or vomiting
- you have narrowing or blockage of the blood vessels leading to the kidneys
- you have a heart condition
- you have liver disease
- you are a diabetic
- “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 Quinapril Tablets”.

Other medicines and Quinapril

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. “Your doctor may need to change your dose and/or to take other precautions: If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Quinapril Tablets” and “Warnings and precautions”).”

The following medicinal products may interact with quinapril, either by increasing or decreasing its effect.

- Tetracycline-an antibiotic
- Blood pressure lowering medicines (captopril, enalapril, lisinopril)
- Antacids-medicines to treat heart burn or indigestion

- Antidiabetic drugs (oral agents e.g. glibenclamide and insulin)
- Non-steroidal anti-inflammatory drugs e.g. aspirin or ibuprofen
- Lithium supplements used for certain mental illness
- Potassium supplements, potassium-containing salt substitutes
- Diuretics (water tablets)
- Anaesthetic agents used in surgery
- Steroids (hydrocortisone, dexamethasone or prednisolone)
- ACTH (tetracosactrin)
- Procainamide (for irregular heart beat)
- Cytostatic drugs to treat cancer
- Immuno suppressants such as ciclosporin
- Allopurinol for gout
- Sympathomimetics found in asthma medication and cough remedies
- Sedatives
- Injectable gold compounds (sodium aurothiomalate) used to treat auto-immune diseases such as rheumatoid arthritis and lupus.

You should not drink alcohol whilst you are taking Quinapril as this can cause hypotension (low blood pressure)

Quinapril tablets with food and drink

Quinapril tablets can be taken with or without food.

Pregnancy and breast-feeding

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking quinapril tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of quinapril tablets. Quinapril tablets are 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 quinapril tablets.

In the case of an older baby your doctor should advise you on the benefits and risks of taking quinapril tablets whilst breast-feeding, compared with other treatments.

Driving and using machines

Quinapril Tablets may cause dizziness and/or tiredness and if you are affected you should not drive or operate any machines or tools.

3. How to take Quinapril tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

These tablets are usually taken once or twice a day.

For hypertension (high blood pressure) the usual starting dose is 10 mg, which may be increased to 20 to 40 mg a day.

For heart failure, or hypertension in combination with a water tablet (diuretic) and/or cardiac glycoside such as digoxin, the usual starting dose is 2.5mg, which may be increased up to 10 to 40mg a day.

Swallow the tablets whole with a drink of water. Do not chew them. It is best to take your tablets approximately the same time each day.

Elderly (over 65 years of age) / kidney problems

In elderly patients and in patients with kidney problems, the usual starting dose for blood pressure is 2.5 mg which may be slowly increased.

Use in children and adolescents (under 18 years of age)

Due to limited experience, Quinapril tablets are not recommended in children and adolescents.

If you take more Quinapril tablets than you should

If you or someone else take(s) too many tablets all together, contact your nearest hospital casualty department / your doctor immediately / a poison centre. You may feel particularly light-headed or faint, your heart rate may slow down and your skin may feel cold and clammy.

If you forget to take Quinapril tablets

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. **Do not take a double dose to make up for a forgotten dose.**

If you stop taking Quinapril tablets

Do not stop taking these tablets, without asking your doctor or pharmacist.

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

If you develop any of the following symptoms, contact a doctor immediately:

- You get a swollen face, tongue and / or throat, severe reddening of the skin (hives) and / or have difficulty in swallowing and/ or breathing (angioedema).

The following undesirable effects have been observed during treatment with quinapril and other ACE inhibitors with the following frequencies:

Common (may affect up to 1 in 10 people)

- Dizziness
- Low blood pressure (Hypotension)
- Cough
- Nausea
- Vomiting
- Diarrhoea
- Headache

- Tiredness
- Insomnia
- Tingling or numbness in the hands or feet
- Chest pain
- Inflammation of pharynx (pharyngitis)
- Indigestion
- Abdominal pain
- Weakness
- Shortness of breath
- Muscle pain
- Joint pain
- Back pain
- High blood potassium levels measured by a blood test.
- Raised creatinine and urea blood levels (used to test your kidney function)
- Runny nose

Uncommon (may affect up to 1 in 100 people)

- Sleep disorders
- Nervousness
- Sleepiness
- Feeling your heartbeat (Palpitations)
- Asystole which is when the heart suddenly stops
- Inflammation of sinus (Sinusitis)
- Chest infection
- Angina
- Dry mouth or throat
- Wind
- Rash
- Itching
- Increased sweating
- Raised amount of proteins in the urine (proteinuria)
- Loss of sexual performance in a man (Impotence)
- Vertigo (spinning sensation)
- Angioedema (a serious allergic reaction with swelling of face, lips, tongue)
- Widening of blood vessels
- Fever
- Swelling of the lower limbs
- Urinary tract infection
- Depression
- Confusion
- Poor vision in one eye (amblyopia)
- Ringing in the ears
- Faster heart beat
- Heart attack
- Serious allergic reaction which causes difficulty in breathing. (angioedema)
- Bronchitis
- Kidney problems
- Transient periods where blood stops flowing in your body. For example, stroke

Rare (may affect up to 1 in 1,000 people)

- Disturbances of balance
- Nerve damage
- Fainting
- Worsening of asthma
- Taste disturbances
- Constipation
- Glossitis (inflammation of the mouth)
- Liver problems
- Erythema multiforme (a painful reddening of the skin with lumps and blisters)
- Silver plaques resembling psoriasis
- A very rare but serious blistering of the skin (pemphigus)
- Brain haemorrhage
- Eosinophilic pneumonia (accumulation of white blood cells in the lungs)
- Hives
- Partial or complete non-mechanical blockage of large and or small intestine (ileus)

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

- Allergic lung disorder (Allergic alveolitis)
- Kidney failure
- Vision disturbances
- Inflammation of the small bowel

Not known (frequency cannot be estimated from the available data)

- Stevens Johnson syndrome (a severe and widespread reddening of the skin with blistering)
- Low haemoglobin in your blood which can cause anaemia
- Low blood pressure which is felt on standing for example feeling light-headed when you stand up (orthostatic hypotension)
- Reduction in white blood cell count seen with blood tests or through getting frequent infections.
- Exfoliative dermatitis
- Severe reduction in the number of white blood cells which makes infection more likely (agranulocytosis)
- Pancreatitis (inflammation of the pancreas)
- Epidermic necrolysis (rash involving reddening, swelling and peeling of the skin, it resembles severe burns.
- Hair loss (alopecia)
- Sensitivity to light
- Jaundice due to impaired excretion of bile pigment (cholestatic icterus)
- Inflammation of the liver (Hepatitis)
- Difficulty in breathing
- Allergic reaction in which the immune system responds to otherwise harmless substances
- Relative decrease of platelets in the blood (thrombocytopenia)

The following side-effects have been reported with other ACE inhibitors and may also occur with Quinapril tablets.

- Breast enlargement in males

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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Quinapril tablets

Keep this medicine out of the sight and reach of children.

Store below 25°C. Do not use these tablets after the expiry date, which is stated on the pack.

The expiry date refers to the last day of that month.

Disposal

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 to protect the environment.

6. Contents of the pack and other information

What Quinapril tablets contain

The active substance is quinapril (as hydrochloride).

The **other ingredients** are:

Heavy Magnesium carbonate, Calcium sulfate dihydrate, Colloidal anhydrous silica, Crospovidone, Povidone, Magnesium stearate.

The coating of Quinapril tablets contains polyvinyl alcohol, titanium dioxide (E171), talc, lecithin, iron oxide yellow (E172) and xanthan gum.

What Quinapril tablets look like and contents of the pack

Quinapril Tablets are available in **four** strengths

Quinapril 5 mg Tablets

– Yellow coloured, Oval shaped, film-coated tablets debossed with ‘5’ on one side and scoreline on the other side.

The score line facilitates breaking of the tablet into equal halves.

Quinapril 10 mg Tablets

– Yellow coloured, capsule shaped, film-coated tablets debossed with ‘10’ on one side and scoreline on the other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Quinapril 20 mg Tablets

– Yellow coloured, circular, film-coated tablets debossed with ‘20’ on one side and scoreline on the other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Quinapril 40 mg Tablets

– Yellow coloured, capsule shaped, film-coated tablets debossed with ‘40’ on one side and plain on the other side.

Quinapril Tablets are available in blister packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer

Lupin Healthcare (UK) Limited
The Urban Building, 2nd floor
3-9 Albert Street, Slough, Berkshire
SL1 2BE, United Kingdom

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