

APPROVED PATIENT INFORMATION LEAFLET

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KWINCO 10/12,5 mg (Tablet)

KWINCO 20/12,5 mg (Tablet)

Quinapril / Hydrochlorothiazide

Read all of this leaflet carefully before you start taking KWINCO.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- - **KWINCO** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT KWINCO CONTAINS:

The active substances are quinapril and hydrochlorothiazide.

KWINCO 10/12,5 mg: Each film coated tablet contains quinapril hydrochloride equivalent to quinapril 10 mg and hydrochlorothiazide 12,5 mg.

Other ingredients for **KWINCO** are crospovidone, lactose monohydrate, magnesium carbonate, magnesium stearate and povidone. The coating ingredients are hydroxypropyl cellulose, hypromellose, iron oxide red, iron oxide yellow, macrogol/PEG 400 and titanium dioxide.

KWINCO 20/12,5 mg: Each film coated tablet contains quinapril hydrochloride equivalent to quinapril 20 mg and hydrochlorothiazide 12,5 mg.

Other ingredients for **KWINCO** are crospovidone, lactose monohydrate, magnesium carbonate, magnesium stearate and povidone. The coating ingredients are hydroxypropyl cellulose, hypromellose, iron oxide red, iron oxide yellow, macrogol/PEG 400 and titanium dioxide.

2. WHAT KWINCO IS USED FOR:

KWINCO is used to treat hypertension (high blood pressure).

Quinapril is in a group of medicines called ACE inhibitors. Quinapril works by preventing a chemical in your blood called angiotensin I from converting into a more potent form (angiotensin II) that increases

salt and water retention in the body and causes the blood vessels to constrict – two actions that tend to increase blood pressure.

Hydrochlorothiazide is a thiazide diuretic (water pill) that helps prevent your body from absorbing too much salt, which can cause fluid retention.

3. BEFORE YOU TAKE KWINCO:

Do not take KWINCO:

- If you have ever had an unusual or allergic reaction to quinapril or hydrochlorothiazide or any ingredient of **KWINCO**.
- If you have ever had an unusual or allergic reaction to sulphur medications.
- If you have ever had angioedema (a condition that causes difficulty swallowing or breathing and painful swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs) related to previous treatment with an ACE-inhibitor or angiotensin receptor blocker.
- If you have hereditary (inherited) / idiopathic (unknown cause) angioedema.
- If you have aortic stenosis (a narrowing of the aortic valve in the heart, slowing blood flow from the heart into the main artery leaving the heart).
- If you have hypertrophic cardiomyopathy (heart muscle disease).
- If you have severe kidney disease or are experiencing problems passing water.
- If you have renal artery stenosis (narrowing of the artery supplying the kidney with blood).
- If you are taking certain diuretics (water tablets used to reduce the amount of water in the body), such as spironolactone, triamterene, amiloride. These medicines do not cause your body to lose potassium.
- If you have porphyria (an inherited disorder of blood pigment metabolism).
- If you have Addison's disease (a condition in which your adrenal glands do not make enough of certain hormones).
- If you are taking lithium.
- If you are pregnant or breastfeeding. See **"Take special care with KWINCO"** and **"Pregnancy and Breastfeeding"**.

Take special care with KWINCO:

KWINCO can harm an unborn baby. If you get pregnant, immediately stop taking KWINCO. Call your doctor right away. Talk to your doctor about other medicines to take to lower your blood pressure.

- If you develop swelling of the face around your lips, tongue, or throat or difficulty swallowing, you should contact your doctor immediately.
- If you are having desensitising treatment with hymenoptera venom, tell your doctor that you are taking **KWINCO**.
- Some conditions can cause your blood pressure to get too low. This includes vomiting, diarrhoea, heart disease, a low-salt diet, or if you have been previously treated with water pills. If this leads to light-headedness, you should contact your doctor. If you are at risk of low blood pressure, your doctor may need to monitor your therapy closely.
- To be sure **KWINCO** is helping your condition; your blood pressure will need to be checked on a regular basis. Your kidney or liver function may also need to be tested. Do not miss any scheduled visits to your doctor.
- The safety and efficacy of **KWINCO** in children have not been established.
- Laboratory tests, including liver function, kidney function, blood pressure, blood counts, and blood electrolytes, may be performed while you use **KWINCO**. These tests may be used to monitor your condition or check for side-effects. Be sure to keep all doctor and laboratory appointments.

Tell your doctor:

- if you have kidney disease.
- if you have liver disease.
- if you have diabetes.
- if you are to undergo surgery or anaesthesia.
- if you have a history of allergy or asthma.
- if you have lupus.
- if you have gout.
- if you have congestive heart failure.

- if you have the following signs and/or symptoms of fluid or electrolyte imbalance: Dryness of mouth; thirst; weakness; lack of interest and energy; drowsiness; restlessness; muscle pain or cramps; low blood pressure; reduced urine production; increased rate of heart beat; nausea and vomiting.

Taking KWINCO with food and drink:

Avoid drinking alcohol, which can increase some of the side-effects of **KWINCO**.

Pregnancy and Breastfeeding:

You should not use **KWINCO** if you are pregnant or breastfeeding your baby.

If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Driving and using machinery:

The ability to engage in activities such as operating machinery or operating a motor vehicle may be impaired due to dizziness and fatigue.

Important Information about some of the ingredients of KWINCO:

KWINCO 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 **KWINCO**.

Taking other medicines with KWINCO:

Before taking **KWINCO**, tell your doctor if you are using any of the following medicines:

- Tetracycline (used to treat infections).
- Lithium (used to treat manic stage of bipolar disorder).
- Potassium supplements.
- Potassium-sparing diuretics (water pills).
- Barbiturates, or narcotics (used for sedation and sleep or used in the treatment of pain).
- Diabetes medications such as insulin or oral medications.
- Corticosteroids such as prednisone or ACTH (used to treat inflammation)
- Non-steroidal anti-inflammatory medications such as indomethacin (used to treat inflammation).

- Medicines for high blood pressure
- Pressor amines such as (norepinephrine, noradrenaline) (used to decrease heart-rate).
- Skeletal muscle relaxants.
- Beta2-agonists (bronchodilators such as salbutamol).

If you are using any of these medicines, you may not be able to take **KWINCO**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **KWINCO** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE KWINCO:

- Take **KWINCO** only as directed by your doctor.
- Do not take more or less of it or take it more often than prescribed by your doctor.
- The usual daily dose of **KWINCO** is between 10/12,5 mg to a maximum of 20/25 mg.
- Tell your doctor if you have kidney or liver impairment.

Always take **KWINCO** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **KWINCO** is too strong or too weak, talk to your doctor or pharmacist.

If you take more KWINCO than you should:

Symptoms of overdose are likely to include a severe drop in blood pressure. Symptoms may also include nausea, weakness, dizziness, dry mouth, thirst, muscle pain or weakness, or feeling like you may pass out.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

If you forget to take KWINCO:

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

5. POSSIBLE SIDE-EFFECTS:

KWINCO can have side-effects.

Get emergency medical help if you have any of these signs of an allergic reaction:

- Hives
- Difficulty breathing
- Swelling of your face, lips, tongue, or throat

Call your doctor at once if you have any of these serious side-effects:

- Feeling weak, light-headed, fainting or feeling faint, particularly when standing. This may mean your blood pressure is too low.
- Jaundice (yellowing of the skin or eyes).
- A severe red, blistering, peeling skin rash.
- A dry mouth, nausea, vomiting, increased thirst, muscle cramps, problems urinating.
- Urinating less than usual, or not at all.
- Fast or uneven heartbeat, palpitations, or chest pain.
- Feeling short of breath.
- Severe abdominal and back pain accompanied with feeling very unwell (inflammation of the pancreas).
- Fever, sore throat, chills, and other signs of infection.
- Bruising or easy bleeding.

Other side-effects include:

- 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.
- 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.
- Inflammation of your sinuses (sinusitis).
- Increased sweating, sensitivity of skin to light.
- Failure/inability to achieve penile erection.
- Viral infection.

Tell your doctor if any of the above side-effects are severe, bothersome, do not go away or about any concerns you have while taking **KWINCO**.

Not all side effects reported for **KWINCO** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **KWINCO**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF KWINCO:

Store in a cool (at or below 25 °C), dry place. Protect from light. Do not remove the blisters from the carton until required.

Store all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF KWINCO:

KWINCO 10/ 12,5 mg:

Blister Packs:

Tablets are packed in blister packs (composed of polyamide/silver coloured aluminium foil/PVC film and a peel able printed white paper laminated silver-coloured aluminium backing foil). Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.

KWINCO 20/12,5 mg

Blister Packs:

Tablets are packed in blister packs (composed of polyamide/silver coloured aluminium foil/PVC film and a peel able printed white paper laminated silver-coloured aluminium backing foil). Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.

HDPE Container Pack:

Tablets are packed in white opaque HDPE containers.

Pack size: 30's: One HDPE container of 30 tablets.

8. IDENTIFICATION OF KWINCO:

KWINCO 10/12,5 mg:

Pink coloured, scored, oval shaped, biconvex, film-coated tablets debossed with 'D' on scored side and '18' on other side.

KWINCO 20/12,5 mg:

Pink coloured, triangular, biconvex, film-coated tablets debossed with 'D' and '19' on either sides of a score line on one side and plain on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

KWINCO 10/ 12,5 mg: 43/7.1.3/1046

KWINCO 20/12,5 mg: 43/7.1.3/1047

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

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11. DATE OF PUBLICATION:

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