

PACKAGE LEAFLET: INFORMATION FOR THE USER

Hemokvin Plus

20/12.5 mg film-coated tablets

QUINAPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE (HCTZ)

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Hemokvin Plus is and what it is used for
2. What you need to know before you take Hemokvin Plus
3. How to take Hemokvin Plus
4. Possible side effects
5. How to store Hemokvin Plus

1. WHAT HEMOKVIN PLUS IS AND WHAT IT IS USED FOR

Hemokvin Plus is used to treat high blood pressure.

Hemokvin Plus contains the active ingredients quinapril and HCTZ. 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. HCTZ 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'.

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 HEMOKVIN PLUS

Do not take Hemokvin Plus:

- If you are allergic to quinapril, hydrochlorothiazide, any of the other ingredients of this medicine, similar drugs or to a group of antibiotics called sulphonamides.
- If you are more than 3 months pregnant. It is also better to avoid Hemokvin Plus in early pregnancy - see pregnancy section.
- 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 a history of angioedema relating to previous treatment with an ACE inhibitor.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions

Talk to your doctor or pharmacist before taking Hemokvin Plus if:

- You have aortic stenosis (narrowing of the main blood vessel from the heart).
- You have kidney disease or use a haemodialysis machine (an artificial kidney).
- You have liver disease.
- You have heart disease or heart failure.
- You are elderly.
- You are of African-Caribbean ethnic origin.
- 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.
- 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 must tell your doctor if you think you are (or might become) pregnant. Hemokvin Plus 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).
- You are breast-feeding or about to start breast-feeding.
- You have diabetes or gout.
- You have systemic lupus erythematosus (SLE) an allergic condition which causes joint pain, skin rashes and fever.
- You have a salt or electrolyte imbalance in your blood (e.g. sodium or potassium), your doctor may want to monitor you more closely.
- 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 this is not treated, it can lead to permanent loss of vision.

- 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 Hemokvin Plus'.

Other medicines and Hemokvin Plus

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 Hemokvin Plus. Your doctor may need to change your dose and/or to take other precautions:

- Angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings 'Do not take Hemokvin Plus' and 'Warnings and precautions').
- Other blood pressure treatments and diuretics (including aliskiren and water tablets).
- Medicines to treat infections called tetracyclines.
- 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.
- Medicines to treat diabetes (including vildagliptin).
- Digitalis glycosides (for example digoxin, for the treatment of heart problems).
- mTOR inhibitors used to treat kidney cancer (including temsirolimus).

Surgery

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

Laboratory Tests

Hemokvin Plus may affect the results of some laboratory tests. Tell your doctor or hospital you are taking Hemokvin Plus if you need to have any tests carried out by your doctor or in hospital.

Hemokvin Plus with food and drink

See section 3 How to take Hemokvin Plus.

Pregnancy, breast-feeding and fertility

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

Hemokvin Plus contains lactose monohydrate

Lactose monohydrate is 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 HEMOKVIN PLUS

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.

Adults

The usual dose of Hemokvin Plus is one tablet each day. Hemokvin Plus can be taken with or without food. Swallow the tablets whole with water. Do not chew, divide or crush the tablets.

Use in children and adolescents

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

If you take more Hemokvin Plus than you should

Taking too many tablets at once may make you unwell. If you take too many Hemokvin Plus tablets, tell your doctor or go to your nearest hospital casualty department immediately.

If you forget to take Hemokvin Plus

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 Hemokvin Plus

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 Hemokvin Plus and seek immediate medical attention if you experience any of the following symptoms as they can be serious.

- Severe allergic (anaphylactoid) reaction to this medicine such as swelling of the face, tongue and throat which cause great difficulty breathing (angioedema).
- Severe abdominal pain causing you to be sick (intestinal angioedema).
- 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.
- Weakness of arms, legs or problems speaking which may be symptoms of a possible stroke.
- 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 Hemokvin Plus, 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.
- Severe abdominal and back pain accompanied with feeling very unwell (pancreatitis).
- Yellowing of the skin or the eyes (jaundice).

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

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
- 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

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
- psoriasis
- swelling of the hands, face and tongue (angioedema)

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

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

Not known: frequency cannot be estimated from the available data

- skin discolouration
- decreased 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 from blood vessels in the brain
- narrowing of the airways in the lungs (bronchospasm)
- liver inflammation (hepatitis)
- short-sightedness
- acute closure glaucoma (increased pressure in the eyes)

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

5. HOW TO STORE HEMOKVIN PLUS

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

Do not store above 25°C. Store in the original package.

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.

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