Fosinopril sodium

The starting dose of 10 mg has not been studied in patients over 75 years of age receiving ACE (angiotensin converting enzyme) inhibitors. Angiotensin II also has a vasconstrictor effect which narrows the blood vessels. By inhibiting this substance, there is a reduction in fluid inside the blood vessels (i.e. a decrease in blood pressure). It is recommended that fosinopril is prescribed if you have high blood pressure, or if the heart is not working effectively (due to heart enlargement).

What you need to know before you take Fosinopril sodium

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

• If you have diabetes and are on treatment with so-called oral (via the mouth) antidiabetes (hormones) or insulin (certain agents used to treat diabetes), as fosinopril can affect the way your body processes these medicines. You should have the amount of potassium in your blood regularly monitored.

• If you are under 18 (in some cases), in particular if you have diabetes-related kidney disease.

• If you need to undergo major surgery and/or an anaesthetic. An excessive drop in blood pressure may occur.

• If you are more than three months pregnant (it is also better to avoid Fosinopril sodium in the first three months of pregnancy – see section 4).

• If you are allergic to fosinopril sodium or any of the other ingredients of this medicine (listed in section 4) or to other angiotensin-converting enzyme (ACE) inhibitors.

• If you suffer from heart failure and your blood pressure is low or normal. A further reduction in blood pressure may occur. If this persists, it may become necessary to stop treatment. Fosinopril may also be used in combination with a water-tablet (thiazides) and a water-tablet (diuretics) and may sometimes be prescribed whenever there is change in dosage. This also applies to you if you have an ischaemic heart disease.

• Your doctor may check your kidney function, blood pressure, and the amount of electrolytes in your blood during use of any other medicines, you may now be at increased risk of experiencing side effects.

• If you are on treatment with aliskiren (a medicine used to treat high blood pressure). You should use fosinopril with extreme caution, particularly if you have poor kidney function. This is because, in some instances, severe infections have been observed in patients taking aliskiren. Patients are advised to have their white blood count periodically checked and to report any symptoms of infection immediately.

• If you do not take Fosinopril sodium as prescribed in this leaflet. In this case, your blood pressure will not be controlled and your heart enlargement may become worse.

• If you have a history of angioedema (swelling caused by a reaction to insect venom (desensitisation therapy, e.g. against wasp and bee stings). This is because angioedema may be temporarily increased in episodes of using fosinopril.

• If you are more than three months pregnant or if you are breastfeeding.

• If you have been prescribed this medicine. The doctor will prescribe it for you and you should not use any other medicine until you have spoken to your doctor.

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• If you are allergic to other medicines containing aliskiren.

• If you use or have used a blood pressure lowering medicine containing aliskiren.

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

• If you have diabetes and have poor kidney function and/or poor blood circulation (see also information under the heading "What Fosinopril sodium is and what it is used for") or if you have already been prescribed to use one or several of the medicines listed above, you are therefore recommended to have your kidney function regularly monitored.

• If you have diabetes and are on treatment with so-called oral (via the mouth) antidiabetes (hormones) or insulin (certain agents used to treat diabetes), as fosinopril can affect the way your body processes these medicines. You should have the amount of potassium in your blood regularly monitored.

• If you are also using lithium (an antidepressant). Combined use is generally not recommended.

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Pregnancy and breast-feeding

Pregnancy
You must tell your doctor or pharmacist if you are pregnant. For your treatment, it is important that you keep taking your medicines, even if you feel no effect. If you do not intend to breast-feed, ask your doctor if you can breast-feed or if you need to. It is important that you contact your doctor or pharmacist if you are not sure.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Fosinopril is not recommended in 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 first month of pregnancy.

Breast-feeding

Driving and using machines
Some people may experience dizziness as a result of an excessive drop in blood pressure, particularly at the start of treatment, whenever there is a dose increase or in change of medication, or in combination with the effects of alcohol.

Find out whether this applies to you before you start driving or using machines.

Fosinopril sodium contains lactose. If your doctor has informed you that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Fosinopril sodium

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

The recommended dose of 10 mg has not been studied in patients with severe NYHA class IV heart failure or in patients over 75 years of age receiving treatment for heart failure. It is recommended to start treatment at a reduced (5 mg) dose in patients at increased risk of hypertension (excessively low blood pressure), such as patients with severe heart failure (NYHA class IV), patients over 75 years of age receiving treatment for heart failure, patients with severe kidney and/or liver impairment and patients on treatment with water tablets (diuretics).

If you are being given Fosinopril sodium for high blood pressure, you will usually start on one 10 mg tablet, once daily. Your doctor will determine whether the 20 mg dose of Fosinopril sodium is sufficient. Some users will need a lower or even higher dose (ranging from 10 to 40 mg per day). If necessary, your doctor will adjust the dosage. If you are using water tablets, these should normally be stopped 2 to 3 days before starting treatment with fosinopril sodium. If you are being given Fosinopril sodium for high blood pressure, treatment should be started at a dose of 10 mg and is recommended that treatment with fosinopril sodium tablets be started for a few days without medical observation, until the blood pressure is stable.

If you are being given Fosinopril sodium in heart failure, you will also start in most cases on a dose of 10 mg tablet once daily; on completion of observation, this dose may be increased in heart failure. On your doctor's advice, the dose may be increased in heart failure. On your doctor's advice, the dose may be increased in heart failure.

Directions for use

Take the tablets with half a glass of water. You can take the tablets before, during, or after a meal or in an empty stomach.

Duration of treatment

You will generally have to use Fosinopril sodium over the long term. Closely follow your doctor's instructions. It is important that you keep taking your medicines, even if you feel no effect.

If you forget taking Fosinopril sodium tablets

You will not experience any withdrawal symptoms if you suddenly stop using Fosinopril and Fosinopril sodium, but the desired effect will be lost and the condition may reappear. In addition the risk of complications due to high blood pressure, especially in the heart, brain and kidneys may occur.

On no account should you stop using the medicine without consulting your doctor.

If you take more Fosinopril sodium than you should

If you have taken too much Fosinopril sodium, contact your doctor or pharmacist immediately. If you have taken too many tablets, you may experience dizziness or fainting.

If you have to take Fosinopril sodium

Do not take a double dose to make up for a forgotten dose. For your treatment, it is important that you keep taking your medicines, even if you feel no effect. If you happen to forget to take your tablets, you can still take the forgotten dose unless it is time for your next dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

All medicines can cause side effects although not everybody gets them. The following side effects have been reported at the approximate frequencies shown.

Common (effects in 1 to 10 users in 100)

• upper respiratory tract infection, sore throat, inflammation of the lining of the nose, viral changes in the blood count, such as agranulocytosis (a very severe blood abnormality (lack of white blood cells) accompanied by sudden high fever, severe sore throat and mouth ulcers)
• low blood pressure
• fluid accumulation in the gut (intestinal angioedema), bowel obstruction; complete (ileus)
• red pinpoint bleeding into the skin (ecchymosis)
• dry mouth, constipation, flatulence
• low blood levels of the blood (anaemia)
• convulsions
• muscular weakness
• appetite disorder, weight fluctuation
• abdominal pain
• nervous disorders (such as anxiety, excitement, depression)
• muscular weakness
• increased sedimentation of red blood cells (ESR), eosinophilia and leukocytosis, skin rash, hyperuricaemia to light or other skin disorders.

Reporting of side effects

If you experience any of these side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. If you can report side effects using the uniform reporting system Yellow Card Scheme (NYHA class III or IV), patients over 75 years of age receiving treatment for heart failure, patients with severe kidney and/or liver impairment and patients on treatment with water tablets (diuretics). risks.

The use of Fosinopril sodium is not recommended in children and adolescents. There is limited clinical trial evidence of the use of Fosinopril in hypertensive children aged 6 years and above. The optimum dose has not been determined in children.

An appropriate dose strength is not available for children weighing less than 50 kg.

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The tablets are packaged in blister PVC/ PE/ PVdC/ aluminium or plastic bottles with a high

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