

Package leaflet: Information for the patient

Kamiren 4 mg prolonged-release tablets doxazosin

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

1. What Kamiren is and what it is used for

Kamiren is one of a group of medicines called alpha-blockers. It is used to treat high blood pressure.

Kamiren can be used to treat high blood pressure (hypertension), by relaxing blood vessels so that blood passes through them more easily. This helps to lower blood pressure.

2. What you need to know before you take Kamiren

Do not take Kamiren if

- you are allergic to active substance, related quinazolines (e.g. prazosin or terazosin), or any of the other ingredients of this medicine (listed in section 6). This may have been itching, reddening of the skin or difficulty in breathing.
- If you have any form of obstruction of the digestive tract.
- If you are under 12 years of age.
- If you have a history of a condition known as ‘orthostatic hypotension’ which is a form of low blood pressure that causes you to feel dizzy or light-headed when you stand up from sitting or lying down.
- If you have an enlarged prostate gland with one of the following: any kind of congestion or blockage in your urinary tract; a longstanding infection of the urinary tract; or you have bladder stones.
- If you have an enlarged prostate gland and have overflow incontinence (you do not feel the urge to urinate), or anuria (your body is not producing any urine) with or without kidney problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking Kamiren as it may not be suitable for you:

- If you are pregnant or trying to become pregnant
- If you have liver disease, kidney disease or heart disease.
- If you are also taking other medicines.
- If you have problems with your heart.

If you are undergoing eye surgery because of cataract (cloudiness of the lens) please inform your eye specialist before the operation that you are using or have previously used Kamiren. This is because this medicine may cause complications during the surgery which can be managed if your specialist is prepared in advance.

Prolonged and sometimes painful erections may occur very rarely. In such case, contact your doctor immediately.

When you start to take Kamiren, you may experience faintness or dizziness caused by low blood pressure when getting up from sitting or lying down. If you feel faint or dizzy, you should sit or lie down until you feel better and avoid situations where you might fall or hurt yourself.

Children and adolescents

Kamiren is not recommended for use in children or adolescents below 18 years as safety and efficacy have not yet been established.

Other medicines and Kamiren

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

There are some medicines that may interact with Kamiren

- Medicines for erectile dysfunction (impotence) such as sildenafil, tadalafil or vardenafil
Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking drugs for erectile dysfunction (impotence) with alpha-blockers. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of your alpha blocker before you start drugs for erectile dysfunction.
- Kamiren may also increase the effects of drugs used to treat high blood pressure (hypertension).
- Medicines to treat bacterial or fungal infections, e.g. clarithromycin, itraconazole, ketoconazole, telithromycin, voriconazole.
- Medicines used in the treatment of HIV e.g. indinavir, nelfinavir, ritonavir, saquinavir.
- Nefazodone, a medicine used to treat depression.

Kamiren with food and drink

See section 3 How to take Kamiren.

Pregnancy and breast-feeding

Pregnancy

The safety of using Kamiren during pregnancy has not been established. If you are pregnant or trying to become pregnant speak to your doctor, who will decide if this medicine is suitable for you.

Breast-feeding

Small amounts of doxazosin, the active substance of Kamiren, can get into your breast milk. You should not use Kamiren during breast-feeding unless your doctor advises you to do so.

Driving and using machines

Take care if you drive or operate machinery. Your tablets may affect your ability to drive or operate machinery safely, particularly when you first start to take them. They may cause drowsiness and could also make you feel weak or dizzy. If you are affected, do not drive or operate machinery and contact your doctor immediately.

Kamiren contains lactose

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 Kamiren

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

Kamiren tablets are a prolonged-release tablet. The medicine is contained within a nonabsorbable shell that has been specially designed to slowly release the medicine. Once swallowed, the medicine (doxazosin) is slowly released into the body from the tablet, until the tablet is empty. Since the empty tablet is eliminated from the body in bowel movements, you may occasionally observe in the stools something that looks like a tablet. This is to be expected and you should not be concerned.

How to take your medicine

- The usual dose is one 4 mg prolonged-release tablet taken every day. Your doctor may wish to increase your dose to 8 mg. This is the maximum dose of this medicine.
- Kamiren can be taken with or without food.
- Swallow your medicine whole with water. Do not chew, divide or crush the tablets.
- Take your tablets as your doctor told you.
- It is important to keep taking your tablets. They help to control your blood pressure.
- Do not change the dose or stop taking the tablets without first checking with your doctor.
- Do not wait until your tablets are finished before seeing your doctor.
- If you are still not sure how to take your tablets, ask your doctor or pharmacist.

If you take more Kamiren than you should

Taking too many tablets at once may make you unwell. If several tablets are taken it may be dangerous. Tell your doctor immediately or go to your nearest hospital casualty department immediately.

If you forget to take your Kamiren

Do not worry. If you forget to take a tablet, leave that dose out completely. Then go on as before. Do not take a double dose to make up for a forgotten tablet.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

STOP taking Kamiren and contact your doctor immediately if you experience the following:

- heart attack
- increased, decreased or irregular heartbeat
- weakness of arms, legs or problems speaking, which may be signs of a stroke
- allergic reactions (hypersensitivity). Symptoms include sudden wheeziness, tightness in chest, difficulty in breathing, swelling of the face, tongue or throat, rash or itching (especially affecting the whole body).

Tell your doctor **immediately** if you experience any of the following symptoms:

- chest pain (angina), wheezing, shortness of breath or difficulty breathing
- feeling your heart beat (palpitations)
- fainting
- yellowing of the skin or the eyes (jaundice)
- low number of white blood cells or blood platelets, which may result in bruising or easy bleeding

The following events have been reported in patients being treated with Kamiren. 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):

- dizziness, feeling of spinning or rotation of surroundings (vertigo), headache
- low blood pressure
- swelling of feet, ankles or fingers
- bronchitis, coughing, respiratory tract (nose, throat, lungs) infection
- nasal stuffiness, sneezing and/or runny nose caused by inflammation of the lining of the nose (rhinitis)
- stomach/abdominal pain, feeling/being sick
- urinary tract infection, cystitis, urinary incontinence (inability to control passing urine), inflammation of the bladder (cystitis)
- sleepiness, general weakness
- Indigestion, dry mouth
- itching
- back pain, muscle pain
- flu-like symptoms.

Uncommon side effects (may affect up to 1 in 100 people):

- constipation, diarrhoea, wind (flatulence), inflammation of the stomach and intestines (gastroenteritis) which can cause diarrhoea and vomiting
- pain or discomfort on passing urine, increased frequency in passing urine, blood in urine
- inflammation of the joints (gout), joint pain, general pain
- sleeplessness, anxiety, depression
- reduced or altered sense of touch or sensation of the hands and feet
- increased appetite or loss of appetite (anorexia), weight gain
- nose bleeds
- skin rash
- ringing or noise in the ears (tinnitus), tremor
- failure/ inability to achieve penile erection (impotence)
- liver enzyme increases which may have an effect on some medical tests
- stroke

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

- Blockage of the digestive tract

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

- faintness or dizziness caused by low blood pressure when getting up from a sitting or lying position
- agitation or nervousness
- hepatitis (liver inflammation) or bile disorder
- hives, hair loss, red or purple patches on the skin, bleeding under the skin
- Tingling or numbness of the hands and feet
- tiredness, generally feeling unwell
- blurred vision
- hot flushes
- muscle cramps, muscle weakness
- disorder in passing urine, needing to pass urine at night, increased number of times of passing urine, increased volume of urine passed
- discomfort or enlargement of the breasts in men
- persistent painful erection of the penis. Seek urgent medical advice.

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

- Little or no semen ejaculated at sexual climax, cloudy urine following sexual climax
- Eye problems may occur during eye surgery for cataract (cloudiness of the lens of the eye). See section "Warnings and precautions".

Other side effects

The frequency of these side effects is unknown:

- little or no semen ejaculated at sexual climax, cloudy urine following sexual climax
- eye problems may occur during eye surgery for cataract (cloudiness of the lens of the eye). See section “Warnings and precautions”.

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:

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store Kamiren

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

This medicinal product does not require any special storage conditions.

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 Kamiren contains

The active substance is doxazosin. Each tablet contains 4mg doxazosin (as mesilate).

The other ingredients are hypromellose, calcium hydrogen phosphate, lactose monohydrate, magnesium stearate and opadry white Y-1-7000 (hypromellose, titanium dioxide (E171) and Macrogol 400).

What Kamiren looks like and contents of the pack

Tablets are white, round biconvex tablets. They are supplied in packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer

KRKA, d.d., Novo mesto, Šmarjška cesta 6, 8501 Novo mesto, Slovenia

This leaflet was last revised in