

PACKAGE LEAFLET: INFORMATION FOR THE USER

KAMIREN

2 mg, 4 mg TABLETS

DOXAZOSIN

• 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 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

The name of your medicine is KAMIREN 2 mg Tablets, KAMIREN 4 mg Tablets (referred to as KAMIREN throughout this leaflet).

1. WHAT KAMIREN IS AND WHAT IT IS USED FOR

Doxazosin is one of a group of medicines called alpha-blockers.

KAMIREN tablets are used to treat high blood pressure (hypertension) or the symptoms caused by enlargement of the prostate gland in men.

In patients taking KAMIREN to treat high blood pressure (hypertension) KAMIREN works by relaxing blood vessels so that blood passes through them more easily. This helps to lower blood pressure.

In patients with enlargement of the prostate gland, KAMIREN is taken to treat frequent and/or poor passing of urine. This is common in patients with enlargement of the prostate gland. KAMIREN works by relaxing muscle around the bladder exit and prostate gland so urine is passed more easily.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE KAMIREN

Do not take KAMIREN if you:

- have ever had an allergic reaction (hypersensitivity) to doxazosin, other types of quinazolines (such as prazosin or terazosin) or any of the other ingredients of KAMIREN tablets. This may have been itching, reddening of the skin or difficulty in breathing.

- are breastfeeding
- are aged under 18 years of age
- have an enlarged prostate gland (benign prostatic hyperplasia) and have low blood pressure
- 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
- 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
- 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:

The following are reasons why KAMIREN may not be suitable for you:

- If you have liver disease
- If you are pregnant or trying to become pregnant
- If you are also taking other medicines
- If you have heart disease

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 KAMIREN may cause complications during the surgery which can be managed if your specialist is prepared in advance.

If any of these apply to you speak to your doctor before taking this medicine.

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.

Your doctor may want to measure your blood pressure regularly at the start of therapy to reduce the possibility of these effects happening.

Other medicines and KAMIREN:

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 lower your blood pressure even more if you are already taking other medicines to treat your blood pressure such as terazosin or prazosin.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Taking KAMIREN with food and drink

KAMIREN can be taken with or without food.

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 and he/she will decide if KAMIREN is suitable for you.

Breastfeeding:

Do not take KAMIREN if you are breast-feeding.

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 make you feel weak or dizzy. If affected, do not drive or operate machinery and contact your doctor immediately.

Important information about some of the ingredients of KAMIREN:

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE KAMIREN

Use in adults and elderly:

Always take KAMIREN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

KAMIREN is usually taken once daily. KAMIREN may be taken in the morning or the evening. You can take your tablets before or after food.

You should take your tablets at the same time each day with a small amount of water.

The initial dose of KAMIREN is 1mg once daily. Thereafter the dose may be gradually increased (within 1-2 weeks interval) to the usual dose (2mg or 4mg daily).

In some circumstances the dose may be increased to a maximum of 8mg daily if you are being treated for prostate enlargement, or to a maximum of 16mg if you are being treated for high blood pressure.

You have been given a calendar pack that will help you remember to take your tablets. If you are taking more than one tablet a day, you must ignore the marking for the day, printed on the back of the blister.

Because high blood pressure is treated in order to

Don't wait until your tablets are finished before seeing your doctor.

If you have impression that the effect of KAMIREN is too strong or too weak, talk to your doctor or pharmacist.

If you forget to take KAMIREN:

If you miss a dose just carry on with the next one as normal. Do not take a double dose to make up for the missed one.

If you take more KAMIREN than you should:

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, KAMIREN can have side effects but not everybody gets them.

STOP taking KAMIREN and call an ambulance immediately if you experience any of the following:

- Heart attack
- Weakness of arms, legs or problems speaking which may be symptoms of a stroke
- Swelling of the face, tongue or throat which may be the result of an allergic reaction to this medicine

Tell your doctor immediately if you experience any of the following symptoms after taking KAMIREN:

- Chest pain, angina
- Shortness of breath, difficulty breathing
- Increased, decreased or irregular heartbeat
- Feeling your heartbeat (palpitations)
- Fainting
- Yellowing of the skin or the eyes (jaundice)
- Low numbers of white blood cells or blood platelets, which may result in increasing frequency of infection, bruising or easy bleeding

The following events have been reported in patients being treated with doxazosin. 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

These can affect between 1 in 10 and 1 in 100 patients:

- 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 pains, feeling/being sick
- Urinary tract infection, urinary incontinence (inability to control passing urine), inflammation of bladder (cystitis)
- Sleepiness, general weakness
- Indigestion, heartburn, dry mouth
- Itching
- Back pain, painful muscles
- Flu-like symptoms

Uncommon side effects:

These can affect between 1 in 100 and 1 in 1,000 patients:

- Constipation, wind, 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), painful joints, general pain
- Swelling of the face
- Sleeplessness, agitation, anxiety, depression or nervousness
- Reduced or altered sense of touch or sensation of the hands and feet
- Increased appetite or loss of appetite, weight gain
- Nose bleeds
- Skin rash
- Ringing or noise in the ears, tremor
- Increased number of times of passing urine
- Muscle cramps, muscle weakness

Very Rare side effects

These can affect less than 1 in 10,000 patients:

- Faintness or dizziness caused by low blood pressure when getting up from a sitting or lying position
- 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
- Aggravated wheezing
- Blurred vision
- Hot flushes
- Disorder in passing urine, needing to pass urine at night, increased volume of urine passed
- Discomfort or enlargement of the breasts in men
- Painful persistent erection of the penis

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 "Take special care with KAMIREN".

If any of the side effects become serious, or you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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.

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

5. HOW TO STORE KAMIREN

There are no special precautions for storage. Keep out of the reach and sight of children. Check the expiry date on the label. Do not use the tablets if the expiry date has passed.

This leaflet was last revised in August 2015.