

KAMIREN XL MODIFIED RELEASE TABLETS

Doxazosin (4 mg)

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What Kamiren XL is used for

Kamiren XL contains the active substance doxazosin, which belongs to a group of medicines called alpha-adrenergic blocking agents (alpha-blockers).

Kamiren XL is recommended for:

- for the treatment of increased blood pressure (hypertension).
- the symptoms caused by enlargement of the prostate gland in men.

How Kamiren XL works

Thanks to special technology, the release of doxazosin in tablets is gradual and continuous. Therefore, with the regular use only a slight variation in levels of doxazosin in the blood was observed.

In patients with **high blood pressure (hypertension)** Kamiren XL relaxes blood vessels so that blood passes through them more easily. This helps to lower blood pressure.

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

Before you use Kamiren XL

- When you must not use it
- if you are allergic (hypersensitive) to doxazosin, other types of quinazolines (e.g. prazosin or terazosin) or any of the other ingredients of Kamiren XL.
- 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 any form of obstruction of the digestive tract
- 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 low blood pressure
- if you are breast-feeding
- if you 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.

- Before you start use it

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

- if you have liver problems,
- if you have heart disease.

When you start to take Kamiren XL 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.

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

When starting the treatment, blood pressure may fall significantly. You may become dizzy so driving motor vehicles and operating machinery is not recommended at that time.

Important information about some of the ingredients of Kamiren XL

Kamiren XL 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.

- Taking other medicines

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 XL may lower your blood pressure even more if you are already taking other medicines to treat high blood pressure.

How to use Kamiren XL

- How much to use

The usual dose is 1 tablet once daily. Your doctor may increase the dose if it decides that it is low.

The maximum dose is 2 tablets daily.

- When to use it

You can take medicine before, during or after meals.

- How long to use it

Keep taking your tablets until your doctor tells you to stop.

- If you forget to use it

Do not take a double dose to make up for a forgotten tablet capsule dose. If you forget to take a dose, take it as soon as possible. If it is almost time for the next dose, leave out the missed dose and continue with the regular dosing schedule.

- If you use too much (overdose)

If you have taken an overdose, consult with your doctor or pharmacist immediately. Too large doses mainly result in low blood pressure, dizziness and vertigo, possibly also fainting. If you experience any of these symptoms, lie down with the head lowered and feet slightly elevated.

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While you are using it

- Things you must do

Swallow the tablet whole with some liquid. You should not chew, break or crush the tablets.

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 XL. This is because Kamiren XL may cause complications during the surgery which can be managed if your specialist is prepared in advance.

- Things you must not do

Breastfeeding

Breastfeeding during treatment with doxazosin is not recommended.

- Things to be careful of

Pregnancy

The safety of using doxazosin during pregnancy has not been established. You may take Kamiren XL during pregnancy only if it is clearly needed.

Side effects

Like all medicines, Kamiren XL can cause side effects, although not everybody gets them.

Common

- respiratory tract (nose, throat, lungs) infection, urinary tract infection
- dizziness, headache, sleepiness
- feeling of spinning or rotation of surroundings (vertigo)
- increased heartbeat (tachycardia), feeling your heartbeat (palpitations)
- low blood pressure or a fall in blood pressure on standing up which causes dizziness, lightheadedness or fainting (postural hypotension)
- bronchitis, coughing, shortness of breath (dyspnea), nasal stuffiness, sneezing and/or runny nose caused by inflammation of the lining of the nose (rhinitis)
- stomach/abdominal pain, indigestion, dry mouth, feeling sick (nausea)
- itching (pruritus)
- back pain, painful muscles
- inflammation of the bladder (cystitis), inability to control passing urine (urinary incontinence)
- general weakness, chest pain, influenza-like symptoms,

- swelling of feet, ankles or fingers.

Uncommon

- allergic drug reaction
- increased appetite or loss of appetite, inflammation of the joints (gout)
- anxiety, depression, sleeplessness (insomnia)
- stroke, fainting, tremor, reduced or altered sense of touch or sensation of the hands and feet,
- ringing or noise in the ears
- heart attack, chest pain (angina pectoris)
- nose bleeds
- constipation, wind, inflammation of the stomach and intestines (gastroenteritis) which can cause diarrhoea and vomiting
- abnormal liver function test
- skin rash
- pain or discomfort on passing urine, increased frequency in passing urine, blood in urine
- painful joints
- failure/ inability to achieve penile erection (impotence)
- weight gain
- swelling of the face, general pain

Very Rare

- low numbers of white blood cells or blood platelets, which may result in bruising or easy bleeding (leukopenia, thrombocytopenia)
- restlessness, nervousness
- faintness or dizziness caused by low blood pressure when getting up from a sitting or lying position, tingling or numbness of the hands and feet
- blurred vision
- decreased or irregular heartbeat
- flushing
- aggravated wheezing
- hepatitis (liver inflammation) or bile disorder, yellowing of the skin or the eyes (jaundice)
- hives, hair loss,
- red or purple patches on the skin, bleeding under the skin (purpura)
- muscle cramps, muscle weakness
- disorder in passing urine, needing to pass urine at night, increased volume of urine passed
- discomfort or enlargement of the breasts in men (gynaecomastia)
- persistent painful erection of the penis. Seek urgent medical advice
- tiredness, generally feeling unwell.

Frequency not known

- 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).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Clopilet

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C. Store in the original package.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- Disposal

No special requirements.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Modified-release tablets: white, round, slightly convex tablets.

Supply

90 modified-release tablets in a folding box.

- Ingredients

Each modified-release tablet contains 4 mg doxazosin as doxazosin mesylate.

Inactive ingredient

Hypromellose, calcium hydrogen phosphate, lactose monohydrate, magnesium stearate, titanium dioxide (E171), macrogol 400.

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Doxazosin (4 mg)

- MAL number:

MAL10100162AZ

Manufacturer

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

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
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Date of revision

01/04/2019

Serial Number

NPRA(R2/1)200828/507