

Colixil XL 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 Colixil XL 4 mg Prolonged-release Tablets are and what they are used for
2. What you need to know before you take Colixil XL 4 mg Prolonged-release Tablets
3. How to take Colixil XL 4 mg Prolonged-release tablets
4. Possible side effects
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6. Contents of the pack and other information

1. WHAT COLIXIL XL 4 MG PROLONGED-RELEASE TABLETS ARE AND WHAT THEY ARE USED FOR

Colixil XL 4 mg Prolonged-release tablets are one of a group of medicines called alpha-blockers.

They are used to treat:

- high blood pressure
- symptoms caused by enlargement of the prostate gland in men.

In patients taking this medicine to treat high blood pressure (hypertension), it 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, this medicine is taken to treat poor and/or frequent passing of urine. This is common in patients with enlargement of the prostate gland (benign prostatic hyperplasia). This medicine 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 COLIXIL XL 4 MG PROLONGED-RELEASE TABLETS
Do not take Colixil XL 4 mg Prolonged-release tablets

- if you are allergic to doxazosin, related quinazolines e.g. prazosin or terazosin, or any of the other ingredients of this medicine (listed in section 6).
- if you have had any form of obstruction of the digestive tract
- if you have an enlarged prostate gland together with congestion of the upper urinary tract, chronic urinary tract infections or bladder stones
- if you suffer from a loss of bladder control (bladder overflow), an inability to urinate, or kidney failure
- if you are being treated for an enlarged prostate gland and you have low blood pressure
- if you have or have ever had a fall in blood pressure on standing up, causing dizziness, light-headedness or fainting

Warnings and precautions

Talk to your doctor before taking this medicine:

- if you have liver disease
- if you have heart disease and in particular cardiac insufficiency or pulmonary oedema (water deposits in the lungs)
- if you undergo a surgery of cataract (clouding of eye lens)
- if you are pregnant or trying to become pregnant
- if you are also taking medicines that are used to treat erection problems (PDE-5 inhibitors, e.g. sildenafil, tadalafil, vardenafil) (see section "Other medicines and Colixil XL 4 mg Prolonged-release tablets")

Dizziness, weakness and in rare cases fainting may occur, especially when you first start taking this medicine. You should therefore be careful at the beginning of treatment, and avoid situations that could lead to injury if these symptoms occur. Should you feel dizzy or faint, lie down and the symptoms should disappear rapidly.

Prolonged and sometimes painful erections may occur very rarely. If this occurs, you should contact a doctor immediately.

Before starting treatment with Colixil XL 4 mg Prolonged-release tablets 4 mg Prolonged-release tablets for an enlarged prostate gland, your doctor may perform tests to rule out other conditions such as prostate cancer that may cause the same symptoms as benign prostatic hyperplasia.

Other medicines and Colixil XL 4 mg Prolonged-release Tablets

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

It is especially important to mention the following before taking this medicine:

- medicines used to treat difficulties in getting an erection (e.g. sildenafil, tadalafil or vardenafil); together with Colixil XL 4mg Prolonged-release tablets they may lower your blood pressure
- Certain patients may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of Colixil XL 4mg Prolonged-release tablets 4 mg Prolonged-release tablets before you start medicines for erectile dysfunction (impotence). Your doctor may start you on the lowest possible dose of medicine for erectile dysfunction, and it is recommended to take it at least 6 hours away from the intake of Colixil XL 4mg Prolonged-release tablets.
- medicines for high blood pressure (called antihypertensives)
- 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.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- If you are pregnant do not take this medicine without consulting your doctor first. The safety of this medicine in pregnancy is not sufficiently established.
- Small amounts of doxazosin, the active substance of this medicine, can get into your breast milk. You should not take this medicine if you are 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 make you feel weak or dizzy. If affected, do not drive or operate machinery and contact your doctor immediately.

Colixil XL 4 mg Prolonged-release tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. HOW TO TAKE COLIXIL XL 4 MG PROLONGED-RELEASE TABLETS

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

Adults (including elderly)

The recommended dose of Colixil XL 4 mg Prolonged-release tablets is 4 mg taken as a single daily dose.

Your doctor may wish to increase your dose to 8 mg once daily. This is the maximum dose of Colixil XL 4 mg Prolonged-release tablets.

Colixil XL 4 mg Prolonged-release Tablet is a prolonged release tablet. The medicine is contained within a non-absorbable shell that has been specially designed to slowly release the medicine. Once swallowed, 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.

Method of administration:

- Do not chew, divide or crush the tablets.
- Swallow the tablets whole with a drink of water.
- You can take these tablets with or without food.

Patients with liver disorders

If you have liver problems, your doctor will monitor you closely during treatment. Colixil XL 4 mg Prolonged-release tablets is not recommended for use in patients with severe liver problems (see section "Warnings and precautions").

Use in children and adolescents

This medicine is not recommended for patients under the age of 18 years.

If you take more of Colixil XL 4 mg Prolonged-release tablets 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.

If you forget to take Colixil XL 4 mg Prolonged-release tablets

Do not worry. If you forget to take a tablet, leave that dose out completely. Then go back to your usual schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking Colixil XL 4 mg Prolonged-release tablets

It is important to keep taking your tablets. 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 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.

Some side effects could be serious:

If any of the following happens, stop taking this medicine and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions such as wheezing, shortness of breath, extreme dizziness or collapse, swelling of the face or throat, or a serious skin rash with red spots or blisters.
- Chest pain, increased or irregular heartbeat, heart attack or stroke.
- Yellowing of the skin or whites of the eyes, itching, loss of appetite, and dark coloured urine, caused by liver problems.
- Unusual bruising or bleeding caused by low blood platelets.
- Persistent painful erection of the penis.

These side effects are uncommon (may affect up to 1 in 100 people) or very rare (may affect up to 1 in 10,000 people).

Other side effects:**Common** (may affect up to 1 in 10 people)

- infections of the respiratory and urinary tract
- dizziness, headache, sleepiness
- feeling of strong heart beats
- low blood pressure
- fall in blood pressure on standing up which may cause dizziness, light-headedness or fainting
- spinning sensation
- itching
- shortness of breath, nasal stuffiness or runny nose (rhinitis)
- inflammation of the airways (bronchitis), cough
- abdominal pain, indigestion, dry mouth, feeling sick
- back pain, muscle pain
- painful and frequent urination, inability to control urination (urinary incontinence)
- weakness, chest pain, flu-like symptoms, swollen hands, ankles or feet

Uncommon (may affect up to 1 in 100 people)

- loss of appetite, increased appetite
- gout (painful and swollen joints)
- anxiety, depression, difficulty in sleeping
- decreased skin sensitivity, fainting, shaking (tremor)
- ringing or noise in the ears
- nose bleeds
- constipation, diarrhoea, wind, vomiting, inflammation of stomach and gut (gastroenteritis)
- abnormal liver function tests
- skin rash
- painful joints
- blood in urine, difficulty or pain on passing urine, abnormal urination frequency
- failure/inability to achieve penile erection
- pain, swelling of the face (facial oedema)
- weight increase

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

- blockage of the digestive tract.

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

- low level of white blood cells
- agitation, nervousness
- tingling or altered sensitivity of the hands and feet
- blurred vision
- slowing of the heart rate
- flushing
- difficulty in breathing or wheezing
- hair loss, purple skin patches, itchy rash
- muscle cramps, muscle weakness
- micturition disorder, frequent need to urinate, increased urination, need to get up during the night in order to urinate (nocturia)
- enlargement of male breasts
- tiredness, generally feeling unwell

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

- ejaculation backwards into the bladder instead of forward through the urethra (retrograde ejaculation, "dry orgasm")
- a certain complication that may occur during cataract surgery (intraoperative floppy iris syndrome, see also 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 the Yellow Card Scheme (www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in Google play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE COLIXIL XL 4 MG PROLONGED-RELEASE TABLETS

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 blister and carton 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 Colixil XL 4 mg Prolonged-release tablets contain

- The active substance is doxazosin (as mesilate). Each tablet contains 4 mg of doxazosin (as mesilate).
- The other ingredients are: macrogol 200, macrogol 900, butylhydroxytoluene (E 321), cellulose microcrystalline, povidone K 30, all-rac- α -tocopherol (E 307), colloidal anhydrous silica, sodium stearyl fumarate, methacrylic acid ethyl acrylate copolymer (1:1) dispersion 30%, colloidal silica, hydrated, macrogol.(1300-1600), titanium dioxide (E 171).

What Colixil XL 4 mg Prolonged-release tablets look like and contents of the pack

Colixil XL 4 mg Prolonged-release tablets are white round biconvex tablets with bossing "DL"

The tablets are packed in PVC/PVDC/ALU blister and inserted in a carton.

Pack size:

14, 28, 30, 56, 98 100 tablets or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Sandoz Ltd.,
Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR

Manufacturer:

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany *or* Lek S.A, ul. Domaniewska 50 C, 02-672 Warszawa, Poland *or* Lek Pharmaceuticals d.d. Verovškova 57, 1526 Ljubljana, Slovenia *or* Synoptis Industrial Sp. z o.o. ul. Rabowicka 15, 62-020 Swarzędz, Poland

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