

Package leaflet: Information for the user

CARSEM 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Carsem XL is and what it is used for

The name of your medicine is Carsem XL 4mg prolonged-release tablets. It belongs to a class of medicines called “alpha blockers.” It can be used to treat high blood pressure or a condition called “Benign Prostatic Hyperplasia” (enlargement of the prostate).

If you suffer from high blood pressure, this can increase your risk of developing heart disease or having a stroke. Carsem XL lowers your blood pressure by relaxing your blood vessels which makes it easier for your heart to pump blood through them.

If you suffer from “Benign Prostatic Hyperplasia” (enlargement of the prostate) you may experience problems passing urine. In men the prostate gland is just below the bladder. If enlarged, it can make it more difficult for urine to flow out of your bladder. Carsem XL works by relaxing muscles around the bladder and prostate gland making it easier to pass urine.

2. What you need to know before you take Carsem XL

Do not take Carsem XL:

- If you are allergic to doxazosin or other similar medicines which are in the same chemical class (e.g. prazosin, terazosin) or any of the other ingredients of this medicine (listed in section 6)
- If you have a orthostatic hypotension (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 suffer from Benign Prostatic Hyperplasia and have
 - low blood pressure
 - an obstruction to your upper urinary tract (tubes running between your kidneys and your bladder).
 - chronic urinary tract infection
 - bladder stones

- If you have or have had a narrowing or blockage in your oesophagus (tube leading from your mouth to your stomach) or intestine or elsewhere in the digestive tract
- If you are breast-feeding
- Carsem XL should not be your only medicine in the treatment of
 - overflow incontinence (leakage of urine even when you feel no urge to urinate)
 - if you have kidney problems or you produce little or no urine

Warnings and precautions

- Talk to your doctor or pharmacist before taking Carsem XL
- If you have previously had surgery to remove a section of your intestine (gut)
- Your medicine may make you feel dizzy and light headed, especially at the start of treatment or if you start treatment again after a break. Rarely this can result in loss of consciousness. If affected you should not drive, operate machinery or participate in any other dangerous activity that requires your full attention.
- If you have heart problems (e.g. heart failure) or if the valves in your heart do not work properly
- If you have liver problems (and especially if you are taking other medicines which are known to be broken down by the liver (e.g. cimetidine)). Check with your doctor or pharmacist if unsure.
- Carsem XL may also affect the results of some blood and urine tests. If you are due to have a blood or urine test make sure that you tell your doctor that you are taking Carsem XL.
- If you are diabetic and have a condition called “Diabetic Autonomic Neuropathy.” Check with your doctor if unsure.
- If you are taking certain medicines used to treat erectile dysfunction (male erection problems) such as sildenafil, tadalafil and vardenafil
- 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 Carsem XL. This is because Carsem XL may cause complications during the surgery which can be managed if your specialist is prepared in advance.
- It is normal if occasionally you see remains in your stool that look like a tablet

Children and adolescents

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

Other medicines and Carsem XL

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

- Other medicines used to treat high blood pressure.
- Non-steroidal anti-inflammatory drugs (NSAIDs) used for pain relief (e.g. ibuprofen and diclofenac sodium)
- Medicines containing estrogens such as the oral contraceptive pill
- Nasal decongestants or cough and cold preparations containing nasal decongestants (e.g. ephedrine and phenylephrine)
- Medicines used in hospital to stimulate your heart (e.g. dopamine, ephedrine, epinephrine, metaraminol or methoxamine)
- Medicines which are known to be broken down by the liver (e.g. cimetidine). Check with your doctor or pharmacist if unsure
- 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) such as sildenafil, tadalafil and vardenafil 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

Carsem XL with food and drink

Food does not affect the way that your medicine works. It can be taken with food or on an empty stomach.

Pregnancy, breast-feeding and fertility

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

If you are pregnant or trying to become pregnant Carsem XL should only be used if your doctor considers it to be absolutely necessary. The effects on your baby are not known.

Carsem XL must not be used if you are breast feeding as it may accumulate in your breast milk and harm your baby.

Driving and using machines

Carsem XL can make you feel light headed and dizzy, especially at the start of treatment or if you restart your medicine after a break. It can also cause drowsiness. If affected you should not drive or operate machinery or participate in any other dangerous activity that requires your full attention.

3. How to take Carsem XL

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

Your medicine may be used to treat high blood pressure or Benign Prostatic Hyperplasia (enlargement of the prostate). The dose for each condition is the same.

Tablets should be swallowed whole with a sufficient amount of fluid. They should not be chewed or crushed. They should be taken at the same time each day.

The recommended dose is

Adults (including the Older people)

The usual dose of Carsem XL is one tablet daily although your doctor may increase your dose to the maximum of two tablets each day.

Use in Children and adolescents

Carsem XL is not recommended for use in children.

Patients with hepatic impairment

If you have liver problems your doctor will monitor you closely during treatment. Carsem XL is not recommended for use in patients with severe liver problems.

If you take more Carsem XL than you should

If you (or someone else) swallow a lot of tablets altogether, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause headache, dizziness, unconsciousness, difficulty breathing, low blood pressure, palpitations (awareness of your own heartbeat), an abnormally fast heart beat, heart rhythm disturbances, nausea and vomiting and may cause low levels of glucose and potassium in your blood. Please take this leaflet, any remaining tablets and the container with you to this hospital or doctor so that they know which tablets were consumed.

If you forget to take Carsem XL

If you miss a dose you should take the missed tablet as soon as you remember. However, if it is nearly time for your next dose then you should skip the missed dose and continue taking your tablets as per normal.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking Carsem XL

Keep taking your medicine according to your doctor's instructions. You should not stop taking your medicine without discussing it with your doctor first.

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.

Your medicine may make you feel dizzy and light headed, especially at the start of treatment or if you start treatment again after a break. Rarely this can result in loss of consciousness.

Stop taking doxazosin and seek emergency medical attention or notify your doctor straight away if one of the following serious side effects occurs:

- Swelling of the face, hands, lips, feet, tongue or throat, difficulty swallowing or breathing (allergic drug reaction)(this side effect is uncommon)
- Chest pain and/or shortness of breath (symptoms of a heart attack or angina pectoris) (this side effect is uncommon)
- Stroke (e.g. weakness or numbness down one side of the body)(this side effect is uncommon)
- Difficulty breathing caused by sudden constriction of the bronchi (bronchospasm) (this side effect is very rare)
- Obstruction to the normal flow of bile (cholestasis) which may cause jaundice (yellowing of the skin or whites of the eyes), inflammation of the liver (hepatitis) (this side effect is very rare)
- Persistent painful erection of the penis (priapism) (this side effect is very rare)

The following side effects have been reported at the approximate frequencies shown:

Common: may affect up to 1 in 10 people

- Rapid heart beat, feeling your heartbeat (palpitations)
- dizziness
- headache
- sleepiness
- Feeling of spinning or rotation of surroundings (vertigo)
- Respiratory problems (stuffy nose, cough, respiratory tract (throat , bronchi , lungs) infections)
- Stomach problems (sickness, stomach pain, dry mouth, upset stomach, indigestion)Urinary infections, urinary incontinence (inability to control passing urine)
- Itching
- Muscle pain, back pain
- Low blood pressure
- Postural hypotension (a form of low blood pressure that causes you to feel dizzy or light-headed when you stand up from sitting or lying down)
- Loss of strength
- Flu-like symptoms
- Swelling of the feet and ankles

Uncommon: may affect up to 1 in 100 people

- increased appetite or loss of appetite, weight gain
- Decreased sense of touch
- fainting
- nose bleeds,
- ringing in the ears,
- tremor (shaking)
- stomach problems (constipation, wind, inflammation of the stomach and intestines (gastroenteritis) which can cause diarrhoea and vomiting)
- urinary problems (pain or discomfort on passing urine, needing to pass urine more often than usual, blood in urine)
- skin rash
- painful joints
- gout
- failure/inability to achieve penile erection (impotence)
- unusual results from liver function tests (blood tests completed by your doctor to monitor the health of your liver)
- anxiety, depression, sleeplessness
- pain

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

- Redness of the face

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

- Disturbances of heart rhythm, slow heartbeat
- Changes to the blood including lower levels of white blood cells and platelets
- Feeling dizzy or light-headed when you stand up from sitting or lying down (dizziness postural)
- Sensation of tingling or numbness (paraesthesia)
- Blurred vision

- Disorder in passing urine, needing to pass urine at night, increased volume of urine passed, increase in the number of times of passing urine
- Loss of hair from the head or body
- Purpura (the appearance of red or purple discolorations on the skin that do not blanch on applying pressure)
- Nettle rash which can cover a lot of your body, hives (urticaria)
- Muscle cramps
- Muscle weakness
- Debility
- General feeling of being unwell
- Swelling of the face
- enlargement of the breasts in men
- Persistent painful erection of the penis. Seek urgent medical advice.
- Nervousness
- Agitation (excitement, restlessness)

Not known: frequency cannot be estimated from the available data

- Certain complications during cataract (cloudiness of the eye lens) operation (Intraoperative floppy iris syndrome, see also “Warnings and precautions”)
- Abnormal taste
- Ejaculation problems

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA

Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carsem XL

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 carton and blister after EXP. The expiry date refers to the last day of that month.

The 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 Carsem XL contains

- The active substance is doxazosin. Each prolonged-release tablet contains 4 mg doxazosin (as doxazosin mesilate).
- The other ingredients are: polyethylene oxide, microcrystalline cellulose, povidone, butylhydroxytoluene, α -tocopherol, colloidal anhydrous silica, sodium stearyl fumarate.
- The other ingredients in the tablet coating are: methacrylic acid – ethyl acrylate copolymer, colloidal anhydrous silica, macrogol, titanium dioxide (E171).

What Carsem XL looks like and contents of the pack

Carsem XL are white, round biconvex, film-coated, prolonged-release tablets with bossing “DL” on one side.

They are available in blister packs containing 14, 15, 28, 30, 50 x 1, 60, 90, 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark:	Myocard
Estonia:	Doxazosin Teva 4 mg
France:	DOXAZOSINE TEVA 4 mg, comprimé à libération prolongée
Ireland:	Carsem XL 4 mg Prolonged-release Tablets
Lithuania:	Doxazosin Teva 4 mg pailginto atpalaidavimo tabletės
Netherlands:	Doxazosine retard 4 mg PCH, tabletten met verlengde afgifte
United Kingdom:	Larbex XL 4mg Prolonged-Release Tablets

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