

# VIAZEM® XL

## Diltiazem Hydrochloride

### Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side-effects get serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

### In this leaflet:

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### 1. WHAT VIAZEM® XL IS AND WHAT IT IS USED FOR

The active ingredient in this medicine is called diltiazem. It belongs to a group of medicines called calcium antagonists which are used to treat high blood pressure, or to help control angina.

### 2. BEFORE YOU TAKE VIAZEM® XL

#### Do not take Viazem® XL:

- if you are allergic to diltiazem or any of the other ingredients in Viazem® XL (see list under 'What Viazem® XL contains'). Azorubine can cause allergic reactions including asthma. Allergy is more common in those people allergic to aspirin
- if you have serious heart problems, particularly if a doctor has told you that you have any of the following conditions;
  - Severe bradycardia (a very slow pulse)
  - Heart block or pre-excitation syndrome or sick sinus syndrome (conditions in which there are problems with the control of your heart rate)
  - Left ventricular failure
- if you are already taking a medicine containing invabradine for the treatment of certain heart diseases
- if you have unstable angina
- if the patient is a child
- if you are pregnant or are breast-feeding.

If you are not sure, talk to your doctor or pharmacist before taking this medicine.

#### Take special care with Viazem® XL:

- if you have suffered from any other heart problems
- if you have suffered a stroke
- if you have had liver or kidney problems
- if you suffer from Crohn's disease or ulcerative colitis.

If you are not sure, talk to your doctor or pharmacist.

#### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any medicines, including medicines obtained without a prescription, in particular any other drug that has been prescribed to treat your blood pressure or any heart condition that you have, such as digitoxin.

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

Diltiazem may inhibit the breakdown of certain medicines such as statins. This may lead to an increased and/or prolonged effect of these medicines including an increased number and severity of side-effects, such as muscle weakness and inflammation or liver infection.

#### Pregnancy and breast-feeding

You should not take this medicine if you are pregnant or are breast-feeding. Women of child-bearing potential should exclude the possibility of pregnancy before commencing treatment. If it is at all possible that you could become pregnant while taking this medicine you should use suitable contraception. You may wish to discuss this with your doctor.

Because diltiazem passes into breast milk, breast-feeding must be stopped while taking this medication.

#### Important information about some of the ingredients of Viazem® XL

The 120mg, 240mg and 300mg capsules contain azorubine (E122). Azorubine can cause allergic reactions including asthma. Allergy is more common in those people allergic to aspirin.

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 VIAZEM® XL

Always take Viazem® XL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Viazem® XL capsules have been specially designed so that you only have to take your capsules once a day. However, you must carry out the following steps to allow your medicine to work properly:

- You must take this medicine as prescribed by your doctor. Usually this will be one capsule to be taken at the same time each day, preferably just before or during a meal.
- You should swallow the whole capsule, preferably with a glass of water. Do not bite, chew or suck the capsule otherwise the medicine will not work properly.
- Do not stop taking this medicine before telling your doctor.

#### If you take more Viazem® XL than you should

Do not exceed the dose prescribed to you by your doctor. If you accidentally take more than the prescribed dose, seek

*Please read the back of this leaflet.*



medical advice immediately and take your medicine and this leaflet with you. Exceeding the correct dose may cause your blood pressure to become too low and you may feel drowsy, dizzy, tired and/or confused. You could also find that your heartbeats become irregular.

#### If you forget to take **Viazem® XL**

If you forget to take a dose, take it as soon as you remember then take the next one the following day, making sure that you leave at least a twelve hour period between the two. **Do not take a double dose to make up for a forgotten capsule.**

**Do not give **Viazem® XL** to children.**

#### 4. POSSIBLE SIDE-EFFECTS

Like all medicines, **Viazem® XL** can cause side-effects, although not everybody gets them.

Allergic skin rashes may range in severity from mild to itchy skin eruptions to a rarer serious condition called Stevens-Johnson syndrome, which may cause fever, chills, ulceration of the mouth, lips or skin.

If you experience symptoms suggestive of Stevens-Johnson syndrome, please consult your doctor or go to your nearest hospital casualty department immediately.

Although most people do not have any problems using this medicine, a number of side-effects may occasionally occur, including:

- leg or ankle swelling
- dizziness
- vomiting
- headache
- stomach upset
- constipation
- flushing
- diarrhoea
- skin rash
- tiredness
- nausea (a feeling of sickness)

#### Important information about your medicine

You may find what appears to be a capsule shell in the toilet. Do not be concerned, as this outer shell does not have to be digested by the body. It does not mean that your medicine is not working.

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

#### 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

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

#### 5. HOW TO STORE VIAZEM® XL

**Keep this medicine out of the sight and reach of children.**

Do not take **Viazem® XL** after the expiry date on the carton. The expiry date is printed on one of the cardboard carton flaps and on the foil blister pack. The expiry date refers to the last day of the month.

Do not store above 25°C.

Store in original package and in a dry place away from any heat source, e.g. direct sunlight, heaters, steam, etc.

Return all unused capsules to your pharmacist. Only keep them if your doctor tells you to. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### 6. FURTHER INFORMATION

##### What **Viazem® XL** contains

The active substance in **Viazem® XL** prolonged release capsules is diltiazem hydrochloride. The other ingredients are sucrose stearate, microcrystalline cellulose (E460), polyvidone, magnesium stearate, talc, methyl hydroxypropylcellulose, polysorbate 80, polyacrylate dispersion and simethicone emulsion. The gelatin capsules contain the following colouring agents: Lavender opaque contains the colourants azorubine (E122), indigotine (E132) and titanium dioxide (E171), white opaque consists of titanium dioxide (E171) and blue green opaque contains quinoline yellow (E104), indigotine (E132) and titanium dioxide (E171). The white printing ink used in your medicine contains shellac, ethyl alcohol, isopropyl alcohol, n-butyl, propylene glycol, sodium hydroxide, polyvinylpyrrolidone and titanium dioxide. The black printing ink contains shellac, ethyl alcohol, isopropyl alcohol, n-butyl, propylene glycol, ammonium hydroxide, potassium hydroxide and black iron oxide.

##### What **Viazem® XL** looks like and contents of the pack

**Viazem® XL** prolonged release capsules are available in five different strengths to help your doctor to prescribe the right amount of diltiazem to lower your blood pressure or control your angina; 120mg, 180mg, 240mg, 300mg and 360mg.

	<b>Capsule body</b>	<b>Capsule cap</b>
120mg capsule	Lavender opaque	Lavender opaque
180mg capsule	White opaque	Blue green opaque
240mg capsule	Blue green opaque	Lavender opaque
300mg capsule	White opaque	Lavender opaque
360mg capsule	Blue green opaque	Blue green opaque

Each pack contains 28 capsules.

**POM**

<b>PL 00240/0375</b>	<b>Viazem® XL 120mg Capsules</b>
<b>PL 00240/0376</b>	<b>Viazem® XL 180mg Capsules</b>
<b>PL 00240/0377</b>	<b>Viazem® XL 240mg Capsules</b>
<b>PL 00240/0378</b>	<b>Viazem® XL 300mg Capsules</b>
<b>PL 00240/0379</b>	<b>Viazem® XL 360mg Capsules</b>

##### Marketing Authorisation Holder:

Thornton & Ross Ltd., Linthwaite, Huddersfield, HD7 5QH, UK.

##### Manufacturer:

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