

Package leaflet: Information for the user

Zemtard 120XL 120mg Prolonged-release Capsules
Zemtard 180XL 180mg Prolonged-release Capsules
Zemtard 240XL 240mg Prolonged-release Capsules
Zemtard 300XL 300mg Prolonged-release Capsules
(Diltiazem Hydrochloride)

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, pharmacist or nurse.
- 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 Zemtard is and what it is used for
2. What you need to know before you take Zemtard
3. How to take Zemtard
4. Possible side effects
5. How to store Zemtard
6. Contents of the pack and other information

1. What Zemtard is and what it is used for

Zemtard contains diltiazem hydrochloride as the active substance. Diltiazem hydrochloride belongs to a group of medicines known as calcium channel blockers.

Zemtard is used to treat high blood pressure (hypertension) in adults. It can also be used to prevent and treat a certain type of chest pain known as angina. Zemtard works by opening up blood vessels so that blood passes through them more easily, and so reduces blood pressure and chest pain in angina.

2. What you need to know before you take Zemtard

Do not take Zemtard

- if you are allergic to diltiazem hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant or could become pregnant
- if you are breast-feeding
- if you have a very slow heart rate, less than 40 beats per minute (severe bradycardia)
- if you have a condition called sick sinus syndrome (an abnormality of heart rate or heart rhythm) or if you suffer from second or third degree heart block (this is a

problem with the electrical impulses of the heart), unless you have a working pacemaker fitted

- if you suffer from left-sided heart failure (left ventricular failure), with symptoms such as shortness of breath and swelling of the ankles
- if you are due to have an operation where you might be given a muscle relaxant called dantrolene (most likely to be administered in hospital under general anaesthesia)
- if you are already taking a medicine containing ivabradine for the treatment of certain heart diseases

Talk to your doctor before taking this product if any of the above apply to you.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Zemtard:

- if you have any liver or kidney problems
- if you are an elderly patient
- if you have a slow heart rate (bradycardia)
- if you have any heart problems such as heart failure or first degree heart block (a problem with the electrical impulses of the heart)
- if you experience mood changes, including depression
- if you are at risk of developing a blockage of the bowel.

If any of the above apply to you, it is important that you tell your doctor, pharmacist or nurse before taking Zemtard and they will decide what to do. It may still be safe for you to take Zemtard.

- prior to general anaesthesia; if you know that you are going to have a general anaesthetic please tell your anaesthetist that you are taking Zemtard.

Children

Zemtard is not suitable for use in children.

Other medicines and Zemtard

You must tell your doctor or pharmacist if you are being treated with dantrolene or ivabradine because you should not take Zemtard (see section 2 'Do not take Zemtard...').

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

In particular, you should inform your doctor or pharmacist if you are taking any of the following medicines:

- alpha-blockers, such as doxazosin or prazosin (medicines used for high blood pressure or prostate enlargement in men)
- amiodarone and other 'antiarrhythmic' medicines (used to treat abnormal heart rhythms)
- rifampicin (used to treat bacterial infections)
- carbamazepine, phenytoin or primidone (used in epilepsy)
- atazanavir or ritonavir (used to treat HIV infection)

- sleeping tablets or sedatives, including midazolam or triazolam which belong to a group of medicines called benzodiazepines, and barbiturates (which can also be used to treat epilepsy)
- other calcium channel blockers (such as nifedipine) and other medicines used to treat high blood pressure
- beta-blockers, such as propranolol or atenolol (medicines used to treat high blood pressure or other heart conditions)
- digoxin (used to treat heart failure and abnormal heart rhythms)
- ciclosporin, sirolimus, tacrolimus or everolimus (used to prevent rejection of a transplanted organ or for the treatment of other immune system disorders)
- cilostazol (used to improve blood circulation to the legs)
- theophylline (used to treat breathing problems)
- general anaesthetics
- tricyclic antidepressants, such as imipramine
- antidepressants known as monoamine oxidase inhibitors/MAOIs, such as moclobemide or phenelzine
- itraconazole (used to treat fungal infections)
- mefloquine (used for treating and preventing malaria)
- corticosteroids, sometimes simply referred to as steroids, such as hydrocortisone, prednisolone or methylprednisolone (they may be prescribed in many different illnesses but their main action is in controlling inflammation)
- simvastatin, atorvastatin or lovastatin (medicines for lowering cholesterol)
- lithium (used in cases of marked mood changes or mania)
- nitrate medicines, such as glyceryl trinitrate or isosorbide mononitrate (used to treat angina)
- ulcer-healing medicines, such as cimetidine and ranitidine

It may still be safe for you to take Zemtard; your doctor or pharmacist will be able to advise you further.

Zemtard with food and drink

Taking Zemtard with food and drink does not affect the way the product works.

Pregnancy, breast-feeding and fertility

Do not take Zemtard if you are pregnant, trying to become pregnant or if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or while breast-feeding.

Driving and using machines

It is safe to drive while taking this medicine, however it may make you feel faint or dizzy. If you find that you are affected you should not drive or operate machinery.

Zemtard contains sucrose

These capsules contain sucrose. 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 Zemtard

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

The recommended dose for adults is between 180mg and 300mg of diltiazem given once a day. This dose may be reduced to 120mg once a day, for elderly patients, or patients with kidney or liver disease.

The label on the carton will tell you how many capsules you should take and when. This product should be taken orally (by mouth). Swallow the capsules whole with a drink of water. Do not crush or chew the capsules.

If you take more Zemtard than you should

If you take too many capsules, contact your nearest hospital casualty department or doctor immediately. Take this leaflet and any remaining capsules with you to show the doctor.

If you forget to take Zemtard

If you miss a dose but remember within 12 hours of the usual time, take it when you remember. If you remember more than 12 hours after your usual time, leave out this dose completely and carry on with the next dose when it is due. Do not take a double dose to make up for a forgotten dose.

If you stop taking Zemtard

Do not stop taking Zemtard without consulting your doctor. Stopping suddenly might make your angina worse.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects, stop taking Zemtard and contact your doctor immediately:

- Slowing of the heart rate (bradycardia)
- Irregular heart rate
- Severe skin rash or itching especially those covering your whole body, severe flaking, blistering or peeling of the skin, with or without a fever
- Signs of an allergic reaction, such as a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

Very common side effects (may affect more than 1 in 10 people)

- Swelling of the hands, ankles or feet

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

- Headache
- Dizziness
- Irregular heart rate
- Flushing (when your face, ears, neck and, occasionally, your upper chest, becomes red in colour) or redness of the skin
- Constipation, indigestion, stomach pain, feeling sick (nausea)
- Feeling generally unwell

Uncommon side effects (may affect up to 1 in 100 people)

- Nervousness
- Difficulty sleeping
- Feeling dizzy, light-headed or faint when you stand or sit up quickly (low blood pressure)
- Loss of appetite, being sick (vomiting), diarrhoea, changes in the way things taste, weight gain
- A worsening of liver function tests (seen on a blood test)

Rare side effects (may affect up to 1 in 1000 people)

- Dry mouth
- Hives

Other side effects have also been reported, but their exact frequency is unknown:

- A reduction in platelets in the blood, which increases the risk of bleeding or bruising (thrombocytopenia)
- Changes in mood, including depression
- Unusual movements of the tongue, muscle spasms in the face, rolling eyes or trembling
- Heart failure
- Inflammation of blood vessels, often with a skin rash
- Swollen gums
- Hepatitis (inflammation of the liver)
- Increased sensitivity to sunlight. You may get sunburnt more easily and more severely than someone not taking Zemtard. You should use sun protection while taking this medicine
- Skin rash
- Sweating
- Enlargement of breast tissue in men
- Tiredness/weakness.

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 website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the 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 Zemtard

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 foil. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package in order to protect from light and moisture.

Do not use this medicine if you notice that the packaging or any of the capsules are damaged.

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 Zemtard contains

The active substance is diltiazem hydrochloride.

Zemtard comes in four different strengths of capsule:

- Zemtard 120XL which contains 120mg of diltiazem hydrochloride per capsule.
- Zemtard 180XL which contains 180mg of diltiazem hydrochloride per capsule.
- Zemtard 240XL which contains 240mg of diltiazem hydrochloride per capsule.
- Zemtard 300XL which contains 300mg of diltiazem hydrochloride per capsule.

The beads in the capsule shells also contain other ingredients: ammonio methacrylate copolymer types A and B, paraffin, talc, sucrose and starch.

The capsule shells are made of gelatin and may contain, depending on the strength of the capsule, the following colouring agents: erythrosine (E127), indigotine (E132), titanium dioxide (E171), red iron oxide (E172), black iron oxide (E172) and yellow iron oxide (E172).

The ink on the capsule shells contains shellac, black iron oxide (E172) and propylene glycol.

What Zemtard looks like and contents of the pack

- Zemtard 120XL are hard gelatin capsules, with a brownish-red cap and an orange body, with “DIL 120” overprinted in black ink.
- Zemtard 180XL are hard gelatin capsules, with a pink cap and a grey body, with “DIL 180” overprinted in black ink.

- Zemtard 240XL are hard gelatin capsules, with a light blue cap and body, with “DIL 240” overprinted in black ink.
- Zemtard 300XL are hard gelatin capsules, with a light blue cap and a white body, with “DIL 300” overprinted in black ink.

Zemtard 120XL, 180XL, 240XL and 300XL are packaged in blister packs containing 28, 30, 56, 60 or 100 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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