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

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, or if you are breast-feeding or planning to breast-feed (see section: 'Pregnancy, breast-feeding and fertility')
- 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) and problems with blood flow to your lungs, 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
- if you are already taking a medicine containing lomitapide used for the treatment of high cholesterol levels (see section: 'Other medicines and Zemtard')

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 history of heart failure or first degree heart block (a problem with the electrical impulses of the heart), new shortness of breath, slow heartbeat or low blood pressure. As cases of kidney injury in patients with such conditions have been reported, your doctor may need to monitor your kidney function.
- if you experience (or are at risk of) mood changes, including depression
- if you are at risk of gut problems
- if you have diabetes
- if you have or ever had asthma
- if you take any beta-blocker medicines

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
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Zemtard can affect the way some other medicines work. Also, some medicines can affect the way Zemtard works.

In particular, you should inform your doctor or pharmacist if you are taking any of the following medicines because you should not take Zemtard (see section: 'Do not take Zemtard'):
- dantrolene (an infusion) used for severe muscle spasms or severe fever (called 'malignant hyperthermia')
- ivabradine used for the treatment of certain heart diseases

- medicines containing lomitapide used for the treatment of high cholesterol levels. Diltiazem may increase the concentration of the lomitapide that may lead to an increase in the likelihood and severity of liver related side effects.

Zemtard may increase the effect of the following medicines:
- alpha-blockers, such as doxazosin, tamsulosin, or prazosin (medicines used for high blood pressure or prostate enlargement in men)
- amiodarone and other 'antiarrhythmic' medicines (used to treat abnormal heart rhythms)
- carbamazepine or phenytoin (used in epilepsy)
- sleeping tablets or sedatives, including midazolam or triazolam which belong to a group of medicines called benzodiazepines (can also be used to treat anxiety)
- 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)
- 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 fluvastatin (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)
- iodinated contrast media (used for tests involving X-rays)
- antiplatelet medicines, such as aspirin or clopidogrel (used to reduce the chance of blood clots forming)

The following medicines can decrease the effect of Zemtard:
- rifampicin (used to treat bacterial infections)
- barbiturates (which can also be used to treat epilepsy)

The following medicines can increase the effect of Zemtard:
- ulcer-healing medicines, such as cimetidine and ranitidine
- atazanavir or ritonavir (used to treat HIV infection)

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
It is advisable to limit the amount of grapefruit juice you drink while taking Zemtard as it can increase the blood levels of the active ingredient diltiazem and may increase

your chance of getting side effects. If you are concerned you should stop drinking grapefruit juice and consult your doctor.

Pregnancy, breast-feeding and fertility
Do not take Zemtard if you are pregnant, trying to become pregnant or if you think you may be pregnant. This is because Zemtard can cause problems for your baby. Do not take Zemtard if you are breast-feeding or planning to breast-feed as small amounts may pass into mothers' milk. Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or while breast-feeding.

Driving and using machines
Zemtard 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. Take before or during a meal. If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

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. The following effects may happen: feeling dizzy or weak, blurred vision, chest pain, shortness of breath, fainting, an unusually fast or slow heartbeat, slurred speech, confusion, decrease of kidney function, coma, and sudden death.

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.

Tests
Your doctor may do regular tests while you are taking this medicine. These might include a check on your heart and blood tests to check on your liver and kidneys.

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
- Signs of an allergic reaction, such as a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- Blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be an illness called 'Stevens-Johnson syndrome'.
- A severe blistering rash in which layers of the skin may peel off to leave large areas of raw exposed skin over the body. You may feel generally unwell and have a fever, chills and aching muscles. This could be an illness called 'Toxic Epidermal Necrolysis'.
- A skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. This could be signs of a serious allergy to the medicine called 'erythema multiforme'.
- Your asthma gets worse
- You have difficulty breathing, wheezing, tightness in the chest (bronchospasm)

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
- Very fast, irregular or forceful heart rate (palpitations)
- Flushing (when your face, ears, neck and, occasionally, your upper chest, becomes red in colour)
- 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 (anorexia), 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
- Itchy, lumpy rash (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. Signs may include being short of breath, feeling tired along with swollen ankles and legs.
- Cardiac arrest
- Inflammation of blood vessels, often with a skin rash (vasculitis)
- Swollen gums
- Hyperglycaemia (high blood sugar). Signs may include passing large amounts of urine, excessive thirst and having a dry mouth or skin.
- Hepatitis (inflammation of the liver). Signs may include high temperature, feeling tired, loss of appetite, stomach pain and feeling sick.
- 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
- A condition in which the body's defence system attacks normal tissue causing symptoms such as swollen joints, tiredness and rashes (called 'lupus-like syndrome')
- 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^{o}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
Galen Limited
Seagoe Industrial Estate
Craigavon
BT63 5UA
UK

Manufacturer
Almac Pharma Services Limited
Almac House
20 Seagoe Industrial Estate
Craigavon
BT63 5QD
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