Pharmacode position

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PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

# Zemret 180 XL, 240 XL and 300 XL

Capsules

**Diltiazem hydrochloride (modified-release capsules)**

**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 side effects not listed in this leaflet, See section 4.

**What is in this leaflet:**



## 1. What Zemret XL is and what it is used for

Zemret XL contains a medicine called diltiazem hydrochloride. It belongs to a group of medicines called calcium channel blockers. It works by making your blood vessels wider. This helps to lower your blood pressure. It also makes it easier for your heart to pump blood around the body. This helps to prevent the chest pain caused by angina.

Zemret XL is used to treat:
- High blood pressure
- Chest pain (angina)

## 2. What you need to know before you take Zemret XL

**Do not take Zemret XL:**
- If you are allergic to diltiazem hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- If you have heart problems, such as:
  - o dizziness, fainting, chest pain, light-headedness or shortness of breath, unless you have a pacemaker (second or third degree heart block)
  - o dizziness, fainting, confusion, palpitations, shortness of breath or tiredness, unless you have a pacemaker (sick sinus syndrome)
  - o shortness of breath, excessive sweating, anxiety and pale skin (left ventricular failure with lung congestion)
  - o very slow heartbeat - less than 50 beats per minute (severe bradycardia)
- If you are already taking lomitapide used for the treatment of high cholesterol levels (see "Other medicines and Zemret XL" section)
- If you are already taking ivabradine for the treatment of certain heart diseases (see "Other medicines and Zemret XL" section)
- If you are already taking asunaprevir used for the treatment of hepatitis C virus infection (see "Other medicines and Zemret XL" section)
- If you are breast-feeding or planning to breast-feed (see "Pregnancy and breast-feeding" section)
- If you are being treated with dantrolene injection (for severe muscle spasms or severe fever) (see "Other medicines and Zemret XL" section)

**Warnings and precautions**

Talk to your doctor or pharmacist before taking this medicine:
- If you have a history of heart failure, 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 have any other heart problem (apart from angina or those described above)
- If you are going to have an operation and will have anaesthesia
- If you are at risk of mood changes, including depression
- If you are at risk of gut problems
- You are taking blood thinners such as direct-acting oral anti-coagulants (e.g. dabigatran, rivaroxaban, apixaban)

Your doctor will check you more closely, particularly when you first start taking the capsules:
- If you are elderly (over 65 years old)
- If you have liver or kidney problems
- If you have diabetes
- If you have or ever had asthma
- You take any beta blocker medicines

**Other medicines and Zemret XL**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Zemret XL **should not be taken** with the following:
- Dantrolene infusion, used to relieve severe muscle spasm or severe fever (called malignant hyperthermia) for conditions such as cerebral palsy, multiple sclerosis or spinal cord injury
- Ivabradine, used for the management of stable heart-related chest pain and heart failure
- 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.
- Asunaprevir used for the treatment of hepatitis C virus infection. Diltiazem may increase the concentration of the asunaprevir that may lead to an increase in the likelihood and severity of liver related side effects

Other medicines which **may interact** with or be affected by Zemret XL:
- Lithium, used to treat depression or mania
- Medicines for chest pain (angina) such as glyceryl trinitrate or isosorbide trinitrate (nitrates)
- Medicines known for prolonging the QT interval
- Rifampicin, an antibiotic used to treat various infections, in particular tuberculosis
- Carbamazepine, phenytoin, used to treat epilepsy
- Iodinated contrast media (used for tests involving X-rays)
- Ciclosporin, used to prevent rejection of an organ following a transplant
- Antiplatelet medicines used to reduce the chance of blood clots forming, such as aspirin or clopidogrel
- Blood thinners such as direct-acting oral anti-coagulants (e.g. dabigatran, rivaroxaban, apixaban)
- Theophylline, used to treat bronchial asthma
- Medicines used for the treatment of irregular heartbeat (e.g amiodarone) or heart failure (e.g. digoxin)
- Medicines used to treat stomach ulcers (e.g. cimetidine and ranitidine)
- Medicines used to treat high blood pressure such as doxazosin, tamsulosin, atenolol, propranolol or acebutolol
- Midazolam, triazolam, used to induce sleepiness or drowsiness before an operation, during minor surgery or as a premedication
- Methylprednisolone (corticosteroid), used to treat inflammation
- Statins, used to treat high cholesterol e.g. atorvastatin, fluvastatin or simvastatin
- Cilostazol, used to treat intermittent cramp-like leg pain when walking caused by insufficient blood supply
- Colchicine, used to treat gout

<u>Tests</u>

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.

**Zemret XL with food and drink**

It is advisable to limit the amount of grapefruit juice you drink while taking Zemret XL 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 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 for advice before taking this medicine.

**Pregnancy**

You should not take this medicine if you are pregnant, might become pregnant or think you may be pregnant. Zemret XL can cause problems for your baby. Talk to your doctor if you think you might be pregnant.

**Breast-feeding**
- Do not breast-feed if you are taking Zemret XL as small amounts of diltiazem may pass into breast milk
- If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking this medicine

**Driving and using machines**

You may feel feeling dizzy while taking this medicine. If affected, you should not drive or operate machinery.

**Zemret XL contains sucrose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## 3. How to take Zemret 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 comes in a modified-release hard gelatin capsule which means the medicine is released over a longer period of time.
- These capsules are to be taken orally, before or during a meal
- You should swallow the capsule whole, with a little water
- Do not crush or chew the capsules
- You may notice remains of the medication (the capsule shell) in your stools. This has no clinical relevance as your body has already absorbed the medicine.

**The recommended dose is:**
**Adults**
The usual starting dose is one Zemret XL 180 mg capsule a day.

If necessary, your doctor may increase your dose up to:
- One Zemret XL 300 mg capsule a day **or**
- Two Zemret XL 180 mg capsules a day.
- One Zemret XL 300 mg capsule and one 180 mg capsule a day.

**Elderly or patients with liver or kidney problems**
**Angina and high blood pressure:**
The recommended starting dose is one Zemret XL 180 mg capsule a day.

If necessary, your doctor may increase this dose to one Zemret XL 300 mg capsule a day.

**Use in children**
This medicine is **not** recommended for use in children.

**If you take more Zemret XL than you should**
If you accidentally take too many capsules, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining capsules with you.
**Symptoms of overdose include:** 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. Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.
If, in an emergency situation, the patient is not treated quickly sudden death is not the only potential outcome.

**If you forget to take Zemret XL**
Take it as soon as you remember unless it is nearly time for your next dose. If you miss a dose, **do not** take a double dose to make up for a forgotten dose.

**If you stop taking Zemret XL**
It is important that you keep taking Zemret XL for as long as your doctor has told you to.

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.

**Seek medical advice immediately if you develop the following symptoms:**
- Allergic reactions: swelling of the face, throat or tongue, fever, difficulty in breathing, dizziness
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioneurotic oedema)
- Difficulty breathing or wheezing (bronchospasm, aggravation of asthma)
- Severe blistering of the skin, mouth, eyes and genitals (Stevens-Johnson Syndrome) or severe blistering of the skin (toxic epidermal necrolysis)
- Abnormal heart rhythm where the heart beats too slowly (AV block, sinoatrial block, congestive heart failure) or stops beating (sinus arrest, cardiac arrest)

Other possible side effects
**Very common side effect** (may affect more than 1 in 10 people)
- Swelling of the calves, ankles or feet

**Common side effects** (may affect up to 1 in 10 people)
- Headache
- Dizziness
- Feeling your heartbeat (palpitations)
- Flushing of the skin
- Indigestion, stomach pain, feeling sick, constipation
- Generally feeling unwell
- Skin rashes (erythema)

**Uncommon side effects** (may affect up to 1 in 100 people)
- Nervousness
- Difficulty sleeping
- Being sick
- Diarrhoea
- Slower heartbeat
- Low blood pressure causing dizziness or lightheadedness after a change in position i.e. when standing up from a lying or sitting position
- Increase in liver enzymes (detected through a blood test)

**Rare side effects** (may affect up to 1 in 1,000 people)
- Dry mouth
- Skin rash rashes with the formation of wheals (urticaria)

**Not known** (frequency cannot be estimated from the available data)
- Reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- Mood changes including depression
- Medicine-induced movement disorders (Extrapyramidal Syndrome)
- Inflammation of blood vessels (vasculitis)
- Swollen gums
- Increased blood sugar levels (hyperglycaemia)
- Inflammation of the liver (hepatitis)
- Increased sensitivity of the skin to sunlight (photosensitivity)
- Peeling of the skin over large areas of the body (exfoliative dermatitis)
- Small raised bumps on the skin that fill with fluid or pus caused by a hypersensitivity (allergy) to medicine (Acute Generalised Exanthematous Pustulosis (AGEP))
- Rash, scaling of the skin (with or without fever)
- Sweating
- Excessive development of the male breast
- 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')
- Rash that may occur on the skin or sores in the mouth (lichenoid drug eruption).

**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 at: 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 Zemret 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/blister after 'EXP'. The expiry date refers to the last day of that month.
- Store in a dry place below 25°C. Store in the original package in order to protect from light.
- 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 to protect the environment.

## 6. Contents of the pack and other information

**What Zemret XL contains**
- Each Zemret 180 XL modified-release capsule contains 180 mg of active substance diltiazem hydrochloride.
- Each Zemret 240 XL modified-release capsule contains 240 mg of active substance diltiazem hydrochloride.
- Each Zemret 300 XL modified-release capsule contains 300 mg of active substance diltiazem hydrochloride.

**The other ingredients are:** acetone, ammonio methacrylate copolymer (Types A and B), gelatin, methylene chloride, paraffin, sugar spheres (**sucrose** and starch), talc and titanium dioxide (E171),
**Zemret 180 XL** also contains: erythrosine (E127), black and red iron oxides (E172).
**Zemret 240 & 300 XL** also contains: indigotine (E132).

**What Zemret XL looks like and contents of the pack**
- Zemret 180 XL: opaque grey body, pink cap, marked 180, containing white and whitish pellets
- Zemret 240 XL: light blue body and cap, marked 240, containing white and whitish pellets
- Zemret 300 XL: white body, light blue cap, marked 300, containing white and whitish pellets

The capsules are available in blister packs containing 28, 30, 56, 60 or 100 capsules.

Not all pack sizes may be marketed.

**Product Licence Numbers:**
- Zemret 180 XL capsules - PL 11311/0449
- Zemret 240 XL capsules - PL 11311/0450
- Zemret 300 XL capsules - PL 11311/0451

**Marketing Authorisation Holder and Manufacturer:**
Tillomed Laboratories Limited
220 Butterfield, Great Marlings
Luton, LU2 8DL, United Kingdom

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Till-Ver.14.2

Production code

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|---|---|---|---|---|---|
| **Product Name** | Zemret [Diltiazem HCl] | **Sap code :** | TBA/Till-Ver.14.2 | **Reference Artwork** | TW149109 (SmPC) * |
| **Packaging Material** | Package leaflet | **Reason of change :** | TW197973 (SmPC) | Proof 1 | 31/07/2025 |
| **Size :** Foil Width | | **Country :** | UK | Proof 2 | 31/07/2025 |
| **Size :** Foil Repeat Length | | **Pack Size :** | All | Proof 3 | 16/01/2026 |
| **Size :** Strip Size | | **Barcode No. :** | NA | | |
| **Size :** PI - Open Size | 175 mm (w) x 380 mm (L) | **Pharmacode :** | TBA | | |
| **Size :** Carton/Label | | **No. of colours :** | **1** | | |
| **PM Style/Type :** | | **Min. Font Size :** | 9 points (Reg text) | | |
| **Remark (If any) :** | * and TW163719 (design) | | | | |

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