

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Tildiem® LA 300mg Prolonged Release Capsules**  
(diltiazem hydrochloride)

Your medicine is known as the above but will be referred to as Tildiem LA throughout the remainder of this leaflet.

This product is available in another strength and all strengths will be referred to throughout this leaflet.

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

**What is in this leaflet:**

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

**1. What Tildiem LA is and what it is used for**

Tildiem LA contains a medicine called diltiazem hydrochloride. This 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.

**Tildiem LA is used for:**

- High blood pressure
- Angina (chest pain)

**2. What you need to know before you take Tildiem LA**

**Do not take Tildiem LA if:**

- x You are allergic (hypersensitive) to diltiazem hydrochloride or any of the other ingredients of Tildiem LA (listed in Section 6 below)  
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- x You are breast-feeding or planning to breast-feed (see below: 'Pregnancy and breast-feeding').
- x You are having a medicine called dantrolene used for severe muscle spasms or severe fever (see below: 'Other medicines and Tildiem LA')
- x You have a very slow heartbeat - less than 50 beats per minute
- x You are already taking a medicine containing ivabradine for the treatment of certain heart diseases
- x You have heart failure and problems with blood flow to your lungs. With these illnesses, you may feel out of breath and have swollen ankles
- x You have any other serious problems with your heart. This includes having an uneven heartbeat (unless you have a pacemaker)
- x You are already taking a medicine containing lomitapide used for the treatment of high cholesterol levels (see section: 'Other medicines and Tildiem LA').
- x You are already taking a medicine containing asunaprevir used for the treatment of hepatitis C virus infection (see section: 'Other medicines and Tildiem LA').

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Tildiem LA.

**Warning and precautions**

Talk to your doctor or pharmacist before taking Tildiem LA 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.
- ▲ You have any other problem with your heart, apart from angina or those described in the previous section.
- ▲ You are going to have an operation.
- ▲ You are at risk of mood changes, including depression.
- ▲ You are at risk of gut problems.

Your doctor will check you more closely particularly when you first start taking Tildiem LA if:

- ▲ You are over 65 years old.
- ▲ You have liver or kidney problems.
- ▲ You have diabetes.
- ▲ You have or ever had asthma.
- ▲ You take any beta blocker medicines.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Tildiem LA.

**Other medicines and Tildiem LA**

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 Tildiem LA can affect the way some other medicines work. Also some medicines can affect the way Tildiem LA works.

**In particular, do not take this medicine and tell your doctor if you are taking:**

- Dantrolene (an infusion) used for severe muscle spasms or severe fever (called 'malignant hyperthermia').
- Medicines containing 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.

- Medicines containing 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.

**Tildiem LA may increase the effect of the following medicines:**

- Medicines for high blood pressure such as doxazosin, tamsulosin, atenolol, propranolol or acebutolol.
- Medicines used for an uneven heartbeat such as amiodarone and digoxin.
- Medicines used for angina such as glyceryl trinitrate or isosorbide trinitrate.
- Medicines used for high levels of cholesterol such as simvastatin, fluvastatin and atorvastatin.
- Ciclosporin used to stop the rejection of organs after a transplant.
- Phenytoin and carbamazepine used for epilepsy.
- Antiplatelet medicines used to reduce the chance of blood clots forming, such as aspirin or clopidogrel.
- Iodinated contrast media (used for tests involving X-rays).
- Theophylline used for breathing problems.
- Lithium used for some types of mental illness.
- Medicines used for sleeplessness and anxiety, such as triazolam or midazolam.
- Methylprednisolone used for inflammation.
- Cilostazol used for intermittent cramp-like pain in your legs when you walk caused by insufficient blood supply in your legs.

**Tildiem LA may make the following medicine work less well:**

- Rifampicin used for tuberculosis.

**The following medicines can increase the effect of Tildiem LA:**

- Medicines for stomach ulcers such as cimetidine and ranitidine.

**Tildiem LA with food and drink**

It is advisable to limit the amount of grapefruit juice you drink while taking Tildiem LA 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**

- You should not take Tildiem LA if you are pregnant, might become pregnant or think you may be pregnant. This is because Tildiem LA can cause problems for your baby. Talk to your doctor if you might be pregnant.
- Do not breast-feed if you are taking Tildiem LA. This is because small amounts may pass into mothers' milk. If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.

**Tildiem LA contains**

Sodium: This medicine contains less than 1 mmol sodium (23mg) per daily dose, that is to say essentially "sodium free".

**Driving and using machines**

You may feel dizzy while taking this medicine. If this happens, do not drive or use any tools or machines.

**3. How to take Tildiem LA**

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

Please find below a translation of the days of the week printed on the blister.

ΔΕΥ	ΤΠΙ	ΤΕΤ	ΠΕΜ	ΠΑΡ	ΣΑΒ	ΚΥΡ
MON	TUE	WED	THUR	FRI	SAT	SUN

**Taking this medicine**

- Take this medicine by mouth.
- Do not break, crush or chew your capsules.
- Swallow the capsules whole with a drink of water.
- 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.

**How much to take**

**Adults:**

**Angina and high blood pressure:**

- The usual starting dose is one Tildiem LA 200mg capsule a day.

**If necessary, your doctor may increase this to:**

- One Tildiem LA 300mg capsule a day or
- Two Tildiem LA 200mg capsules a day.
- One Tildiem LA 300mg capsule and one Tildiem LA 200mg capsule a day.

**Over 65 years or adults with liver or kidney problems:**

**Angina and high blood pressure:**

- The usual starting dose is one Tildiem LA 200mg capsule a day.

**If necessary, your doctor may increase this dose to:**

- One Tildiem LA 300mg capsule a day.

**Children and adolescents**

Tildiem LA should not be given to children.

**If you take more Tildiem LA than you should**

If you take more capsules than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. 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 take more Tildiem LA than you should contact your doctor or nearest hospital straight away:

- Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.