PACKAGE LEAFLET:
INFORMATION FOR THE USER

Tildiem LA 200mg and 300mg Prolonged Release Capsules, Hard

Diltiazem hydrochloride

sanofi

Is this leaflet hard to see or read? Phone 0800 035 2525 for help

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:

× You are allergic (hypersensitive) to diltiazem hydrochloride or any of the other ingredients of Tildiem LA (listed in section 6).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

× You are breast-feeding or planning to breast-feed (see below: 'Pregnancy and breast-feeding').

× You are having a medicine called dantrolene used for severe muscle spasms or severe fever (see below: 'Other medicines and Tildiem LA').

× You have a very slow heartbeat – less than 50 beats per minute

× You are already taking a medicine containing ivabradine for the treatment of certain heart diseases.

× 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.

× You have any other serious problems with your heart. This includes having an uneven heartbeat (unless you have a pacemaker).

× You are already taking a medicine containing lomitapide used for the treatment of high cholesterol levels (see section: 'Other medicines and Tildiem LA').

× 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.

Warnings 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.

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▲ 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 (23 mg) 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.

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.

If, in an emergency situation, the patient is not treated quickly sudden death is not the only potential outcome.

If you forget to take Tildiem LA

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Tildiem LA

Keep taking Tildiem LA until your doctor tells you to stop. Do not stop taking them just because you feel better. If you stop, your illness may get 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Tildiem LA can cause side effects although not everyone gets them.

Stop taking and see a doctor or go to a hospital straight away if:
Frequency unknown (cannot be estimated from the available data)

- You have an **allergic reaction.** The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have a red or lumpy skin rash, swollen eyelids, face, lips, throat, or tongue, difficulty in swallowing.
- Your asthma gets worse.
- You have difficulty breathing, wheezing, tightness in the chest (called 'bronchospasm').
- You get 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'.
- You get 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'.
- You have 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. These could be signs of a serious allergy to the medicine called 'erythema multiforme'.

Tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

Common (affects less than 1 in 10 people)

- Slow or uneven heartbeat
- Very fast, uneven or forceful heartbeat (palpitations)

Frequency unknown (cannot be estimated from the available data)

- Skin rash caused by narrow or blocked blood vessels (called 'vasculitis')
- Being short of breath, feeling tired along with swollen ankles and legs. This could be signs of heart failure.
- Unusual movements of the tongue, muscle spasms in your face, rolling eyes and trembling
- High temperature, feeling tired, loss of appetite, stomach pain, feeling sick. These can be signs of inflammation of the liver (called 'hepatitis').
- Passing large amounts of urine, excessive thirst and having a dry mouth or skin. These may be signs of high blood sugar (hyperglycaemia).
- Get sunburnt easier, and which may be more severe than in someone not taking Tildiem LA. You should use sun protection whilst taking this medicine.
- Breast enlargement in men

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Tell your doctor as soon as possible if you have any of the following side effects:
Very common (affects more than 1 in 10 people)
- Swelling of the lower legs

Common (affects less than 1 in 10 people)
- Indigestion, stomach pain, constipation, and diarrhoea

Uncommon (affects less than 1 in 100 people)
- Feeling dizzy, light-headed or faint when you stand or sit up quickly (low blood pressure)

Rare (affects less than 1 in 1000 people)
- Dry mouth
- Itchy, lumpy rash (called 'urticaria')

Frequency unknown (cannot be estimated from the available data)
- Swollen gums

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:
Common (affects less than 1 in 10 people)
- Headache
- Flushing (feeling of warmth)
- Feeling sick (nausea) or being sick (vomiting)
- General feeling of being unwell
- Weakness or tiredness
- Feeling dizzy
- Skin redness

Uncommon (affects less than 1 in 100 people)
- Difficulty sleeping

Frequency unknown (cannot be estimated from the available data)
- Mood changes, including depression
- Bleeding or bruising under the skin
- 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)

Blood tests
Tildiem LA can change the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly.

Reporting of side effects
If you get any side effects, talk to your doctor, 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 Tildiem LA

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 after 'EXP'. The expiry date refers to the last day of that month.
Store below 25°C in the original packaging.
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 Tildiem LA contains
- Each Tildiem LA 200mg capsule contains 200mg of the active substance diltiazem hydrochloride. Each Tildiem LA 300mg capsule contains 300mg of the active substance diltiazem hydrochloride.
- The other ingredients are microcrystalline cellulose, carmellose sodium, acrylic and methacrylic esters copolymer, ethylcellulose, diacetylated monoglycerides, magnesium stearate, gelatin, and titanium dioxide (E171).

Tildiem LA 200mg capsules also contains red iron oxide (E172) and black iron oxide (E172).
Tildiem LA 300mg capsules also contains yellow iron oxide (E172).

What Tildiem LA look like and contents of the pack
Tildiem LA 200mg capsules are opaque capsules with a grey body and pink cap. Tildiem LA 300mg capsules are supplied as opaque capsules with a white body and yellow cap.

The capsules are provided in blister packs containing 7 or 28 capsules. Not all pack sizes may be marketed.

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This leaflet does not contain all the information about your medicine. If you have any further questions or are not sure about anything, ask your doctor or pharmacist.

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