

Tildiem® LA 300mg Prolonged-Release Hard Capsules

(diltiazem hydrochloride)

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine.

- * 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- * If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Your medicine is called Tildiem LA 300mg Prolonged-Release Hard Capsules but will be referred to as Tildiem LA throughout the leaflet.

In this leaflet:

- 1 What Tildiem LA is and what it is used for
- 2 Before you take Tildiem LA
- 3 How to take Tildiem LA
- 4 Possible side effects
- 5 How to store Tildiem LA
- 6 Further 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 Before you take Tildiem LA

Do not take this medicine and tell your doctor if:

- * 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.
- * You are having a medicine called dantrolene used for severe muscle spasms or severe fever (see Section below: 'Taking other medicines').
- * You have a very slow heartbeat - less than 40 beats per minute.
- * 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 are pregnant, might become pregnant or think you may be pregnant (see Section below: 'Pregnancy and breast-feeding')
- * You have any other serious problems with your heart. This includes having an uneven heartbeat (unless you have a pacemaker)

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.

Take special care with Tildiem LA Check with your doctor or pharmacist before taking your medicine if:

- * You are breast-feeding or planning to breast feed (see Section below: 'Pregnancy and breast-feeding').
- * You have any other problem with your heart, apart from angina or those described above under 'Do not take this medicine and tell your doctor if'
- * You are going to have an operation.
- * You are at risk of having a blockage in the gut.

Your doctor will check you more closely particularly when you first start taking the capsules if:

- * You are over 65 years old
- * You have liver or kidney problems
- * You have diabetes

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken 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')

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 pravastatin
- * Ciclosporin used to stop the rejection of organs after a transplant
- * Carbamazepine used for epilepsy
- * Theophylline used for breathing problems
- * Lithium used for some types of mental illness
- * Medicines used as sedatives or as sleeping aids such as midazolam and triazolam
- * methylprednisolone (corticosteroid)

The following medicine may make Tildiem LA 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

Pregnancy and breast-feeding

- * Do 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
- * Breast-feeding should be avoided 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

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 Tildiem LA exactly as your doctor has told you. You should 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 LA Tildiem 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:

Tildiem LA should not be given to children.

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(diltiazem hydrochloride)

Patient Information Leaflet (continued)

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, coma, and confusion.

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:

- * You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- * 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 this 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:

- * Skin rash caused by narrow or blocked blood vessels (called 'vasculitis')
- * Slow or uneven heartbeat
- * Very fast, uneven or forceful heartbeat (palpitations)
- * 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 (hyperglycemia).
- * Being more sensitive to the sun than usual
- * Breast enlargement in men
- * Bruising easily (due to low blood clotting agents)

Tell your doctor as soon as possible if you have any of the following side-effects:

- * Swelling of the lower parts of your legs and arms
- * Feeling dizzy, light-headed or faint when you stand or sit up quickly (low blood pressure)
- * Indigestion, stomach pain, constipation, diarrhoea and dry mouth
- * Swollen gums
- * Itchy, lumpy rash (called 'urticaria')
- * Bruising easily (due to low blood clotting agents)

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- * Headache
- * Flushing (feeling of warmth)
- * Feeling sick (nausea) or being sick (vomiting)
- * General feeling of being unwell
- * Weakness or tiredness
- * Feeling dizzy
- * Feeling more nervous than usual

- * Difficulty sleeping
- * Mood changes (including feeling low)

Blood tests

Tildiem can change the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 How to store Tildiem LA

Keep out of the sight and reach of children.

Do not store above 25°C.

Store in the original packaging.

Do not use Tildiem LA after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

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 Further information

What Tildiem LA contains

Each Tildiem LA 300mg prolonged release capsule, hard 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) and yellow iron oxide (E172).

What Tildiem LA look like and contents of the pack

Tildiem LA 300mg capsules are supplied as opaque capsules with a white body and yellow cap.

The capsules are provided in blister packs containing 28 prolonged release hard capsules.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Manufactured by:

Sanofi Winthrop Industrie 6 Boulevard de l'Europe 21800 Quetigny France.

Tildiem LA is a registered trademark of Sanofi.

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Is this leaflet hard to see or read?
Phone LTT Pharma Limited,
Tel: +44 (0)1527 505414 for help.