

## Package leaflet: Information for the user

# Tildiem® Retard 120 mg Prolonged Release Tablets (diltiazem hydrochloride)

Your medicine is known by the above name but will be referred to as Tildiem Retard throughout this leaflet.

This medicine is available in another strength.

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

## 1. What Tildiem Retard is and what it is used for

Tildiem Retard 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 Retard is used for:

- High blood pressure
- Angina (chest pain)

## 2. What you need to know before you take Tildiem Retard

### Do not take Tildiem Retard if:

- You are allergic (hypersensitive) to diltiazem hydrochloride or any of the other ingredients of Tildiem Retard (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 Retard').
- You have a very slow heartbeat – less than 50 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 already taking a medicine containing ivabradine for the treatment of certain heart diseases.
- 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 Retard').
- You are already taking a medicine containing asunaprevir used for the treatment of hepatitis C virus infection (see section: 'Other medicines and Tildiem Retard').

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 Retard.

### Warnings and precautions

Talk to your doctor or pharmacist before taking Tildiem Retard 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.
- 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.
- You are taking blood thinners such as direct acting oral anti-coagulants (example: dabigatran, rivaroxaban, apixaban) along with Tildiem Retard.

Your doctor will check you more closely particularly when you first start taking the Tildiem Retard 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 Retard.

### Other medicines and Tildiem Retard

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

Tildiem Retard may lead to increase in level of Colchicine (drug used to treat gout) when administered concomitantly.

Tildiem Retard may lead to increased risk of bleeding if taken along with blood thinners such as direct acting oral anti-coagulants (example: dabigatran, rivaroxaban, apixaban).

Tildiem Retard may lead to QT prolongation (ECG changes such as changes in heart rate, rhythm along with symptoms of dizziness), when administered along with drugs with the potential/known for prolonging the QT interval.

### 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 Retard 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 or 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 Retard may make the following medicine work less well:

- Rifampicin used for tuberculosis.

### The following medicines can increase the effect of Tildiem Retard:

- Medicines for stomach ulcers such as cimetidine and ranitidine.

### Tildiem Retard with food and drink

It is advisable to limit the amount of grapefruit juice you drink while taking Tildiem Retard 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 Retard if you are pregnant, might become pregnant or think you may be pregnant. This is because Tildiem Retard can cause problems for your baby. Talk to your doctor if you might be pregnant.
- Do not breast-feed if you are taking Tildiem Retard. 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.

### Tildiem Retard contains:

- **Sucrose.** If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine.
- **Sodium.** This medicine contains less than 1 mmol sodium (23 mg) per tablet that is to say essentially 'sodium free'.

## 3. How to take Tildiem Retard

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 tablets.
- Swallow the tablets whole with a drink of water.
- Tildiem Retard tablets are coated with a special membrane which allows the medicine to be released slowly throughout the day. This membrane may pass through the body unchanged. If this happens, do not worry, it does not affect the way your medicine works.
- 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 dose is one tablet twice a day.  
**If necessary, your doctor may increase this to:**
- One Tildiem Retard 90mg tablet three times a day or
- Two Tildiem Retard 120mg tablets twice a day.

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

#### Angina:

- Your doctor will usually start you on another strength - Tildiem 60mg tablet.

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

- One Tildiem Retard 90mg tablet twice a day or
- One Tildiem Retard 120mg tablet twice a day.

#### High blood pressure:

- The usual starting dose is one Tildiem 120mg Retard tablet a day.

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

- One Tildiem Retard 90mg tablet twice a day or
- One Tildiem Retard 120mg tablet twice a day.

### Children and adolescents

Tildiem Retard should not be given to children.

### If you take more Tildiem Retard than you should

If you take more tablets 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 Retard 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 treated quickly sudden death is not only the potential outcome.

### If you forget to take Tildiem Retard

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 Retard

Keep taking Tildiem Retard 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 Retard 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. You should use sun protection whilst taking this medicine.
- Breast enlargement in men

**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 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](http://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 Retard**

- **Keep 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.
- This medicinal product does not require any special storage conditions.

Do not throw away 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.

If your tablets show signs of deterioration or discolouration seek the advice of your pharmacist who will tell you what to do.

**6. Contents of the pack and other information**

**What Tildiem Retard contains**

- Each prolonged release tablet contains 120 mg diltiazem hydrochloride.
- Also contains sodium dihydrogen citrate, sucrose, povidone, magnesium stearate, macrogol 6000, modified polyvinylchloride polymer (coating polymer), tributyl acetylcitrate, sodium carbonate, ethyl vanillin, titanium dioxide (E171).

**What Tildiem Retard looks like and contents of the pack**

White to off-white, round, convex tablets with no markings.

Available in blister packs of 60 tablets.

Manufactured by Sanofi Winthrop Industrie, 30-36 Avenue Gustave Eiffel, Tours, France. Procured from within the EU and repackaged by Product Licence Holder Uni Health Distribution Ltd, Unit G4 Riverside Industrial Estate, Riverside Way, Dartford, Kent, DA1 5BS.

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

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