

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Tildiem® Retard 90mg and 120mg Prolonged Release Tablets

(diltiazem hydrochloride)

**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.

The name of your medicine is Tildiem Retard 90mg Prolonged Release Tablets or Tildiem Retard 120mg Prolonged Release Tablets but it will be referred to as Tildiem Retard throughout this leaflet.

### In this leaflet:

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

- Angina (chest pain)
- High blood pressure

## 2. Before you take Tildiem Retard



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

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.



**Take special care with Tildiem Retard**

**Check with your doctor or pharmacist before taking your medicine if:**

- You are breast-feeding or planning to breast feed (see Section: 'Pregnancy and breast-feeding')
- 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 having a blockage in the gut

Your doctor will check you more closely particularly when you first start taking your tablets if:

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

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



### 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 Retard can affect the way some other medicines work. Also some medicines can affect the way Tildiem Retard 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 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 pravastatin
- Ciclosporin used to stop the rejection of organs after a transplant
- Carbamazepine used for epilepsy
- Theophylline used for breathing problems
- Lithium used for types of mental illness
- Medicines used as sedatives or as sleeping aids such as midazolam and triazolam
- Methylprednisolone (corticosteroid)

**The following medicines may make Tildiem Retard 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

### Pregnancy and breast-feeding

- Do not take Tildiem Retard if you are pregnant, might become pregnant or think you may be pregnant. This is because Tildiem Retards 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 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 other tools or machines.

**Important information about some of the ingredients of Tildiem Retard**

Tildiem Retard contains:

- **Sucrose.** If you have been told by your doctor that you can not tolerate some sugar, talk to your doctor before taking this medicine.
- **Sodium.** This product contains 6.30mg (1x Tildiem Retard 90mg Prolonged Release Tablet) or 8.42mg (1x Tildiem Retard 120mg Prolonged Release Tablet). To be taken into consideration by patients on a sodium controlled diet.

## 3. How to take Tildiem Retard

Always take Tildiem Retard 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 tablets
- Swallow the tablets whole with a drink of water
- Tildiem Retard 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 (90mg or 120mg) twice a day.

If necessary, your doctor may increase this to:

- Two Tildiem Retard 90mg tablets twice 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 tablets twice a day or
- One Tildiem Retard 120mg tablets 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 tablets twice a day or
- One Tildiem Retard 120mg tablets twice a day

### Children:

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, coma and confusion.

#### 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 everybody 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 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:

- 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')
- Being more sensitive to the sun than usual
- Breast enlargement in men

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

- Swelling of the lower legs
- Feeling dizzy, light-headed or faint when you stand or sit up quickly (low blood pressure)
- Indigestion, stomach pain, constipation, diarrhea 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 gets serious or last 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
- Pain in joints
- Mood changes (including feeling low)
- Difficulty sleeping
- Feeling more nervous than usual

### Blood tests

Tildiem Retard can change the levels of liver enzyme 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 listed on this leaflet, please tell your doctor or pharmacist.

## 5. How to store Tildiem Retard

- Keep out of the reach and sight of children.
- Do not use Tildiem Retard after the expiry date which is stated on the carton after 'Exp'. The expiry date refers to the last day of that month.
- Store in the original packaging. This medicinal product does not require any special temperature storage conditions.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Further Information

### What Tildiem Retard contains

- The active ingredient in Tildiem Retard is diltiazem hydrochloride, 90mg or 120mg.
- The tablets also contain sodium dihydrogen citrate, sucrose, povidone, magnesium stearate, macrogol 6000, coating polymer (contains polyvinyl chloride, polyvinyl acetate and polyvinyl alcohol), acetyl tributyl citrate, sodium hydrogen carbonate, ethyl vanillin, titanium dioxide (E171)

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

Tildiem Retard are off-white, biconvex tablets with no markings.

The tablets are in blister packs containing 56 tablets.

**Manufactured by:** Sanofi Winthrop Industrie, 30-36 avenue Gustave Eiffel, 37000 Tours, France.

**Procured from within the EU and repackaged by the PPA holder:** B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**Tildiem® Retard 90mg Prolonged Release Tablets**  
**PPA No: 1328/101/001**

**POM**

**Tildiem® Retard 120mg Prolonged Release Tablets**  
**PPA No: 1328/101/002**

**POM**

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