# BI-TILDIEM® SR 120 mg prolonged-release coated tablets

diltiazem

SANOFI

**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 or are unsure of anything, ask your doctor or pharmacist for more information.
- 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 any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, talk to your doctor or pharmacist.

**What is in this leaflet:**



## 1. WHAT Bi-Tildiem SR 120 mg, prolonged-release coated tablets ARE AND WHAT THEY ARE USED FOR

**Pharmacotherapeutic group**

SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS/ BENZOTHIAZEPINE DERIVATIVES

This medicine belongs to the class of calcium channel blockers.

**Therapeutic indications**

This medicine is used to prevent attacks of angina pectoris, particularly in patients with effort angina or unstable angina.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE Bi-Tildiem SR 120 mg, prolonged-release coated tablets

**Contraindications**

If you have been told by your doctor that you are intolerant to some sugars, contact him/her before taking this medicine.

**Do not take Bi-Tildiem SR 120 mg, prolonged-release coated tablets in the following situations:**
- allergy to diltiazem or to any of the other ingredients
- very slow heart rate (less than or equal to 40 beats per minute)
- sinus node dysfunction (heart rate disorder)
- second- or third-degree atrioventricular block not corrected by a pacemaker (heart conduction disorders)
- left ventricular failure with congestion in the lungs (impaired heart function)
- in combination with dantrolene (by infusion), pimozide, cisapride, dihydroergotamine, ergotamine, nifedipine, sertindole.

Unless otherwise indicated by your doctor, **this medicine SHOULD GENERALLY NOT BE USED** during pregnancy or in combination with esmolol (in certain cases), beta-blockers used for the treatment of heart failure (bisoprolol, carvedilol, metoprolol, nebivolol), other beta-blockers, triazolam or ivabradine.

**Precautions for use**

**Take especial care with Bi-Tildiem SR 120 mg, prolonged-release coated tablets**

**Special warnings**

Use of this medicine is not recommended in patients with fructose intolerance, glucose/galactose malabsorption syndrome or sucrase/isomaltase deficiency (rare hereditary diseases).

ALWAYS KEEP OUT OF THE REACH OF CHILDREN.

**Precautions for use**

This medicine should be used WITH CAUTION:
- in elderly subjects,
- in patients with kidney or liver failure,
- in patients with low heart rate or certain heart conduction disorders.

If you are to undergo general anesthesia, tell your doctor that you are taking diltiazem.

This medicine can be associated with mood disorders (for example: depression).

This medicine acts on intestinal motility. It must be used with caution in patients at risk of developing an intestinal obstruction.

Tablet residue may be found in your stools. Follow your doctor's advice.

**Other medicines and Bi-Tildiem SR 120 mg, prolonged-release coated tablets**

TO AVOID POSSIBLE INTERACTIONS BETWEEN SEVERAL MEDICINES, particularly if you are taking dantrolene (infusion), pimozide, cisapride, dihydroergotamine, ergotamine, nifedipine, sertindole, esmolol (in certain cases), beta-blockers used in the treatment of heart failure (bisoprolol, carvedilol, metoprolol, nebivolol), other beta-blockers, triazolam or ivabridine.

ALWAYS INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER TREATMENT YOU MAY BE TAKING.

**Pregnancy and breast-feeding**

**Pregnancy**

Use of this medicine is not recommended during pregnancy or in women of child-bearing age who are not using contraception. If you discover that you are pregnant, tell your doctor immediately and follow his/her instructions with regard to your treatment. Tell your doctor if you are planning to have a baby.

**Breast-feeding**

This medicince should be avoided if you are breast-feeding. If the use of Bi-Tildiem SR 120 mg, prolonged-release coated tablets is necessary, the infant should be fed using an alternative method (bottles, etc.).

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

The ability to drive or use machines may be impaired.

**List of excipients with specific effects:** sucrose.

## 3. HOW TO TAKE Bi-Tildiem SR 120 mg, prolonged-release coated tablets

**How many Bi-Tildiem SR 120 mg, prolonged-release coated tablets you should take** The usual dosage is 1 tablet morning and evening. Dosage depends on the condition and medical prescription.

Children: As the safety and efficacy of this medicine have not been demonstrated in this population, diltiazem should not be used in children.

STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

**How Bi-Tildiem SR 120 mg, prolonged-release coated tablets should be taken**

Oral use.

Tablets should not be chewed, but swallowed whole, with a little water. With prolonged-release tablets, once the active substance has been released, tablet residue is usually found in the stools.

**How often Bi-Tildiem SR 120 mg, prolonged-release coated tablets should be taken**

One tablet morning and evening.

**How long Bi-Tildiem SR 120 mg, prolonged-release coated tabletsshould be taken**
STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

**If you take more Bi-Tildiem SR 120 mg, prolonged-release coated tablets than you should**

If you take too high a dose, call your doctor immediately.

**If you forget to take Bi-Tildiem SR 120 mg, prolonged-release coated tablets**

Contact your doctor.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Bi-Tildiem SR 120 mg, prolonged-release coated tablets can cause side effects, although not everybody gets them.
In general, the frequency of side effects is classed as follows:
- very common (more than 1 in 10 patients),
- common (more than 1 in 100 patients and less than 1 in 10 patients),
- uncommon (more than 1 in 1,000 patients and less than 1 in 100 patients),
- rare (more than 1 in 10,000 patients and less than 1 in 1,000 patients),
- very rare (less than 1 in 10,000 patients).

**Heart disorders:**
- Common: certain heart conduction disorders, palpitations,
- Uncommon: poorly tolerated slow heart rate,
- Not known: congestive heart failure, other heart conduction disorders.



**Vascular disorders:**
These disorders are related to the way the medicine works and occur more readily in elderly subjects.
- Common: flushing,
- Uncommon: postural hypotension,
- Not known: inflammation of the small blood vessels (vasculitis).

**Digestive disorders:**
- Common: constipation, stomach ache, nausea, dyspepsia,
- Uncommon: vomiting, diarrhea,
- Rare: dry mouth,
- Not known: excessive enlargement of the gums.

**Skin disorders:**
- Common: erythema,
- Rare: hives,
- Not known:
  - sudden swelling of the face and neck (angioedema) of allergic origin,
  - various types of skin rash, such as erythema multiforme (in particular Stevens-Johnson syndrome and toxic epidermal necrolysis), acute generalized exanthematous pustulosis (mucous membrane damage or blister-like skin reactions): stop treatment immediately and consult your doctor.
  - skin reactions triggered by exposure to the sun or UV rays (photosensitization reactions such as lichenoid keratosis on areas of exposed skin),
  - sweating,

  erythema, sometimes with fever and/or desquamation,
  rash.

**Liver disorders:**
- Uncommon: increase in hepatic enzymes (generally temporary),
- Not known: clinical hepatitis reversible on treatment discontinuation.

**Nervous system disorders:**
- Common: headache, dizziness,
- Not known: extrapyramidal symptoms (*disorder with rigidity, trembling, and abnormal movements*), generally reversible on treatment discontinuation.

**Psychiatric disorders:**
- Uncommon: nervousness, insomnia,
- Not known: mood changes (especially depression).

**Reproductive system disorders:**
Not known: breast swelling in men, reversible on treatment discontinuation.

**Blood and lymphatic system disorders:**
- Not known: reduction in the number of platelets in the blood.

**General disorders:**
- Very common: swelling of the lower limbs,
- Common: faintness, fatigue.

If you notice any side effects not listed in this leaflet, or if any of the side effects becomes serious, please tell your doctor or pharmacist.

## 5. HOW TO STORE Bi-Tildiem SR 120 mg, prolonged-release coated tablets

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 box.

Store below 30°C.

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 Bi-Tildiem SR 120 mg, prolonged-release coated tablets contain**
**The active substance is:**
Diltiazem hydrochloride.....120 mg
For one prolonged-release coated tablet

**The other ingredients are:**
Sodium dihydrogen citrate, sucrose, povidone, magnesium stearate, macrogol 6000, modified PVC, acetyl tributyl citrate, sodium bicarbonate, ethyl vanillin, titanium dioxide (E171).

**What Bi-Tildiem SR 120 mg, prolonged-release coated tablets look like and contents of the pack**
This medicine is supplied as prolonged-release coated tablets. Box of 28.

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1-13, boulevard Romain Rolland - 75014 Paris, France

**Manufacturer**
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