For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

DILZEM CD

1. **Generic Name**
   Diltiazem Hydrochloride Extended Release Capsules U.S.P.

2. **Qualitative and quantitative composition**

DILZEM CD 90
Each hard gelatine capsule contains:
Diltiazem Hydrochloride I.P……. 90 mg
(In the form of extended release pellets)
Excipients……q.s.
Approved colours used in hard gelatin capsule shell

DILZEM CD-120
Each hard gelatin capsule contains:
Diltiazem Hydrochloride I.P. 120 mg
(In the form of extended release pellets)
Approved colours used in hard gelatin capsule shell

DILZEM CD-180
Each hard gelatin capsule contains:
Diltiazem Hydrochloride I.P. 180 mg
(In the form of extended release pellets)
Approved colours used in hard gelatin capsule shell

The excipients are colloidal silicon dioxide, hydroxy propyl methyl cellulose, sugar globule, talc, diethyl phthalate, ammoniomethacrylate copolymer, eudragit rlpo, isopropyl alcohol, methylene chloride.

3. **Dosage form and strength**
   Dosage Form: Hard gelatin capsule
   Strength: 90, 120, 180 mg

4. **Clinical particulars**

4.1 Therapeutic indication

Dilzem CD is indicated in the management of angina pectoris particularly chronic stable angina. It can be used concomitantly with beta blockers and/or nitrates in patients of angina who remain symptomatic despite adequate doses of the latter. It may also be used in angina due to coronary artery spasm. Dilzem CD is also indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive medications.

4.2 Posology and method of administration

Route of administration
Oral.

Dosage may be taken with or without food, and should be swallowed whole and not chewed.

Angina
Adults:
The usual initial dose is 90 mg twice daily. Dosage may be increased gradually to 120 mg twice daily, or 180 mg twice daily if required. Patients' responses may vary and dosage requirements can differ significantly between individual patients.

Elderly and patients with impaired renal or hepatic function:
In the elderly, dosage should commence at 120 mg diltiazem hydrochloride once daily and the dose carefully titrated as required.

Hypertension
Adults:
The usual dose is one diltiazem hydrochloride 120 mg capsule twice daily.

Patients may benefit by titrating from a lower total daily dose.

Elderly and patients with impaired renal or hepatic function:
The starting dose should be 120 mg diltiazem hydrochloride once daily, increasing to one diltiazem hydrochloride 90 mg capsule twice daily and then to one diltiazem hydrochloride 120 mg capsule twice daily if clinically indicated.

Children:
The diltiazem hydrochloride preparations are not recommended for children. Safety and efficacy in children has not been established.

In order to avoid confusion, it is suggested that patients once titrated to an effective dose using either diltiazem hydrochloride capsules should remain on this treatment and should not be changed between different presentations.

Diltiazem hydrochloride capsules should not be taken at the same time as an alcoholic beverage.

4.3 Contraindications
Hypersensitivity to diltiazem or to any of the excipients.

Pregnancy and in women of child bearing capacity.

Patients with severe bradycardia (less than 40 bpm), second or third degree heart block, sick sinus syndrome, decompensated cardiac failure, patients with left ventricular failure with pulmonary congestion.

Concurrent use with dantrolene infusion because of the risk of ventricular fibrillation.

4.4 Special warnings and precautions for use
The product should be used with caution in patients with reduced left ventricular

function.

Patients with mild bradycardia (risk of exacerbation), first degree AV block or prolonged PR interval should be observed closely.

Diltiazem is considered unsafe in patients with acute porphyria.

Prior to general anaesthesia, the anaesthesist must be informed of ongoing diltiazem treatment. Depression of cardiac contractility, conductivity and automaticity, as well as the vascular dilatation associated with anaesthetics may be potentiated by calcium channel blockers.

Increase of plasma concentrations of diltiazem may be observed in the elderly and in patients with renal or hepatic insufficiency. The contraindications and precautions should be carefully observed and close monitoring, particularly of heart rate, should be carried out at the beginning of treatment.

Calcium channel blocking agents, such as diltiazem, may be associated with mood changes, including depression.

Like other calcium channel antagonists, diltiazem has an inhibitory effect on intestinal motility. Therefore, it should be used with caution in patients at risk to develop an intestinal obstruction. It residues from slow release formulations of the product may pass into the patient's stools; however, this finding has no clinical relevance.

4.5 Drugs interactions

Concomitant use contraindicated:
Dantrolene (infusion): Lethal ventricular fibrillation is regularly observed in animals when intravenous verapamil and dantrolene are administered concomitantly. The combination of a calcium antagonist and dantrolene is therefore potentially dangerous.

Concomitant use requiring caution:
Lithium: Risk of increase in lithium-induced neurotoxicity.

Nitrate derivatives: Increased hypotensive effects and faintness (additive vasodilatating effects): In all the patients treated with calcium antagonists, the prescription of nitrate derivatives should only be carried out at gradually increasing doses.

Theophylline: Increase in circulating theophylline levels.

Alpha-antagonists: Increased antihypertensive effects:

Concomitant treatment with alpha-antagonists may produce or aggravate hypotension. The combination of diltiazem with an alpha-antagonist should be considered only with the strict monitoring of the blood pressure.

Amiodarone, digoxin: Increased risk of bradycardia:

Caution is required when these are combined with diltiazem, particularly in elderly

subjects and when high doses are used. Diltiazem hydrochloride may cause small increases in plasma levels of digoxin, requiring careful monitoring of AV conduction.

Beta-blockers: Possibility of rhythm disturbances (pronounced bradycardia, sinus arrest), sinoatrial and atrioventricular conduction disturbances and heart failure (synergistic effect). Patients with pre-existing conduction defects should not receive the combination of diltiazem and beta-blockers. Such a combination must only be used under close clinical and ECG monitoring, particularly at the beginning of treatment.

Other antihypertensive drugs:
Enhanced antihypertensive effect may occur with concomitant use of other antihypertensive drugs (e.g. beta-blockers, diuretics, ACE-inhibitors) or drugs that cause hypotension such as aldesleukin and antipsychotics.

Other antiarrhythmic agents:
Since diltiazem has antiarrhythmic properties, its concomitant prescription with other antiarrhythmic agents, is not recommended (additive risk of increased cardiac adverse effects). This combination should only be used under close clinical and ECG monitoring.

Carbamazepine: Increase in circulating carbamazepine levels:
It is recommended that the plasma carbamazepine concentrations be assayed and that the dose should be adjusted if necessary.

Rifampicin: Risk of decrease of diltiazem plasma levels after initiating therapy with rifampicin: The patient should be carefully monitored when initiating or discontinuing rifampicin treatment.

Anti-H2 agents (cimetidine, ranitidine): Increase in plasma diltiazem concentrations. Patients currently receiving diltiazem therapy should be carefully monitored when initiating or discontinuing therapy with anti-H2 agents. An adjustment in diltiazem daily dose may be necessary.

Protease inhibitors (e.g. atazanavir, ritonavir): Increase in plasma diltiazem concentrations.

Ciclosporin: Increase in circulating cyclosporin levels:
It is recommended that the cyclosporin dose be reduced, renal function be monitored, circulating cyclosporin levels be assayed and that the dose should be adjusted during combined therapy and after its discontinuation.

General information to be taken into account:
Due to the potential for additive effects, caution and careful titration are necessary in patients receiving diltiazem concomitantly with other agents known to affect cardiac contractility and/or conduction.

Diltiazem is metabolized by CYP3A4. A moderate (less than 2-fold) increase of diltiazem plasma concentration in cases of co-administration with a stronger CYP3A4 inhibitor has been documented. Diltiazem is also a CYP3A4 isoform inhibitor. Co-administration with other CYP3A4 substrates may result in an increase in plasma concentration of either co-administered drug (e.g. cilostazol, ivabradine, sirolimus,

tacrolimus). Care should be exercised in patients taking these drugs. Concomitant use of diltiazem with cilostazol and ivabradine should be avoided.

Co-administration of diltiazem with a CYP3A4 inducer may result in a decrease of diltiazem plasma concentrations.

Barbiturates (phenobarbital, primidone): serum levels of diltiazem may be decreased by concomitant usage of CYP3A4 inducers.

Phenytoin: serum levels of diltiazem may be decreased by concomitant usage of CYP3A4 inducers. Diltiazem may increase serum levels of phenytoin.

Benzodiazepines (midazolam, triazolam): Diltiazem significantly increases plasma concentrations of midazolam and triazolam and prolongs their half-life. Special care should be taken when prescribing short-acting benzodiazepines metabolized by the CYP3A4 pathway in patients using diltiazem.

Diltiazem may increase bioavailability of tricyclic antidepressants.

Corticosteroids (methylprednisolone): Inhibition of methylprednisolone metabolism (CYP3A4) and inhibition of P-glycoprotein: The patient should be monitored when initiating methylprednisolone treatment. An adjustment in the dose of methylprednisolone may be necessary.

Statins (simvastatin, atorvastatin, lovastatin): Diltiazem is an inhibitor of CYP3A4 and has been shown to significantly increase the AUC of some statins. The risk of myopathy and rhabdomyolysis due to statins metabolised by CYP3A4 may be increased with concomitant use of diltiazem. When possible, a non CYP3A4-metabolised statin should be used together with diltiazem, otherwise close monitoring for signs and symptoms of a potential statin toxicity is required.

Diltiazem hydrochloride capsules should not be taken at the same time as alcohol, as it may increase the rate of release of diltiazem from the prolonged release preparation. In addition, the combination of alcohol and diltiazem may have an additive vasodilatory effect.

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy and lactation

There is very limited data from the use of diltiazem in pregnant patients. Diltiazem has been shown to have reproductive toxicity in certain animal species (rat, mice, rabbit). Diltiazem is contraindicated during pregnancy, as well as in women of child-bearing potential not using effective contraception.

Diltiazem is excreted in breast milk at low concentrations. Breast-feeding while taking this drug should be avoided. If use of diltiazem is considered medically essential, an alternative method of infant feeding should be instituted.

4.7 Effects on ability to drive and use machines

Diltiazem has been reported to cause adverse reactions such as dizziness (common) and malaise (common), which may impair patients' ability to drive or operate machinery to a varying extent depending on the dosage and individual susceptibility. However, no studies have been performed. Therefore, patients should not drive or operate machinery if affected.

4.8 Undesirable effects

The following frequencies are the basis for assessing undesirable effects:
Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

	Very common	Common	Uncommon	Rare	Not known
Blood and lymphatic system disorders					Thrombocytopenia
Immune system disorders			Hypersensitivity		
Psychiatric disorders			Nervousness, insomnia		Mood changes (including depression)
Nervous system disorders		Headache, dizziness			Extrapyramidal syndrome
Cardiac disorders		Atrioventricular block (may be of first, second or third degree; bundle branch block may occur), palpitations	Bradycardia		Sinoatrial block, congestive heart failure
Vascular disorders		Flushing	Orthostatic hypotension		Vasculitis (including leukocytoclastic vasculitis), hypotension
Gastrointestinal disorders		Constipation, dyspepsia, gastric pain, nausea	Vomiting, diarrhoea	Dry mouth	Gingival hyperplasia
Hepatobiliary disorders			Hepatic enzymes increase (AST,		Hepatitis

			ALT, LDH, ALP increase)		
Skin and subcutaneous tissue disorders		Erythema, pruritus		Urticaria	Photosensitivity (including lichenoid keratosis at sun exposed skin areas), angioneurotic oedema, rash, erythema multiforme (including Steven-Johnson's syndrome and toxic epidermal necrolysis), hyperhidrosis, exfoliative dermatitis, acute generalized exanthematous pustulosis, desquamative erythema with or without fever, allergic dermatitis
Reproductive system and breast disorders					Gynaecomastia
General disorders and administration site conditions	Peripheral oedema	Malaise, fatigue			

Reporting of suspected adverse reactions
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

4.9 Overdose

The clinical effects of acute overdose can involve pronounced hypotension possibly leading to collapse, sinus bradycardia with or without isorhythmic dissociation and atrioventricular conduction disturbances.

Treatment in a hospital setting will include gastric lavage and/or osmotic diuresis.

Conduction disturbances may be managed by temporary cardiac pacing.

Proposed corrective treatments: atropine, vasopressors, inotropic agents, glucagon and calcium gluconate infusion.

Symptomatic bradycardia and high grade atrioventricular block may respond to atropine and isoprenaline.

The formulation employs a prolonged release system which will continue to release diltiazem for some hours.

5. Pharmacological properties

5.1 Mechanism of Action

Diltiazem is an antianginal agent and calcium antagonist. Diltiazem inhibits transmembrane calcium entry in myocardial muscle fibres and in vascular smooth muscle fibres, thereby decreasing the quantity of intracellular calcium available to the contractile proteins.

5.2 Pharmacodynamic properties

Pharmacotherapeutic group: Selective calcium channel blocker with direct cardiac effects.

ATC Code: C08D B01.

Diltiazem is an antianginal agent and calcium antagonist. Diltiazem inhibits transmembrane calcium entry in myocardial muscle fibres and in vascular smooth muscle fibres, thereby decreasing the quantity of intracellular calcium available to the contractile proteins.

5.3 Pharmacokinetic properties

Diltiazem hydrochloride capsules is a form characterised by prolonged release of diltiazem hydrochloride in the digestive tract.

Diltiazem is 80% bound to human plasma proteins (albumin, acid glucoproteins).

The biotransformation routes are:
- Deacetylation
- Oxidative o- and n-demethylation
- Conjugation of the phenolic metabolites.

The primary metabolites, n-demethyldiltiazem and desacetyldiltiazem exert less pharmacological activity than diltiazem. The other metabolites are pharmacologically inactive.

After administration of 180 to 300 mg of diltiazem hydrochloride capsules, a peak plasma concentration of 80 to 220 ng/ml, respectively, is obtained after about 5.5 hours.

The elimination half-life varies from 6 to 8 hours, depending on the strength.

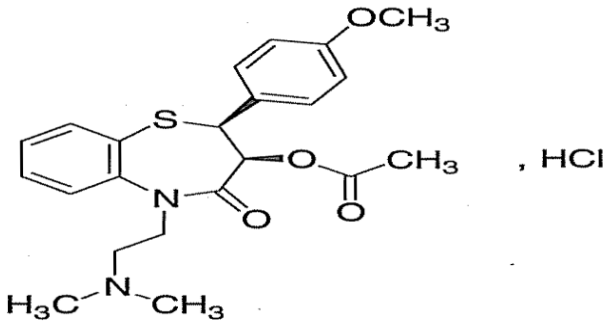
6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the prescribing information.

7. Description

Diltiazem Hydrochloride is (2S,3S)-2,3,4,5-Tetrahydro-5-(2-dimethylaminoethyl)-2-(4-methoxyphenyl)-4-oxobenzo[b]thiazepin-3-yl acetate hydrochloride. Having molecular Formula C22H26N2O4S, HCL and Molecular weight 451. The chemical structure is:



DILZEM CD 90:
Yellow/Transparent hard gelatin size '2' capsules containing white to off white pellets, cap is having print 'DILZEM CD 90' and body is having print Torrent logo(square emblem only) on it.

DILZEM CD 120:
Blue/Transparent hard gelatin capsules containing white to off white pellets. Cap is having print 'DILZEM CD 120' and body is having print Torrent logo(Squre emblem only) on it.

DILZEM CD 180:
Green/Transparent hard gelatin capsules containing white to off white pellets. Cap is having print 'Dilzem CD 180' and body is having print Torrent logo(square emblem only) on it.

8. Pharmaceutical particulars

8.1 Incompatibilities

Not applicable.

8.2 Shelf Life

Do not use later than the date of expiry.

8.3 Packaging information

Dilzem CD is available in Blister strip of 10 Capsules.

8.4 Storage and handing instructions

Store at a temperature not exceeding 30°C, protected from light and moisture.

9. Patient Counselling Information

Read all of this leaflet carefully before you start using 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.
• 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. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

9.1 What Dilzem CD is and what it is used for

Dilzem CD contain the active ingredient diltiazem.

Dilzem CD is indicated in the management of angina pectoris particularly chronic stable angina. It can be used concomitantly with beta blockers and/or nitrates in patients of angina who remain symptomatic despite adequate doses of the latter. It may also be used in angina due to coronary artery spasm. Dilzem CD is also indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive medications

Dosage may be taken with or without food, and should be swallowed whole and not chewed

9.2 What you need to know before you use Dilzem CD

Do not take Dilzem CD if you:

- are allergic (hypersensitive) to diltiazem or any of the other ingredients of the capsules;
- have a slow or irregular heart beat;
- have heart failure (which can cause shortness of breath or ankle swelling).

Children should not take these capsules.

Warnings and precautions

Talk to your doctor or pharmacist before taking these tablets if you:

- have liver or kidney problems as your doctor may monitor you more closely;
- have porphyria (a rare disease of the blood pigments);
- have bowel problems.

Other medicines and Dilzem CD

Please tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. If you take Dilzem CD capsules with some other medicines, the effect of Dilzem CD capsules or the other medicine

may be changed.

Tell your doctor if you are taking:

- any other medicines for high blood pressure, such as beta blockers (for example atenolol), diuretics (for example bendrofluazide) or ACE inhibitors (examples include captopril and enalopril);
- medicines known as alpha blockers, which you may be taking to treat high blood pressure or prostate disorders (for example prazosin);
- any medicines which may cause low blood pressure or slow heart beat (for example aldesleukin to treat cancer of the kidneys, or antipsychotics to treat mental and behavioural disorders);
- ivabradine to treat angina;
- anti-arrhythmic medicines to treat an irregular or rapid heart beat (for example digoxin, amiodarone or beta-blockers);
- cilostazol to treat intermittent claudication (a condition that causes leg pain due to a restriction in blood supply to the muscles);
- medicines known as statins to reduce cholesterol levels in your blood (examples include simvastatin, atorvastatin or lovastatin);
- medicines known as H2 antagonists to treat stomach ulcers, indigestion or heartburn, such as cimetidine or ranitidine;
- carbamazepine or phenytoin to treat seizures, fits or convulsions;
- medicines known as benzodiazepines to treat anxiety or help you sleep (examples include midazolam or triazolam);
- medicines known as barbiturates to either treat fits or to help you sleep (examples include phenobarbital or primidone);
- antidepressants known as tricyclic antidepressants (examples include amitriptyline or imipramine) or lithium;
- rifampicin to treat tuberculosis;
- ciclosporin, sirolimus or tacrolimus to prevent organ transplant rejection or treat other immune system disorders;
- a specific type of medicine known as a protease inhibitor to treat HIV (examples include atazanavir or ritonavir);
- dantrolene (a muscle relaxant);
- theophylline to treat breathing problems such as asthma;
- medicines known as nitrate derivatives to treat angina or high blood pressure (examples include glyceryl trinitrate or isosorbide mononitrate);
- medicines for inflammation or allergies, known as steroids (for example methylprednisolone).

If you are having a general anaesthetic, tell your doctor that you are taking these capsules.

Dilzem CD capsules with alcohol
Do not take Dilzem CD capsules at the same time as an alcoholic drink.

Ask your doctor for advice before taking any medicine.

Pregnancy, breastfeeding and fertility
Do not take Dilzem CD capsules if you are pregnant, likely to become pregnant or are breastfeeding.

Ask your doctor for advice before taking any medicine.

Driving and using machines
The capsules may cause a number of side effects such as dizziness and a general feeling of being unwell. These could affect your ability to drive and are usually most noticeable when you start taking the capsules, or when changing to higher dose. If you are affected you should not drive or operate machinery.

9.3 How to use Dilzem CD

Always take Dilzem CD capsules exactly as your doctor has told you. The label on your medicine will tell you how many capsules to take and how often.

Adults (over 18 years of age)
If you are taking these capsules to treat angina the usual starting dose is one 90 mg capsule every 12 hours.

If you are taking these capsules to lower your blood pressure then the usual dose is one 120 mg capsule every 12 hours. However, if you are elderly or have kidney or liver problems then you may need to start on a lower dose. Your doctor will decide how many capsules you should take.

Children
Children should not take these capsules.

Do not exceed the dose recommended by your doctor. You should check with your doctor or pharmacist if you are not sure.

Swallow your capsules whole with a glass of water. **Do not chew or crush the capsules.**

You should take your capsules every 12 hours. For instance, if you take a capsule at 8 o'clock in the morning, you should take your next capsule at 8 o'clock in the evening.

If you take more Dilzem CD capsules than you should or if someone accidentally swallows your capsules
Call your doctor or hospital straight away. People who have taken an overdose may become very unwell, feel faint, have a slow heart beat and lose consciousness. They may need emergency treatment in hospital. When seeking medical attention make sure that you take this leaflet and any remaining capsules with you to show to the doctor.

If you forget to take Dilzem CD capsules
If you remember within 4 hours of the time your capsule was due, take your capsule straight away. Take your next capsule at your normal time. If you are more than 4 hours late, please call your doctor or pharmacist for advice. Do not take a double dose to make up for a forgotten capsule.

If you stop taking Dilzem CD capsules
You should not stop taking these capsules unless your doctor tells you to. If you want to

stop taking your capsules, discuss this with your doctor first.

If you have any further questions on the use of Dilzem CD capsules ask your doctor.

9.4 Possible Side Effects

Like all medicines, Dilzem CD capsules can cause side effects, although not everybody gets them.

Look out for the following severe allergic reactions. They have occurred in a small number of people, although their exact frequency cannot be estimated:

- swelling of the face or throat;
- skin rash or itching especially those covering your whole body, severe flaking, blistering or peeling of the skin, with or without a fever.

Tell your doctor immediately if you get any of these.

Very common: may affect more than 1 in 10 people

- Swelling of the hands, ankles or feet.

Common: may affect up to 1 in 100 people

- Feeling sick, abdominal pain, indigestion, constipation.
- Dizziness, headache.
- Flushing or redness of the skin, itching.
- A fast, slow or irregular heartbeat.
- Generally feeling unwell.
- Tiredness.

Uncommon: may affect up to 1 in 100 people

- Diarrhoea, being sick.
- A feeling of faintness, especially on standing up.
- Nervousness.
- Difficulty in sleeping.
- A worsening in liver function tests (seen in a blood test).

Rare: may affect up to 1 in 1,000 people

- Dry mouth.
- Hives.

Frequency not known (frequency cannot be estimated from the available data)

- Heart failure which can cause shortness of breath or ankle swelling.
- Inflammation of the liver.
- Changes in muscle tone and/or abnormalities of movement.
- Mood changes, including depression.
- Skin problems such as an increased sensitivity to sunlight.
- A reduction in blood platelets which increases the risk of bleeding or bruising.
- Breast enlargement in men.
- Bleeding, tender or enlarged gums.

- Inflammation of blood vessels (often with skin rash).
- Sweating.
- Low blood pressure.

You may see the remains of the capsules in your faeces. This should not affect how the capsules work.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

9.5 How to store Dilzem CD

Keep out of the sight and reach of children.

Do not use any capsules after the expiry date which is stated on the carton.

Store at a temperature not exceeding 30°c, protected from light and moisture.

Do not take your capsules if they are broken or crushed as this can be dangerous and can cause serious problems such as overdose.

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 to protect the environment.

9.6 Contents of the pack and other information

What Dilzem CD contains:

- The active substance is Diltiazem Hydrochloride I.P. Each capsule contains 90 mg, 120 mg or 180 mg of diltiazem hydrochloride.

- The excipients are colloidal silicon dioxide, hydroxy propyl methyl cellulose, sugar globule, talc, diethyl phthalate, ammoniomethacrylate copolymer, eudragit rlpo, isopropyl alcohol, methylene chloride.

What are the contents of the pack
Dilzem CD is available in Blister strip of 10 Capsules.

10. Details of manufacturer

Manufactured by:
TORRENT PHARMACEUTICALS LTD.
Vill. Bhud & Makhnu Majra, Teh. Baddi-173 205,
Dist. SOlan (H.P.), INDIA.

11. Details of permission or licence number with date

Mfg License no. MNB/05/183 Dated 22.09.2010

12. Date of revision

Dec 2019

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/DILZEM CD 90,120,180mg/DEC-19/03/PI