

DILTIAZEM HYDROCHLORIDE

NOVOPTIN

60mg TABLET



CALCIUM CHANNEL BLOCKER

FORMULATION:

Each tablet contains:
Diltiazem Hydrochloride 60mg

DESCRIPTION:

White to off-white, round convex tablet, Blister Pack x 10's (Box of 100's)

WHAT IS IN THE MEDICINE?

NOVOPTIN contains the active ingredient, Diltiazem Hydrochloride. (Diltiazem Hydrochloride). A white or almost white, crystalline powder. Freely soluble in water, in dichloromethane, and in methyl alcohol; slightly soluble in dehydrated alcohol. Diltiazem belongs to a group of medicines called calcium channel blockers. These medicines work to lower blood pressure and ease anginal chest pain by preventing the narrowing of blood vessels.

STRENGTH OF THE MEDICINE: See Formulation

WHAT IS THIS MEDICINE USED FOR?

Oral: Unstable Angina Pectoris including Angina Due to Coronary Artery Spasm or Following Myocardial Infarction: Diltiazem is indicated for the treatment of angina pectoris due to coronary artery spasm. Diltiazem has been shown to be effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (resting angina with ST-segment elevation occurring during attacks).

Chronic Stable Angina (Classic Effort-associated Angina): Diltiazem is indicated for the management of chronic stable angina in patients who cannot tolerate therapy with beta-blockers and/or nitrates or who remain symptomatic despite adequate doses of these agents.

Hypertension: Diltiazem is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive medications, such as diuretics.

Kidney Transplantation: Diltiazem is indicated for the prevention of graft failure following kidney transplantation. Diltiazem is indicated for the reduction of cyclosporin A nephrotoxicity during immunosuppressive therapy after kidney transplantation.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Oral: Ischemic Heart Disease (Exertional Angina Pectoris Due to Atherosclerotic Coronary Artery Disease or Angina Pectoris at Rest Due to Coronary Artery Spasm): The initial dose is 120 mg/day in equally divided doses, administered preferably before meals, and at bedtime; dosage should be increased gradually in equally divided doses (two to four times daily) at 1- to 2-day intervals until optimum response is obtained. The optimum dosage range appears to be 180 mg/day to 360 mg/day. Doses up to 480 mg/day may be administered in some cases.

Hypertension: Dosages must be adjusted to each patient's needs. The initial dose is 120 mg/day to 240 mg/day in equally divided doses, administered preferably before meals, and at bedtime. Maximum antihypertensive effect is usually observed at 14 days of chronic therapy; therefore, dosage adjustments should be scheduled accordingly. The usual dosage range is 240 mg/day to 360 mg/day. There is an additive antihypertensive effect when diltiazem is used with other antihypertensive agents. Therefore, the dosage of diltiazem or the concomitant antihypertensive(s) may need to be adjusted when adding one to the other.

Kidney Transplantation: The initial dose is 120 mg/day in two equally divided doses. Depending on the patient's blood pressure, dosage may be increased up to a maximum of 360 mg/day given in three equally divided doses. The optimum dosage range appears to be 180 mg/day to 360 mg/day.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

Do not take DILTIAZEM if you:

- are allergic to Diltiazem Hydrochloride or any of the other ingredients of this medicine.
- are a woman of a child-bearing potential and are not using contraception.
- are pregnant, think you may be pregnant or are breast-feeding.
- are currently in shock (reduced blood flow to vital organs)
- suffer from any serious heart problems such as heart failure with shortness of breath and abnormal heart rhythm, which may result in palpitation.
- have a very low pulse rate or low blood pressure
- are currently receiving an infusion of a muscle relaxant called dantrolene
- are currently taking ivabradine, as taking it together with DILTIAZEM may lower your heart rate

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?

It is contraindicated in patients with sick sinus syndrome, pre-existing second or third degree atrioventricular block or marked bradycardia, and should be used with care in patients with lesser degrees of atrioventricular block or bradycardia, as well as those taking drugs such as beta blockers or digoxin.

Cardiac Conduction: Diltiazem prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block.

Concomitant use of Diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction.

Congestive Heart Failure: Although Diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in either cardiac index or in consistent negative effects on contractility (dp/dt). Experience with Diltiazem used alone or in combination with beta-blockers in patients with impaired ventricular function is very limited.

Caution should be exercised when using the drug in such patients.

Hypotension: Decreases in blood pressure associated with Diltiazem therapy may occasionally result in symptomatic hypotension.

Acute Hepatic Injury: In rare instances, significant elevations in enzymes such as alkaline phosphatase, lactate dehydrogenase (LDH), serum glutamic oxaloacetic transaminase (SGOT), serum glutamic-pyruvic transaminase (SGPT), and other phenomena consistent with acute hepatic injury have been noted. These reactions have been reversible upon discontinuation of drug therapy.

Laboratory Monitoring: Diltiazem Hydrochloride is extensively metabolized by the liver and excreted by the kidneys and in the bile. As with any drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. General: Dermatological events may be transient and may disappear despite continued use of diltiazem. However, skin eruptions progressing to erythema multiforme and/or exfoliative dermatitis (Epidermal necrolysis) have also been in - frequently reported. Should a dermatological reaction persist, the drug should be discontinued.

The drug should be used with caution in patients with impaired renal or hepatic function.

UNDESIRABLE EFFECTS:

Headache, ankle edema, hypotension, dizziness, flushing, fatigue, and nausea and other gastrointestinal disturbances (including anorexia, vomiting, constipation or diarrhea, taste disturbances, and weight gain). Gingival hyperplasia has also been reported.

PHARMACOKINETICS:

Diltiazem is rapidly and almost completely absorbed from the gastrointestinal tract following oral administration, but undergoes extensive first-pass hepatic metabolism. The availability has been reported to be about 40%. Diltiazem is about 80% bound to plasma proteins. It is distributed into the breast milk. It is extensively metabolized in the liver; one of the metabolites, desacetyldiltiazem has been reported to have 25 to 50% of the activity of the parent compound. The half life of diltiazem is about 3 to 5 hours.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

Increased depression of cardiac conduction with risk of bradycardia and atrioventricular block may occur when Diltiazem is given with drugs such as amiodarone, beta blockers, digoxin and mefloquine. Enhanced antihypertensive effect may occur with concomitant use of other antihypertensives or drugs that cause hypotension such as aldeseleukin and antipsychotics. Interactions may also be expected with enzyme inducers, such as carbamazepine, phenobarbital, phenytoin and rifampicin, and with enzyme inhibitors such as cimetidine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Diltiazem. These include:

- Dantrolene (a muscle relaxant)
- Some other medicines for your heart or high blood pressure (eg. beta blockers; digoxin, amiodarone, nitrates)
- Cyclosporin, which you may have been given after an operation or because of rheumatoid arthritis
- Rifampicin (an antibiotic)
- Cimetidine or ranitidine (for ulcers or reflux)
- Diazepam (for depression, alcohol withdrawal or anxiety)
- Carbamazepine (for bipolar disorder or epilepsy)
- Lithium (for bipolar disorder)
- Theophylline (for asthma and other breathing problems)
- Certain drugs used to treat prostate problems
- Inhaled anaesthetic agents such as halothane, isoflurane, enflurane (for surgery)
- Drugs used to lower your blood cholesterol (including simvastatin, lovastatin)
- Benzodiazepines or medicines used as sedatives or to treat anxiety such as midazolam, triazolam
- Corticosteroids such as methylprednisolone, prednisone, cortisone
- Antiarrhythmics or medicines used to treat irregular heart beats.

These medicines may be affected by Diltiazem, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you. Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Diltiazem.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally. Do not take a double dose to make up for the dose that you missed.

SIGNS AND SYMPTOMS OF OVERDOSE:

In the event of overdosage or exaggerated response, appropriate supportive medical care should be employed in addition to gastric lavage.

The following measures may be considered.

- Bradycardia: Administer atropine (0.60-1.0 mg); if there is no response to vagal blockade, cautiously administer isoproterenol.
- High-Degree AV Block: Treat as for bradycardia above; fixed high-degree AV block should be treated with cardiac pacing.
- Cardiac Failure: Administer inotropic agents (isoproterenol, dopamine or dobutamine) and diuretics.
- Hypotension: Administer vasopressors (e.g., dopamine or levarterenol bitartrate).

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

Immediately telephone your doctor or Poisons Information Center or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much Diltiazem.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

HOW SHOULD YOU KEEP THIS MEDICINE?

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

Keep out of reach and sight of children.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

If any of the following happen, stop taking Diltiazem and tell your doctor immediately or go to casualty at your nearest hospital:

- you feel continuously light headed or dizzy
 - you notice your heart beating irregularly, slowly or very quickly
 - you feel pain, which may be severe, in your left arm and chest
 - you have blisters and bleeding in the lips, eyes, mouth, nose or genitals
 - you have skin reactions such as red, painful or itchy spots, blisters or peeling of the skin.
- These are very serious side effects. You may need urgent medical attention or hospitalization.

CAUTION:

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

ADR REPORTING STATEMENT:

*For suspected adverse drug reaction, report to FDA: www.fda.gov/ph Patient must seek medical attention immediately at the first sign of any adverse drug reactions.

AVAILABILITY:

Alu/PVC Clear Blister Pack of 10's (Box of 100's)

REGISTRATION NO : DRP - 6605

DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

15 April 2020

DATE OF REVISION OF PATIENT INFORMATION LEAFLET

August 2021

REFERENCE : DILZEM/ Martindale 36th Edition

SHELF-LIFE 36 Months

Manufactured by:

SAN MARINO Laboratories CORP.
#1 Crisanto delos Reyes Street,
Brgy. Javalera, Gen., Trias Cavite