

## PATIENT MEDICATION INFORMATION :

### APO-DILTIAZ

*diltiazem HCl*  
Antianginal Agent  
Apotex

### APO-DILTIAZ SR

*diltiazem HCl*  
Antihypertensive Agent—Antianginal Agent  
Apotex

### APO-DILTIAZ CD

*diltiazem HCl*  
Antihypertensive Agent—Antianginal Agent  
Apotex

*Date of Revision: December 16, 2019*

## Patient Medication Information: APO-DILTIAZ CD:

### IMPORTANT: PLEASE READ

Read this carefully before you start taking APO-DILTIAZ CD and each time you get a refill. This leaflet is a summary and will not tell you everything about APO-DILTIAZ CD. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about APO-DILTIAZ CD.

## ABOUT THIS MEDICATION:

### What the medication is used for:

APO-DILTIAZ CD is used for:

- the management of effort associated **angina** (chest pain)
- the treatment of mild to moderate **high blood pressure**.

APO-DILTIAZ CD should normally be used in those patients in whom treatment with other blood pressure reduction medications has been ineffective, or have been associated with unacceptable side effects.

### What it does:

APO-DILTIAZ CD belongs to the group of drugs called “calcium channel blockers” or “calcium antagonists”.

APO-DILTIAZ CD relaxes the arteries, thereby lowering blood pressure.

APO-DILTIAZ CD reduces the amount of oxygen that your heart muscle needs. This helps control chest pain.

### When it should not be used:

Do not use APO-DILTIAZ CD if:

- You are pregnant or plan to become pregnant.
- You are breastfeeding.
- You have a known allergy to diltiazem or to any of the non-medicinal ingredients.
- You have very low blood pressure (<90 mmHg systolic).
- You have very slow heartbeat (40 beats/minute or less)
- You have heart rhythm disorders in the absence of a pacemaker.
- You have severe heart failure with fluid in the lungs.
- You are taking a medicine called dantrolene used for severe muscle spasms or severe fever.
- You are using ivabradine

### **What the medicinal ingredient is:**

Diltiazem Hydrochloride

### **What the non-medicinal ingredients are:**

Eudragit, methylcellulose, microcrystalline cellulose, polysorbate 80, talc and tributyl citrate. The capsule shell contains the non-medicinal ingredients gelatin, iron oxide black (300 mg only), FD&C blue #1 and titanium dioxide.

### **What dosage forms it comes in:**

Capsules: 120 mg, 180 mg, 240 mg, and 300 mg

## **WARNINGS AND PRECAUTIONS:**

### **BEFORE you use APO-DILTIAZ CD talk to your doctor or pharmacist if:**

- You have very low blood pressure.
- You have ever had a bad or unusual reaction to any drug containing diltiazem in the past.
- You have heart, liver, or kidney disease.
- You have high blood sugar or diabetes.
- You are 65 years or older.
- You have a history of heart failure, new shortness of breath, slow heartbeat or low blood pressure. Cases of kidney injury in patients with such conditions have been reported.

## **INTERACTIONS WITH THIS MEDICATION:**

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

Additional monitoring of your dose or condition may be needed if you are taking other drugs.

The following may interact with APO-DILTIAZ CD:

- Antifungal medications with a name ending inazole;
- Medications used to control the immune system such as cyclosporine;
- Certain antibiotics should not be taken with APO-DILTIAZ CD such as erythromycin, rifampin. Check with your pharmacist if not sure;
- Sleeping pills such as benzodiazepines (midazolam, triazolam);
- Other blood pressure medications: alpha antagonists, beta-blockers;

- Heart medications: Amiodarone, digoxin, digitalis, flecainide, nifedipine, propafenone, quinidine, verapamil; ivabradine
- Anaesthetics;
- Lithium and imipramine used for some types of mental illness;
- Drugs that dilate the blood vessels: short and long acting nitrates;
- Medications used to control seizures: carbamazepine, phenobarbital, phenytoin;
- Warfarin used as anticoagulant;
- Cholesterol lowering medications: statins;
- Theophylline used for breathing problems;
- Terfenadine or ranitidine used for allergies;
- Medications used to control stomach ulcers such as cimetidine will increase the effects of APO-DILTIAZ CD;
- Multivitamins with minerals (calcium-containing products);
- Drugs to treat inflammation: corticosteroids, methylprednisolone;
- Dantrolene used for severe muscle spasms or severe fever.
- Acetylsalicylic acid (Aspirin) or antiplatelet drugs such as ticagrelor, cilostazol, clopidogrel, dipyridamol, ticlopidine.
- X-Ray contrast agents.

**Alcohol** may cause low blood pressure and dizziness when you go from lying or sitting to standing up. This can especially occur after the first dose and when the dose is increased. Tell your doctor if you experience dizziness, light-headedness, fainting, decreased blood pressure or increased heart rate.

**Grapefruit juice** when consumed too often while taking APO-DILTIAZ CD may cause headache, irregular heartbeat, edema (swelling), unexplained weight gain, and chest pain. Tell your doctor if this happens to you. Your doctor may recommend that grapefruit juice be avoided if this happens to you.

## PROPER USE OF THIS MEDICATION:

Do not miss doses or take extra doses, unless your doctor tells you. If you are not clear about the directions, ask your doctor or pharmacist.

Take APO-DILTIAZ CD exactly as your doctor tells you.

- APO-DILTIAZ CD is taken once a day.
- Dosage should be individualised.

**Swallow capsules whole.** DO NOT chew or crush APO-DILTIAZ CD capsules.

### Usual Adult Dose:

#### Angina:

**Starting dose:** 120 mg to 180 mg once a day. Dose may be slowly (over 7 to 14 days) increased up to 360 mg a day. Always follow your doctor's instructions.

#### High blood pressure:

**Usual starting doses:** 180 to 240 mg once a day. 120 mg a day may be used in some patients.

**Maximum dose:** 360 mg a day.

### Overdose:

If you think you have taken too much APO-DILTIAZ CD, contact a health care professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

### Missed Dose:

If a dose of this medication has been missed, it should be taken as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM:

Side effects may include:

- Headache, dizziness, malaise;
- Nausea (feeling like vomiting);
- Flushing (facial redness) or feeling unusually warm;
- Unusual tiredness and weakness;
- Upset stomach.

APO-DILTIAZ CD can cause abnormal blood results. Your doctor will decide when to perform blood tests and will interpret the results.

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
<b>Symptom / effect</b>		<b>Talk with your healthcare professional</b>		<b>Stop taking drug and seek immediate medical help</b>
		<b>Only if severe</b>	<b>In all cases</b>	
<b>Common</b>	<b>Low Blood Pressure:</b> dizziness, fainting, light-headedness. May occur when you go from lying or sitting to standing up.	√		
	<b>Fast, slow, or irregular heartbeat</b>		√	
	<b>Peripheral edema:</b> swelling of the ankles	√		
	<b>Respiratory tract infection:</b> pharyngitis, rhinitis		√	
	<b>Allergic Reaction:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your healthcare professional		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Uncommon	<b>Depression:</b> low mood, lack of interest in usual activities, change in sleep and appetite.	√		
	<b>Heart block:</b> A disease in the electrical system of the heart causing lightheaded ness, fainting and irregular heartbeat.			√
	<b>Heart Attack:</b> shortness of breath, chest pain			√
	<b>Angina:</b> Chest pain		√	
	<b>Heart Failure:</b> shortness of breath, leg swelling, and exercise intolerance		√	
	<b>Eye Problems:</b> decreased vision, irritation, sore red eyes	√		
	<b>Increased blood sugar:</b> frequent urination, thirst, and hunger	√		
Rare	<b>Liver Disorder:</b> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your healthcare professional		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Unknown	<b>Serious Skin Reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, hypersensitivity Syndrome):</b> any combination of itchy skin rash, redness, blistering and peeling of the skin and /or of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or joint pain, yellowing of the skin or eyes, dark urine.			√

***This is not a complete list of side effects. For any unexpected effects while taking APO-DILTIAZ CD, contact your doctor or pharmacist.***

## HOW TO STORE IT:

Store at room temperature 15°C to 30°C. Protect unit dose packages from humidity and light.

**Keep out of sight and reach of children.**

## REPORTING SIDE EFFECTS

### REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting](#) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

Note: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

## MORE INFORMATION:

**If you want more information about APO-DILTIAZ CD:**

- Talk to your healthcare professional

- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>). Find the Consumer Information on the manufacturer's website <http://www.apotex.ca/products>, or by calling 1-800-667-4708.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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## Patient Medication Information: APO-DILTIAZ:

### **IMPORTANT: PLEASE READ**

Read this carefully before you start taking APO-DILTIAZ and each time you get a refill. This leaflet is a summary and will not tell you everything about APO-DILTIAZ. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about APO-DILTIAZ.

### **ABOUT THIS MEDICATION:**

#### **What the medication is used for:**

APO-DILTIAZ is used for:

- the management of angina resulting from coronary artery spasm
- the management of effort-associated **angina** (chest pain)

#### **What it does:**

APO-DILTIAZ belongs to the group of drugs called "calcium channel blockers" or "calcium antagonists".

APO-DILTIAZ relaxes the arteries, thereby lowering blood pressure.

APO-DILTIAZ reduces the amount of oxygen that your heart muscle needs. This helps control chest pain.

#### **When it should not be used:**

Do not use APO-DILTIAZ if:

- You are pregnant or plan to become pregnant.
- You are breastfeeding.
- You have a known allergy to diltiazem or to any of the non-medicinal ingredients.
- You have very low blood pressure (<90 mmHg systolic).
- You have very slow heartbeat (40 beats/minute or less)
- You have heart rhythm disorders in the absence of a pacemaker.
- You have severe heart failure with fluid in the lungs.
- You are taking a medicine called dantrolene used for severe muscle spasms or severe fever.
- You are using ivabradine

#### **What the medicinal ingredient is:**

Diltiazem Hydrochloride

#### **What the non-medicinal ingredients are:**

colloidal silicon dioxide, FD&C blue #1 (30 mg tablet only), FD&C yellow #6 (60 mg tablet only), D&C yellow #10, hydroxypropyl methylcellulose, lactose, magnesium stearate, polyethylene glycol and titanium dioxide

## What dosage forms it comes in:

Tablets: 30 mg and 60 mg.

## WARNINGS AND PRECAUTIONS:

### BEFORE you use APO-DILTIAZ talk to your doctor or pharmacist if:

- You have very low blood pressure.
- You have ever had a bad or unusual reaction to any drug containing diltiazem in the past.
- You have heart, liver, or kidney disease.
- You have high blood sugar or diabetes.
- You are 65 years or older.
- You have a history of heart failure, new shortness of breath, slow heartbeat or low blood pressure. Cases of kidney injury in patients with such conditions have been reported.

## INTERACTIONS WITH THIS MEDICATION:

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

Additional monitoring of your dose or condition may be needed if you are taking other drugs.

The following may interact with APO-DILTIAZ:

- Antifungal medications with a name ending in azole;
- Medications used to control the immune system such as cyclosporine;
- Certain antibiotics should not be taken with APO-DILTIAZ such as erythromycin, rifampin. Check with your pharmacist if not sure;
- Sleeping pills such as benzodiazepines (midazolam, triazolam);
- Other blood pressure medications: alpha antagonists, beta-blockers;
- Heart medications: Amiodarone, digoxin, digitalis, flecainide, nifedipine, propafenone, quinidine, verapamil; ivabradine
- Anaesthetics;
- Lithium and imipramine used for some types of mental illness;
- Drugs that dilate the blood vessels: short and long acting nitrates;
- Medications used to control seizures: carbamazepine, phenobarbital, phenytoin;
- Warfarin used as anticoagulant;
- Cholesterol lowering medications: statins;
- Theophylline used for breathing problems;
- Terfenadine or ranitidine used for allergies;
- Medications used to control stomach ulcers such as cimetidine will increase the effects of APO-DILTIAZ
- Multivitamins with minerals (calcium-containing products);
- Drugs to treat inflammation: corticosteroids, methylprednisolone;
- Dantrolene used for severe muscle spasms or severe fever.
- Acetylsalicylic acid (Aspirin) or antiplatelet drugs such as ticagrelor, cilostazol, clopidogrel, dipyridamole, ticlopidine.



- X-Ray contrast agents.

**Alcohol** may cause low blood pressure and dizziness when you go from lying or sitting to standing up. This can especially occur after the first dose and when the dose is increased. Tell your doctor if you experience dizziness, light-headedness, fainting, decreased blood pressure or increased heart rate.

**Grapefruit juice** when consumed too often while taking APO-DILTIAZ may cause headache, irregular heartbeat, edema (swelling), unexplained weight gain, and chest pain. Tell your doctor if this happens to you. Your doctor may recommend that grapefruit juice be avoided if this happens to you.

## PROPER USE OF THIS MEDICATION:

Do not miss doses or take extra doses, unless your doctor tells you. If you are not clear about the directions, ask your doctor or pharmacist.

Take APO-DILTIAZ exactly as your doctor tells you.

APO-DILTIAZ is taken once a day.

Dosage should be individualised.

### Usual Adult Dose:

#### Angina

**Starting dose:** 30 mg 4 times daily. Dose may be slowly increased up to 240 mg (given in 3-4 equally divided doses) at one to two day intervals. Always follow your doctor's instructions.

### Overdose:

If you think you have taken too much APO-DILTIAZ, contact a health care professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

### Missed Dose:

If a dose of this medication has been missed, it should be taken as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM:

Side effects may include:

- Headache, dizziness, malaise;
- Nausea (feeling like vomiting);
- Flushing (facial redness) or feeling unusually warm;
- Unusual tiredness and weakness;
- Upset stomach.

APO-DILTIAZ can cause abnormal blood results. Your doctor will decide when to perform blood tests and will interpret the results.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM		TALK WITH YOUR HEALTHCARE PROFESSIONAL		STOP TAKING DRUG AND SEEK IMMEDIATE MEDICAL HELP
Symptom / effect		Only if severe	In all cases	Stop taking drug and seek immediate medical help
<b>Symptom / effect</b> <b>Common</b>	<b>Low Blood Pressure:</b> dizziness, fainting, light-headedness. May occur when you go from lying or sitting to standing up.	√		
	<b>Fast, slow, or irregular heartbeat</b>		√	
	<b>Peripheral edema:</b> swelling of the ankles	√		
	<b>Respiratory tract infection:</b> pharyngitis, rhinitis		√	
	<b>Allergic Reaction:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
<b>Uncommon</b>	<b>Depression:</b> low mood, lack of interest in usual activities, change in sleep and appetite.	√		
	<b>Heart block:</b> A disease in the electrical system of the heart causing lightheaded ness, fainting and irregular heartbeat.			√
	<b>Heart Attack:</b> shortness of breath, chest pain			√
	<b>Angina:</b> Chest pain		√	
	<b>Heart Failure:</b> shortness of breath, leg swelling, and exercise intolerance.		√	

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
<b>Symptom / effect</b>		<b>Talk with your healthcare professional</b>		<b>Stop taking drug and seek immediate medical help</b>
		<b>Only if severe</b>	<b>In all cases</b>	
	<b>Eye Problems:</b> decreased vision, irritation, sore red eyes	√		
	<b>Increased blood sugar:</b> frequent urination, thirst, and hunger	√		
<b>Rare</b>	<b>Liver Disorder:</b> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		√	
<b>Unknown</b>	<b>Serious Skin Reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, hypersensitivity Syndrome):</b> any combination of itchy skin rash, redness, blistering and peeling of the skin and /or of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or joint pain, yellowing of the skin or eyes, dark urine.			√

*This is not a complete list of side effects. For any unexpected effects while taking APO-DILTIAZ, contact your doctor or pharmacist.*

## HOW TO STORE IT:

Store at room temperature 15°C to 30°C. Protect unit dose packages from humidity and light.

**Keep out of sight and reach of children.**

## REPORTING SIDE EFFECTS

### REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting](#) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

Note: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

## MORE INFORMATION:

### If you want more information about APO-DILTIAZ:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>). Find the Consumer Information on the manufacturer's website <http://www.apotex.ca/products>, or by calling 1-800-667-4708.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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## Patient Medication Information: APO-DILTIAZ SR:

### IMPORTANT: PLEASE READ

Read this carefully before you start taking APO-DILTIAZ SR and each time you get a refill. This leaflet is a summary and will not tell you everything about APO-DILTIAZ SR. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about APO-DILTIAZ SR.

## ABOUT THIS MEDICATION:

### What the medication is used for:

APO-DILTIAZ SR is used for:

- the management of effort associated **angina** (chest pain)
- the treatment of mild to moderate **high blood pressure**.

APO-DILTIAZ SR should normally be used in those patients in whom treatment with other blood pressure reduction medications has been ineffective, or have been associated with unacceptable side effects.

### What it does:

APO-DILTIAZ SR belongs to the group of drugs called "calcium channel blockers" or "calcium antagonists".

APO-DILTIAZ SR relaxes the arteries, thereby lowering blood pressure.

APO-DILTIAZ SR reduces the amount of oxygen that your heart muscle needs. This helps control chest pain.

### When it should not be used:

Do not use APO-DILTIAZ SR if:

- You are pregnant or plan to become pregnant.
- You are breastfeeding.

- You have a known allergy to diltiazem or to any of the non-medicinal ingredients.
- You have very low blood pressure (<90 mmHg systolic).
- You have very slow heartbeat (40 beats/minute or less)
- You have heart rhythm disorders in the absence of a pacemaker.
- You have severe heart failure with fluid in the lungs.
- You are taking a medicine called dantrolene used for severe muscle spasms or severe fever.
- You are using ivabradine

### **What the medicinal ingredient is:**

Diltiazem Hydrochloride

### **What the non-medicinal ingredients are:**

Eudragit, methylcellulose, microcrystalline cellulose, polysorbate 80, talc and tributyl citrate. The capsule shell contains the non-medicinal ingredients gelatin, titanium dioxide, FD&C blue #1, FD&C red #40, FD&C yellow #6 and D&C yellow #10.

### **What dosage forms it comes in:**

Capsules: 60 mg, 90 mg and 120 mg.

## **WARNINGS AND PRECAUTIONS:**

### **BEFORE you use APO-DILTIAZ SR talk to your doctor or pharmacist if:**

- You have very low blood pressure.
- You have ever had a bad or unusual reaction to any drug containing diltiazem in the past.
- You have heart, liver, or kidney disease.
- You have high blood sugar or diabetes.
- You are 65 years or older.
- You have a history of heart failure, new shortness of breath, slow heartbeat or low blood pressure. Cases of kidney injury in patients with such conditions have been reported.

## **INTERACTIONS WITH THIS MEDICATION:**

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

Additional monitoring of your dose or condition may be needed if you are taking other drugs.

The following may interact with APO-DILTIAZ SR:

- Antifungal medications with a name ending in azole;
- Medications used to control the immune system such as cyclosporine;
- Certain antibiotics should not be taken with APO-DILTIAZ SR such as erythromycin, rifampin. Check with your pharmacist if not sure;
- Sleeping pills such as benzodiazepines (midazolam, triazolam);
- Other blood pressure medications: alpha antagonists, beta-blockers;
- Heart medications: Amiodarone, digoxin, digitalis, flecainide, nifedipine, propafenone, quinidine, verapamil; ivabradine

- Anaesthetics;
- Lithium and imipramine used for some types of mental illness;
- Drugs that dilate the blood vessels: short and long acting nitrates;
- Medications used to control seizures: carbamazepine, phenobarbital, phenytoin;
- Warfarin used as anticoagulant;
- Cholesterol lowering medications: statins;
- Theophylline used for breathing problems;
- Terfenadine or ranitidine used for allergies;
- Medications used to control stomach ulcers such as cimetidine will increase the effects of APO-DILTIAZ SR;
- Multivitamins with minerals (calcium-containing products);
- Drugs to treat inflammation: corticosteroids, methylprednisolone;
- Dantrolene used for severe muscle spasms or severe fever.
- Acetylsalicylic acid (Aspirin) or antiplatelet drugs such as ticagrelor, cilostazol, clopidogrel, dipyridamole, ticlopidine.
- X-Ray contrast agents.

**Alcohol** may cause low blood pressure and dizziness when you go from lying or sitting to standing up. This can especially occur after the first dose and when the dose is increased. Tell your doctor if you experience dizziness, light-headedness, fainting, decreased blood pressure or increased heart rate.

**Grapefruit juice** when consumed too often while taking APO-DILTIAZ SR may cause headache, irregular heartbeat, edema (swelling), unexplained weight gain, and chest pain. Tell your doctor if this happens to you. Your doctor may recommend that grapefruit juice be avoided if this happens to you.

## PROPER USE OF THIS MEDICATION:

Do not miss doses or take extra doses, unless your doctor tells you. If you are not clear about the directions, ask your doctor or pharmacist.

Take APO-DILTIAZ SR exactly as your doctor tells you.

APO-DILTIAZ SR is taken once a day.

Dosage should be individualised.

**Swallow capsules whole.** DO NOT chew or crush APO-DILTIAZ SR capsules.

### Usual Adult Dose:

#### Angina

120 to 360 mg/day. **Initiation of treatment and individual titration of dosage should be carried out using the conventional tablets.** Always follow your doctor's instructions.

#### High blood pressure

**Usual dose:** 120 to 360 mg per day administered in two equally divided doses.

**Maximum dose:** 360 mg a day.

### Overdose:

If you think you have taken too much APO-DILTIAZ SR, contact a health care professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

### Missed Dose:

If a dose of this medication has been missed, it should be taken as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM:

Side effects may include:

- Headache, dizziness, malaise;
- Nausea (feeling like vomiting);
- Flushing (facial redness) or feeling unusually warm;
- Unusual tiredness and weakness;
- Upset stomach.

APO-DILTIAZ SR can cause abnormal blood results. Your doctor will decide when to perform blood tests and will interpret the results.

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
<b>Symptom / effect</b>		<b>Talk with your healthcare professional</b>		<b>Stop taking drug and seek immediate medical help</b>
		<b>Only if severe</b>	<b>In all cases</b>	
<b>Common</b>	<b>Low Blood Pressure:</b> dizziness, fainting, light-headedness.  May occur when you go from lying or sitting to standing up.	√		
	<b>Fast, slow, or irregular heartbeat</b>		√	
	<b>Peripheral edema:</b> swelling of the ankles	√		
	<b>Respiratory tract infection:</b> pharyngitis, rhinitis		√	
	<b>Allergic Reaction:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your healthcare professional		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Uncommon	<b>Depression:</b> low mood, lack of interest in usual activities, change in sleep and appetite.	√		
	<b>Heart block:</b> A disease in the electrical system of the heart causing lightheaded ness, fainting and irregular heartbeat.			√
	<b>Heart Attack:</b> shortness of breath, chest pain			√
	<b>Angina:</b> Chest pain		√	
	<b>Heart Failure:</b> shortness of breath, leg swelling, and exercise intolerance.		√	
	<b>Eye Problems:</b> decreased vision, irritation, sore red eyes	√		
	<b>Increased blood sugar:</b> frequent urination, thirst, and hunger	√		
Rare	<b>Liver Disorder:</b> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		√	



<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
<b>Symptom / effect</b>		<b>Talk with your healthcare professional</b>		<b>Stop taking drug and seek immediate medical help</b>
		<b>Only if severe</b>	<b>In all cases</b>	
<b>Unknown</b>	<b>Serious Skin Reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, hypersensitivity Syndrome):</b> any combination of itchy skin rash, redness, blistering and peeling of the skin and /or of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or joint pain, yellowing of the skin or eyes, dark urine.			√

*This is not a complete list of side effects. For any unexpected effects while taking APO-DILTIAZ SR, contact your doctor or pharmacist.*

## HOW TO STORE IT:

Store at room temperature 15°C to 30°C. Protect unit dose packages from humidity and light.

**Keep out of sight and reach of children.**

## REPORTING SIDE EFFECTS

<b>REPORTING SIDE EFFECTS</b>
<p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> <li>• Visiting the Web page on <a href="#">Adverse Reaction Reporting</a> for information on how to report online, by mail or by fax; or</li> <li>• Calling toll-free at 1-866-234-2345.</li> </ul> <p>Note: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</p>

## MORE INFORMATION:

**If you want more information about APO-DILTIAZ SR:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>). Find the Consumer Information on the manufacturer's website <http://www.apotex.ca/products>, or by calling 1-800-667-4708.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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