

PART III: CONSUMER INFORMATION

Pr ADALAT® XL®

Nifedipine extended-release tablets, Bayer
Standard

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ADALAT XL. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ADALAT XL is used for:

Chronic Stable Angina

ADALAT XL may be used in patients to manage chronic stable angina.

High Blood Pressure

ADALAT XL may be used in patients to manage mild to moderate high blood pressure.

What it does:

ADALAT XL manages high blood pressure and chronic stable angina. It is called a “calcium channel blocker”. Although the mechanism by which ADALAT XL reduces blood pressure and relieves angina is not fully known, it is believed to be brought about as a result of the ability of ADALAT XL to widen and relax blood vessels.

When it should not be used:

You should not use ADALAT XL if you:

- are allergic to nifedipine, or to any of the nonmedicinal ingredients
- have allergies to other drugs that are similar to ADALAT XL (dihydropyridines calcium antagonists)
- are pregnant, breastfeeding, or a woman of childbearing age
- have severe low blood pressure or are in shock
- are taking the medicine rifampicin
- have a Kock pouch (a pouch or reservoir created inside the abdomen with a portion of large

bowel for which a tube or catheter can be inserted through the abdominal wall to drain the reservoir)

- have moderate to severe liver disease
- have severe narrowing in your stomach or intestines

What the medicinal ingredient is:

Nifedipine

What the nonmedicinal ingredients are:

Cellulose acetate, hydroxypropyl cellulose, hypromellose, magnesium stearate, pharmaceutical shellac, polyethylene glycol 3350, polyethylene oxide, propylene glycol, red ferric oxide, sodium chloride, synthetic black iron oxide, and titanium dioxide.

What dosage forms it comes in:

The medication in ADALAT XL is packed within a nonabsorbable shell that has been specially designed to slowly release the drug at a constant rate over time so that the body can absorb it. The shell will pass into your stool after your body has absorbed the medicine. This is normal and is nothing to worry about.

Extended release tablets 20 mg, 30 mg, 60 mg

WARNING AND PRECAUTIONS

Before you use ADALAT XL, talk to your doctor or pharmacist if you:

- are pregnant or breastfeeding
- have heart failure, liver disease, kidney disease, or coronary artery disease
- have unstable angina (sudden chest pain that occurs at rest and gets increasingly worse)
- have recently had a heart attack or you have a heart condition called aortic stenosis (narrowing of a valve in your heart)
- have pre-existing gastrointestinal narrowing disease
- have diabetes
- have a history of poor blood circulation in the brain.
- are scheduled for surgery with a general anaesthetic
- are a man and have been repeatedly unsuccessful at fathering a child by in vitro fertilization

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to ADALAT XL. Your ability to drive or to operate machinery may be impaired particularly at the start of treatment, when changing the medication, or in combination with alcohol.

INTERACTIONS WITH THIS MEDICATION

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

The following may interact with ADALAT XL:

Drug-Drug interactions

- azole antifungals (ketoconazole, itraconazole or fluconazole)
- cyclosporine
- carbamazepine
- cimetidine, ranitidine
- diltiazem
- digoxin
- erythromycin, clarithromycin
- fluoxetine
- HIV protease inhibitors (indinavir, nelfinavir, ritonavir, saquinavir, or amprenavir)
- nefazodone
- phenobarbital
- phenytoin
- quinidine
- quinupristin/dalfopristin
- tacrolimus
- rifampicin
- valproic acid
- blood pressure lowering drugs including beta blockers
- benzodiazepines
- cisapride
- coumarin anticoagulants
- warfarin
- imipramine
- propafenone
- terfenadine

Drug-Food interactions

DO NOT eat grapefruit or drink grapefruit juice while you are using this medicine.

Drug-Herb Interactions

Saint John's Wort

PROPER USE OF THIS MEDICATION

You must swallow ADALAT XL tablets whole. Do not bite, chew, divide or crush the tablets. This can result in a large immediate release of the drug.

You can take this medication with or without food.

Your doctor will tell you how much of this medicine to use and how often. Your dose may need to be changed several times in order to find out what works best for you. Follow your doctor's treatment plan exactly so that you reach and maintain your blood pressure targets, and get relief from angina. Do not use more medicine or use it more often than your doctor tells you to.

Do not discontinue a medication on your own. If you have a problem with a drug, always tell your doctor.

Dosage should be individualised.

Usual dose:

Doses greater than 90 mg a day are not recommended.

Chronic Stable Angina

- Starting Dose: 30 mg once a day

High Blood Pressure

- Starting Dose: 20 mg to 30 mg once a day
- Usual Maintenance Dose: 30 to 60 mg once a day.

Overdose

In case of accidental overdose call your healthcare professional or poison control centre immediately, even if there are no symptoms.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose

If you miss a dose or forget to use your medicine, use it as soon as you can. If it is almost time for your next dose, wait until then to use the medicine and skip the missed dose. Do not use extra medicine to make up for a missed dose unless instructed by your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- headaches, anxiety, numbness and/or pins and needles (hypoesthesia), confusion, insomnia, nervousness, weakness, excessive muscle movement
- dizziness, fatigue
- nausea, upset stomach, indigestion, dry mouth
- enlargement of the gums
- muscle or joint pain, leg cramps, back pain
- rash, itch, sensitivity to the sun
- impotence, breast enlargement in men, menstrual disorder for women
- abnormally large production of urine, the need to urinate at night, lack of urine or incontinence
- eye pain

If any of these affects you severely, tell your doctor, nurse or pharmacist.

ADALAT XL can cause abnormal blood test 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

Symptom / Effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Wheezing or trouble breathing			✓
	Angina Pectoris: chest tightness, chest pain			✓
	Edema: swelling of tissues of the hands, ankles, feet or legs	✓		
	Abdominal cramps		✓	

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

Symptom / Effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
	Vomiting		✓	
	Diarrhea		✓	
	Irregular heartbeat			✓
	Fast heartbeat			✓
Uncommon	Constipation		✓	
	Allergic Reactions: difficulty breathing or swallowing, rash or hives (redness, intense itching and burning), swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs			✓
	Low Blood Pressure: dizziness, fainting, lightheadedness		✓	
Unknown	Liver Disorder (hepatitis and cholestasis): yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
	Myocardial Infarction: heart attack			✓

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

Symptom / Effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Toxic Epidermal Necrolysis: severe skin peeling, especially in the mouth and eyes			✓
Intestinal (bowel) Obstruction: swollen, hard or painful abdomen, vomiting, and constipation/no stools.			✓

This is not a complete list of side effects. For any unexpected effects while taking ADALAT XL, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (15 to 30°C). Protect from light and humidity.

Keep out of reach and sight of children.

Never share your medicine with anyone.

Ask your healthcare professional about the best way to dispose of any outdated medicine or medicine no longer needed.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:
 - Canada Vigilance Program
 - Health Canada
 - Postal Locator 0701E
 - Ottawa, Ontario
 - K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Website at www.healthcanada.gc.ca/medeffect.

Note: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your health professional or pharmacist first, or Bayer Medical Information at 1-800-265-7382 or canada.medinfo@bayer.com.

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.bayer.ca> or by contacting the manufacturer at the above-mentioned phone number and e-mail address.

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