

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE  
PATIENT MEDICATION INFORMATION**

**Pr**AMITRIPTYLINE – 10

**Pr**AMITRIPTYLINE – 25

**Pr**AMITRIPTYLINE – 50

Amitriptyline Hydrochloride Tablets, USP

Read this carefully before you start taking AMITRIPTYLINE and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about AMITRIPTYLINE.

**Serious Warnings and Precautions**

- **Electrical problems with the heart (QT interval prolongation)** - A heart problem called “prolonged QT interval” (which is shown on your electrocardiogram, ECG) and problems with the heart rhythm (rapid or irregular heart beat) have been reported in people taking AMITRIPTYLINE. This can be serious and cause sudden death. If you experience dizziness, fainting, a rapid heart beat or heart palpitations while taking AMITRIPTYLINE get immediate medical help.
- **Thoughts of suicide and worsening of your depression** - If you are depressed, you can sometimes have thoughts of harming or killing yourself. These thoughts may be increased when first starting antidepressants like AMITRIPTYLINE, since these medicines take time to work. If you have thoughts of suicide or harming yourself while taking AMITRIPTYLINE get immediate medical help.

**What AMITRIPTYLINE is used for?**

AMITRIPTYLINE is used in adults to treat depression.

**How does AMITRIPTYLINE work?**

AMITRIPTYLINE is an antidepressant that belongs to a group of medicines known as tricyclic antidepressants. It is not known exactly how AMITRIPTYLINE works. It is thought to increase the concentration of certain chemicals in the brain which can help with the symptoms of depression.

**What are the ingredients in AMITRIPTYLINE?**

Medicinal ingredients: Amitriptyline Hydrochloride

Non-Medicinal ingredients: Colloidal Silicon Dioxide, Croscarmellose Sodium, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol/Macrogol and Titanium Dioxide

In addition to the above ingredients the tablets also contain the following non-medical ingredients:

10 mg Tablet: FD&C blue No. 1 Aluminum Lake.

25 mg Tablet: FD&C Blue No. 2 Aluminum Lake, FD&C Yellow No.5 (Tartrazine) Aluminum Lake.

50 mg Tablet: Black Iron Oxide, Red Iron Oxide, and Yellow Iron Oxide.

**AMITRIPTYLINE comes in the following dosage forms:**

Tablets: 10 mg, 25 mg, 50 mg

**Do not use AMITRIPTYLINE if:**

- are allergic to amitriptyline or any of the other ingredients of this medicine
- have recently experienced a heart attack or heart failure
- have a severe liver disease
- are taking a medicine known as monoamine oxidase inhibitors (MAOIs), also used to treat depression
- have taken a MAOI within the last 14 days

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take AMITRIPTYLINE. Talk about any health conditions or problems you may have, including if you:**

- have heart problems such as changes in heart rhythm which are seen on an electrocardiogram (ECG), heart block, or heart disease
- have a slow heart beat (bradycardia)
- have glaucoma or increased pressure in your eyes
- have liver problems.
- have or have had a history of epilepsy, seizures or fits.
- have difficulty passing urine
- have an enlarged prostate
- have thyroid problems or are taking thyroid medication
- have bipolar disorder
- have schizophrenia
- have a blood disease with abnormal particles in the blood called “blood discrasia”
- have problems with your electrolytes including low levels of calcium, potassium or magnesium in your blood
- are dehydrated or suffer from excessive sweating, vomiting or diarrhea, or an eating disorder
- are undergoing electroconvulsive therapy (ECT) to treat mental health problems
- are scheduled to have surgery
- are pregnant or planning to become pregnant
- are breastfeeding or planning to breastfeed. You and your healthcare professional should decide if you should breastfeed or take AMITRIPTYLINE. You should not do both.
- are 65 years of age or older

**Other warnings you should know about:**

**Driving and Using Machines:** AMITRIPTYLINE can affect your ability to drive and operate machinery. Do not drive or operate machinery until you know how AMITRIPTYLINE affects you.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with AMITRIPTYLINE:**

- monoamine oxidase inhibitors (MAOIs) also used to treat depression, such as selegiline and phenelzine
- medicines such as adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine which may be found in cough and cold medication and anesthetics used in surgery
- other medicines used to treat depression such as other tricyclic antidepressants and selective serotonin reuptake inhibitors (SSRIs) like fluoxetine, sertraline, and paroxetine.
- anticholinergic drugs such as certain medicines used to treat glaucoma, Parkinson's disease and stomach and gut problems, like atropine and hyoscyamine
- cimetidine, used to treat stomach ulcers
- sedatives used to treat anxiety and sleep disorders
- disulfiram, used to treat alcoholism
- medicines used to treat schizophrenia and other mental health problems, such as primozide, sertindole and haloperidol
- high blood pressure medications such as clonidine and methyldopa
- medicines used to treat irregular heartbeat such as quinidine, propafenone, flecainide, disopyramide, amiodarone and sotalol
- astemizole and terfenadine, used to treat allergies and hayfever
- cisapride, used to treat certain types of indigestion
- methadone, used to treat pain and for detoxification
- diuretics or "water pills" such as furosemide
- thyroid medication
- medicines used to treat bacterial infections such as erythromycin, clarithromycin, tacrolimus and ciprofloxacin.
- medicines used to treat malaria such as quinine, halofantrine and chloroquine
- medicines used to treat fungal infections such as ketoconazole
- domperidone used to treat nausea and vomiting and increase milk supply in breastfeeding mothers
- medicines used to treat nausea and vomiting in cancer patients such as ondansetron
- medicines used to treat cancer such as sunitinib and vorinostat
- medicines used to treat breathing problems like asthma and COPD such as salmeterol

You should avoid drinking alcohol while taking AMITRIPTYLINE.

**How to take AMITRIPTYLINE:**

- Always take AMITRIPTYLINE exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

- Swallow the tablets whole with water. Do not chew them.

Even if you feel better, do not stop taking AMITRIPTYLINE without first talking to your healthcare professional. Stopping AMITRIPTYLINE suddenly can cause serious withdrawal symptoms.

**Usual adult dose:**

The recommended initial dose is 75 mg daily in three divided doses of 25 mg.

Depending on how you respond, your doctor may gradually increase your dose.

Maximum daily dose : 150 mg a day.

**Overdose:**

If you think you have taken too much AMITRIPTYLINE, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forget to take AMITRIPTYLINE, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose. Do not take two doses at the same time to make up for a missed dose.

**What are possible side effects from using AMITRIPTYLINE?**

These are not all the possible side effects you may feel when taking AMITRIPTYLINE. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- nausea, vomiting
- stomach pain
- constipation
- diarrhea
- drowsiness
- dizziness
- fatigue
- restlessness
- headache
- dry mouth, sore mouth
- unpleasant taste in the mouth
- black tongue
- itching
- changes in weight (loss or gain)
- weakness
- increased sweating

AMITRIPTYLINE can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Mental health problems:</b> confusion, hallucinations, trouble sleeping, excitement, nightmares, problems with attention, anxiety		✓	
<b>Nervous system problems:</b> shaking, numbness and tingling of the hands and feet, clumsiness and lack of coordination, loss of balance, uncontrolled twitching or jerking, slurred speech, ringing in the ears, coma		✓	
<b>Neuroleptic malignant syndrome:</b> very high fever, irregular heartbeat, rapid breathing, muscle stiffness, altered mental state			✓
Difficulty passing urine	✓		
<b>Glaucoma:</b> increased pressure in the eye, blurred vision, eye pain		✓	
<b>Electrical problems with the heart (QT interval prolongation):</b> dizziness, fainting, fast heartbeat, palpitations			✓
<b>Heart attack:</b> chest pain, tightness or pressure that may spread to your neck, jaw or back, nausea, indigestion, shortness of breath, cold sweat, fatigue, dizziness			✓
<b>Stroke:</b> sudden numbness or weakness in the face, arm or leg, confusion, trouble speaking, blurred vision, trouble walking, dizziness, loss of balance			✓
<b>High blood pressure:</b> headache, fatigue, vision problems		✓	
<b>Heart problems (enlarged heart, heart disease):</b> weakness, fatigue, shortness of breath especially during exercise, light-headedness, chest pain, palpitations, fainting, swelling in your feet, ankles and legs		✓	
<b>Bone marrow depression:</b> easy bruising, bleeding, nose bleeds, bleeding gums, red spots on the skin, fever and chills, rash, extreme fatigue, pale skin and lips			✓
Increased sensitivity of the skin to sun	✓		

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Allergic reaction:</b> rash, hives, swelling of the face, lips and tongue or throat, difficulty swallowing or breathing.			✓
<b>Liver problems:</b> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
<b>Reproductive problems:</b> swelling of testicles, impotence in men, increase in breast tissue (in men and women), change in sex drive		✓	
<b>Increased or decreased blood sugar:</b> frequent urination, thirst, hunger, shakiness, sweating and chills, irritability, confusion, dizziness	✓		
Unusual hair loss or thinning		✓	
<b>Mania:</b> elevated or irritated mood, decreased need for sleep, racing thoughts		✓	
<b>Serotonin syndrome:</b> a combination of most or all of the following: confusion, restlessness, sweating, shaking, shivering, hallucinations, sudden jerking of the muscles, fast heartbeat			✓
<b>Seizures or fits</b>			✓
<b>New or worsened emotional or behavioural problems:</b> feeling angry, aggressive, worried, agitated, hostile or impulsive, feeling violent or suicidal, thoughts of hurting yourself or other people, feeling like you are not yourself or that you are less inhibited			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

## 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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) 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.*

## Storage:

Store between 15°C and 30°C. Keep in a tightly closed container.

Keep out of reach and sight of children.

## If you want more information about AMITRIPTYLINE:

- Talk to your healthcare professional
- Find the full prescribing information that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); or by contacting Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [info@prodoc.qc.ca](mailto:info@prodoc.qc.ca).

This leaflet was prepared by  
Pro Doc Ltée  
Laval, Québec  
H7L 3W9

Last revised: November 4, 2019