**Sheri Spirt, M.D.**
www.sherispirtmd.com
16 East 96th Street 1A
New York, NY 10128
Phone: 212 595-6901

Nortryptiline

**Warnings**

**Black Box Warnings**

In short-term studies, antidepressants increased the risk of suicidal thinking and behavior in children, adolescents, and young adults (<24 years) taking antidepressants for major depressive disorders or other psychiatric illnesses

This increase was not seen in patients aged over age 24 years; a slight decrease in suicidal thinking was seen in adults over age 65 years

In children and young adults, risks must be weighed against the benefits of taking antidepressants

Patients should be monitored closely for changes in behavior, clinical worsening, and suicidal tendencies; this should be done during the initial 1-2 months of therapy and dosage adjustments

The patient’s family should communicate any abrupt changes in behavior to the healthcare provider

Worsening behavior and suicidal tendencies that are not part of the presenting symptoms may require discontinuation of therapy

This drug is not approved for use in pediatric patients

**Contraindications**

Hypersensitivity

Any drugs or conditions that prolong QT interval

Acute recovery post-MI

Coadministration with serotonergic drugs

* Concomitant with or within 14 days of MAOIs (serotonin syndrome)
* Starting nortriptyline in a patient who is being treated with linezolid or IV methylene blue is contraindicated because of an increased risk of serotonin syndrome
* If linezolid or IV methylene blue must be administered, discontinue nortriptyline immediately and monitor for CNS toxicity; may resume nortriptyline 24 hours after last linezolid or methylene blue dose or after 2 weeks of monitoring, whichever comes first

**Cautions**

BPH

Urinary/GI retention

Hyperthyroidism

Seizure disorder

Brain tumor

Respiratory impairment

Bipolar mania

Clinical worsening and suicidal ideation may occur despite medication in adolescents and young adults (18-24 years)

Potentially life-threatening serotonin syndrome reported when coadministered with drugs that impair serotonin metabolism (in particular, MAOIs, including nonpsychiatric MAOIs, such as linezolid and IV methylene blue)

Risk of anticholinergic side effects

May cause bone marrow suppression (rare)

May cause orthostatic hypotension

Risk of mydriasis; may trigger angle closure attack in patients with angle closure glaucoma with anatomically narrow angles without a patent iridectomy

May cause sedation and impair physical or mental abilities

Withdraw gradually

Bone fractures have been associated with antidepressant treatment; consider possibility of bone fractures in patients if antidepressant treated patient presents with unexplained bone pain, swelling, bruising or point tenderness

Use with caution in patients who would not tolerate frequent hypotensive episodes, including patients with cardiovascular disease, hypovolemia or with concurrent medication that predisposes for hypotension/bradycardia

Use caution in patients with cardiovascular disease, diabetes mellitus (may alter glucose regulation), hepatic/renal impairment, and the elderly

Abrupt discontinuation or interruption of antidepressant therapy has been associated with a discontinuation syndrome, which may include vomiting, diarrhea, headaches, dizziness, chills, tremors, paresthesias, somnolence, fatigue, and sleep disturbances

May increase the risk of adverse effects associated with electroconvulsive therapy; discontinue therapy prior to electroconvulsive therapy if possible

Due to risk of drug interaction with anesthesia and of cardiac arrhythmia, discontinuation of therapy prior to elective surgery recommended

### Absorption

Onset of action: 1-3 weeks

Peak plasma time: 7-8.5 hr

Steady-state therapeutic plasma concentration: 50-150 ng/mL

### Distribution

Protein bound: 93-95%

Vd: 21 L/kg

### Metabolism

Hepatic CYP2D6

### Elimination

Half-life: 28-31 hr

Excretion: Urine, feces

IMPORTANT: HOW TO USE THIS INFORMATION: This is a summary and does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

NORTRIPTYLINE - ORAL

(nor-TRIP-ti-leen)

COMMON BRAND NAME(S): Aventyl, Pamelor

WARNING: Antidepressant medications are used to treat a variety of conditions, including depression and other mental/mood disorders. These medications can help prevent suicidal thoughts/attempts and provide other important benefits. However, studies have shown that a small number of people (especially people younger than 25) who take antidepressants for any condition may experience worsening depression, other mental/mood symptoms, or suicidal thoughts/attempts. Therefore, it is very important to talk with the doctor about the risks and benefits of antidepressant medication (especially for people younger than 25), even if treatment is not for a mental/mood condition. Tell the doctor right away if you notice worsening depression/other psychiatric conditions, unusual behavior changes (including possible suicidal thoughts/attempts), or other mental/mood changes (including new/worsening anxiety, panic attacks, trouble sleeping, irritability, hostile/angry feelings, impulsive actions, severe restlessness, very rapid speech). Be especially watchful for these symptoms when a new antidepressant is started or when the dose is changed.

USES: This medication is used to treat mental/mood problems such as depression. It may help improve mood and feelings of well-being, relieve anxiety and tension, and increase your energy level. This medication belongs to a class of medications called tricyclic antidepressants. It works by affecting the balance of certain natural chemicals (neurotransmitters) in the brain.

OTHER USES: This section contains uses of this drug that are not listed in the approved professional labeling for the drug but that may be prescribed by your health care professional. Use this drug for a condition that is listed in this section only if it has been so prescribed by your health care professional.

This medication may also be used to help quit smoking.

HOW TO USE: Read the Medication Guide provided by your pharmacist before you start taking nortriptyline and each time you get a refill. If you have any questions, consult your doctor or pharmacist.

Take this medication by mouth, usually 1 to 4 times daily or as directed by your doctor. If you are using the liquid form, measure the dose carefully using a special measuring device/spoon. Do not use a household spoon because you may not get the correct dose.

The dosage is based on your medical condition and response to treatment. To reduce your risk of side effects (such as dry mouth, dizziness), your doctor may direct you to start this medication at a low dose and gradually increase your dose. Follow your doctor's instructions carefully.

Take this medication regularly in order to get the most benefit from it. To help you remember, take it at the same time(s) each day. Do not increase your dose or use this drug more often or for longer than prescribed. Your condition will not improve any faster, and your risk of side effects will increase.

It is important to continue taking this medication even if you feel well. Do not stop taking this medication without consulting your doctor. Some conditions may become worse when this drug is suddenly stopped. Also, you may experience symptoms such as mood swings, headache, tiredness, and sleep change. To prevent these symptoms while you are stopping treatment with this drug, your doctor may reduce your dose gradually. Consult your doctor or pharmacist for more details. Report any new or worsening symptoms right away.

This medication may not work right away. You may see some benefit within a week. However, it may take up to 4 weeks before you feel the full effect.

Tell your doctor if your condition persists or worsens (such as your feelings of sadness get worse, or you have thoughts of suicide).

SIDE EFFECTS: See also Warning section.

Drowsiness, dizziness, dry mouth, blurred vision, constipation, weight gain, or trouble urinating may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

To reduce the risk of dizziness and lightheadedness, get up slowly when rising from a sitting or lying position.

To relieve dry mouth, suck on (sugarless) hard candy or ice chips, chew (sugarless) gum, drink water, or use a saliva substitute.

To prevent constipation, maintain a diet adequate in fiber, drink plenty of water, and exercise. If you become constipated while using this drug, consult your pharmacist for help in selecting a laxative.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if any of these rare but serious side effects occur: persistent heartburn, shaking, mask-like facial expressions, muscle spasms, severe stomach/abdominal pain, decreased sexual ability/desire, enlarged/painful breasts.

This medication may increase serotonin and rarely cause a very serious condition called serotonin syndrome/toxicity. The risk increases if you are also taking other drugs that increase serotonin, so tell your doctor or pharmacist of all the drugs you take (see Drug Interactions section). Get medical help right away if you develop some of the following symptoms: fast heartbeat, hallucinations, loss of coordination, severe dizziness, severe nausea/vomiting/diarrhea, twitching muscles, unexplained fever, unusual agitation/restlessness.

Get medical help right away if you have any very serious side effects, including: severe dizziness, fast/irregular heartbeat, fainting, seizures, eye pain/swelling/redness, widened pupils, vision changes (such as seeing rainbows around lights at night).

A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS: See also Warning section.

Before taking nortriptyline, tell your doctor or pharmacist if you are allergic to it; or to other tricyclic antidepressants (such as amitriptyline); or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: breathing problems, liver problems, recent heart attack, problems urinating (such as due to enlarged prostate), overactive thyroid (hyperthyroidism), personal or family history of glaucoma (angle-closure type), personal or family history of mental/mood conditions (such as bipolar disorder, psychosis), family history of suicide, seizures, conditions that may increase your risk of seizures (such as other brain disease, alcohol withdrawal).

Nortriptyline may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can rarely cause serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting) that need medical attention right away.

The risk of QT prolongation may be increased if you have certain medical conditions or are taking other drugs that may cause QT prolongation. Before using nortriptyline, tell your doctor or pharmacist of all the drugs you take and if you have any of the following conditions: certain heart problems (heart failure, slow heartbeat, QT prolongation in the EKG), family history of certain heart problems (QT prolongation in the EKG, sudden cardiac death).

Low levels of potassium or magnesium in the blood may also increase your risk of QT prolongation. This risk may increase if you use certain drugs (such as diuretics/"water pills") or if you have conditions such as severe sweating, diarrhea, or vomiting. Talk to your doctor about using nortriptyline safely.

This drug may make you drowsy or dizzy or cause blurred vision. Do not drive, use machinery, or do any activity that requires alertness or clear vision until you are sure you can perform such activities safely. Limit alcoholic beverages.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

This medication may make you more sensitive to the sun. Avoid prolonged sun exposure, tanning booths, and sunlamps. Use a sunscreen and wear protective clothing when outdoors.

The liquid form of this medication may contain alcohol. Caution is advised if you have diabetes, alcohol dependence, liver disease, or any other condition that requires you to limit/avoid alcohol in your diet. Ask your doctor or pharmacist about using this product safely.

If you have diabetes, this drug may make it harder to control your blood sugar levels. Monitor your blood sugar levels regularly and tell your doctor of the results. Your doctor may need to adjust your diabetes medication, exercise program, or diet.

Older adults may be more sensitive to the side effects of this drug, especially dry mouth, dizziness, confusion, difficulty urinating, and QT prolongation (see above).

During pregnancy, this medication should be used only when clearly needed. Since untreated mental/mood problems (such as depression, anxiety, panic disorder) can be a serious condition, do not stop using this medication unless directed by your doctor. If you are planning pregnancy, become pregnant, or think you may be pregnant, immediately discuss with your doctor the benefits and risks of using this medication during pregnancy.

This medication passes into breast milk and may have undesirable effects on a nursing infant. Consult your doctor before breast-feeding.

DRUG INTERACTIONS: Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: arbutamine, "blood thinners" (such as warfarin), disulfiram, thyroid supplements, anticholinergic drugs (such as benztropine, belladonna alkaloids), certain drugs for high blood pressure (drugs that work in the brain such as clonidine, guanabenz, reserpine).

Taking MAO inhibitors with this medication may cause a serious (possibly fatal) drug interaction. Avoid taking MAO inhibitors (isocarboxazid, linezolid, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranylcypromine) during treatment with this medication. Most MAO inhibitors should also not be taken for two weeks before and after treatment with this medication. Ask your doctor when to start or stop taking this medication.

The risk of serotonin syndrome/toxicity increases if you are also taking other drugs that increase serotonin. Examples include street drugs such as MDMA/"ecstasy," St. John's wort, certain antidepressants (including SSRIs such as fluoxetine/paroxetine, SNRIs such as duloxetine/venlafaxine), among others. The risk of serotonin syndrome/toxicity may be more likely when you start or increase the dose of these drugs.

Other medications can affect the removal of nortriptyline from your body, thereby affecting how nortriptyline works. These drugs include cimetidine, terbinafine, drugs to treat irregular heart rate (such as quinidine/propafenone/flecainide). This is not a complete list.

Many drugs besides nortriptyline may affect the heart rhythm (QT prolongation in the EKG), including amiodarone, cisapride, dofetilide, pimozide, procainamide, quinidine, sotalol, macrolide antibiotics (such as erythromycin), among others. Therefore, before using nortriptyline, report all medications you are currently using to your doctor or pharmacist.

Tell your doctor or pharmacist if you are taking other products that cause drowsiness, including alcohol, antihistamines (such as cetirizine, diphenhydramine), drugs for sleep or anxiety (such as alprazolam, diazepam, zolpidem), muscle relaxants, and narcotic pain relievers (such as codeine).

Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain decongestants or ingredients that cause drowsiness. Ask your pharmacist about using those products safely.

Nortriptyline is very similar to amitriptyline. Do not use medications containing amitriptyline while using nortriptyline.

OVERDOSE: If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: extreme drowsiness, hallucinations, fast/irregular heartbeat, fainting, slow/shallow breathing, seizures.

NOTES: Do not share this medication with others.

Laboratory and/or medical tests (such as EKG, liver tests, nortriptyline blood level) may be performed from time to time to monitor your progress or check for side effects. Keep all medical appointments. Consult your doctor for more details.

MISSED DOSE: If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE: Store at room temperature between 68-77 degrees F (20-25 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.