

AMITRIPTYLINE COMPOUND

What is this medicine?

Amitriptyline (a-mee-TRIP-ti-leen)

- Amitriptyline is a tricyclic antidepressant that may be prescribed to patients with mood disorders.
- It may be used to reduce discomfort caused by nerve (neuropathic) pain.
- It may also be used for other conditions as determined by your doctor.

Compounded Drug Forms: capsule, suppository, cream, gel

What should I tell my health care provider before I take this medicine?

- Allergy to amitriptyline
- Pregnant or may become pregnant; are breastfeeding
- Are scheduled to have surgery
- History of cardiovascular disease
- Have slow transit time in the gastrointestinal tract
- Have liver disease
- Have kidney disease or on dialysis
- Have urinary retention or BPH (benign prostatic hyperplasia)
- Have bipolar disorder
- Have had suicidal thoughts or behavior in the past
- Have a seizure disorder
- Have ophthalmic conditions
- Have myasthenia gravis

How should I use this medicine?

Follow the package directions provided by Belmar Pharma Solutions and by your prescriber. Your dosage is based on your medical condition and response to therapy. Follow the dosing schedule provided carefully.

Oral dosage forms may be taken with or without food. If it upsets your stomach take it with a small meal.

Topical products can be applied to the inner arm, upper thigh, back of the knee, tops of the feet and inner wrists. It is recommended to rotate sites to ensure even retention of the hormone. Cover treated skin with clothes to avoid contact with people or pets.

Vaginal preparations should be inserted using your finger or the applicator provided. Suppositories may leak and may be more convenient to use at bedtime.

What if I miss a dose?

- If you miss a dose, take it as soon as possible.
- If it is almost time for your next dose, skip the missed dose and continue with your regular dosing schedule.
- Do not take double the dose at once.

What should I watch for while using this medicine?

Belmar Pharma Solutions recommends yearly checkups with your provider including, but not limited to, a hormone level test, PAP smear and mammogram.

What may interact with this medicine?

- Drug interactions exist with this medication.
- Discuss your medication regimen with your health care provider to determine the best therapy for you.

What side effects may I notice from receiving this medicine?

Possible side effects that may occur and may go away as your body gets used to the medication include:

- Sleepiness, dizziness, fatigue, or weakness
- Headache

- Anxiety
- Feeling nervous and excitable
- Diarrhea, stomach pain, nausea, vomiting, or decrease in appetite
- Change in taste
- Dry mouth
- Mouth sores
- Weight gain or loss

Serious Side Effects:

Contact your doctor immediately or seek medical attention if you experience:

- Seizures
- Changes in mood or behavior, such as feeling depressed, nervous, restless or grouchy; having panic attacks; new or worsening changes in mood or actions; having thoughts of suicide or acting on thoughts of suicide
- Signs of high or low blood sugar
 - Fruity-smelling breath, dizziness, fast breathing, fast heartbeat, confusion, sleepiness, weakness, flushing, headache, feeling thirstier or hungrier than normal, urinating more frequently than usual, shakiness, sweating
- Hallucinations
- Trouble sleeping or bad dreams
- Ringing in the ears
- Eye pain, change in vision, or swelling or redness in or around the eye
- Unexplained bruising or bleeding, flu-like symptoms
- Abnormal burning, numbness or tingling in joints
- Signs of liver problems
 - Urine darker in color than normal, feeling tired, lack of appetite, upset stomach or stomach pain, stool that is light in color, vomiting, or yellow skin or eyes
- Difficulty controlling body movements; problems with the tongue, face, mouth, or jaw
- Weakness on one side of the body, difficulty speaking, difficulty thinking, change in balance, drooping on one side of the face, blurry vision
- Pain or pressure in the chest, fast or abnormal heartbeat
- Severe headache or dizziness, fainting, or vision changes
- Change in interest in sex or signs of other sexual problems
- Swollen testicles, swollen breasts or nipple discharge
- Change in color of the tongue
- Constipation that is severe, or stomach pain
- Changes in how you sweat

You may experience side effects not listed. Contact your doctor with questions.

An allergic reaction to this medication is unlikely but seek medical attention if it occurs. Symptoms of an allergic reaction include rash, itching, swelling, severe dizziness, trouble breathing.

Contraindications

Amitriptyline is contraindicated within 14-days of taking MAOIs (monoamine oxidase inhibitors) or cisapride, or if you have recently recovered from a heart attack.

Where should I keep my medicine?

Store at room temperature between 59- and 86-degrees F, unless otherwise specified on the packaging.

Additional Information:

- Do not share this medication with others.
- Keep out of reach of children and pets.

- If an overdose is suspected contact your local poison control center at 1-800-222-1222 or go to the nearest emergency room.

If you have any questions concerning this or any of your medications, a pharmacist is available during normal business hours to answer your questions. You may report side effects to the FDA at 1-800-FDA-1088.

Consumer Information Use and Disclaimer: This information should not be used to decide whether or not to take this medication or any other medication. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does not include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. For questions about the source of any of the information provided herein, pharmacists at Belmar Pharma Solutions are available. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of this medicine.

Do not flush down a toilet or pour down a drain. Check with your pharmacist if you have questions about the best way to dispose of medications. There may be a drug take-back program in your area.

References:

1. Amitriptyline. Drug Facts and Comparisons. Facts and Comparisons eAnswers. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed November 2022.
2. *Pagano R, Wong SB.* Use of Amitriptyline Cream in the Management of Entry Dyspareunia Due to Provoked Vestibulodynia. *J Low Genit Tract Dis.* 2012 Oct;16(4):394-97. doi: 10.1097/LGT.0b013e3182449bd6. Accessed November 2022.
3. *Shakshuki A, Yeung P, Agu RU.* Compounded Topical Amitriptyline for Neuropathic Pain: In Vitro Release from Compounding Bases and Potential Correlation with Clinical Efficacy. *Can J Hosp Pharm.* 2020 Mar-Apr;73(2):133-40. Epub 2020 Apr 1. Accessed November 2022.