

# AMITRIPTYLINE 25 MG TABLETS

## Amitriptyline Hydrochloride

**Read all of this leaflet carefully before you start taking this medicine. It contains important information.**

- Keep this leaflet. You may want to read it again.
- If you have any other questions, or if there is something you do not understand, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Never give it to someone else. It may not be the right medicine for them even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

**What is in this leaflet:**

1. What Amitriptyline is and what it is used for
2. What you need to know before you take Amitriptyline Tablets
3. How to take Amitriptyline Tablets
4. Possible side effects
5. How to store Amitriptyline Tablets
6. Contents of the pack and other information

**1. What Amitriptyline is and what it is used for**

- Amitriptyline belongs to a group of drugs called tricyclic antidepressants (TCADs). It prolongs the effect of noradrenaline and serotonin levels (substances which transmit nerve impulses) in the brain to relieve the symptoms of depression.
- Amitriptyline is used to treat depression. It is also used to treat night bedwetting in children aged 6 years and above as third line therapy only.

**2. What you need to know before you take Amitriptyline Tablets**

**Do not take this medicine if you:**

- have previously suffered an **allergic reaction** to a medicine containing Amitriptyline or other anti-depressant medicines
- are allergic to any of the other ingredients of this tablet (See section 6 further information)
- suffer from any severe **liver disease**
- or the patient is under 6 years of age
- suffer from **heart problems** (e.g. abnormal heart beats, coronary artery disease)
- have suffered a **heart attack** within the last three months
- are taking or have you recently taken (within the last 14 days) any other medicines for depression (tricyclic antidepressants), particularly monoamine oxidase inhibitors (**MAOIs**),
- are taking sibutramine, (medicine used for weight loss) or amiodarone (medicine used to treat irregular heart rhythm)
- are pregnant or are breast feeding
- suffer or you have ever suffered from any **mental illness** other than depression
- suffer from mania (a mood disorder characterised by high levels of excitement and activity)

**Warnings and precautions**

**Talk to your doctor or pharmacist before taking these tablets if you:**

- have any blood disorders (you may bruise easily, frequently suffer from infections or be anaemic)
- have any mental illness (e.g. schizophrenia or manic depression)
- have **high blood pressure** due to a **tumour near the kidney** (phaeochromocytoma)
- have **porphyria** (a genetic disorder of the red blood cells)
- have liver problems
- **cannot pass urine** or have an **enlarged prostate gland**
- have an **overactive thyroid gland** and are taking medicines to treat a thyroid disorder
- have a history of **epilepsy** or have suffered recently from **convulsions**
- are being given electroconvulsive therapy (**ECT**)
- have increased pressure in the eye (known as **narrow-angle glaucoma**)

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking amitriptyline tablets.

A heart problem called “prolonged QT interval” (which is shown on your electrocardiogram, ECG) and heart rhythm disorders (rapid or irregular heart beat) have been reported with amitriptyline. Tell your doctor if you:

- have slow heart rate
- have or had a problem where your heart cannot pump the blood round your body as well as it should (a condition called heart failure),
- are taking any other medication that may cause heart problems or
- have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood

**Thoughts of suicide and worsening of your depression or anxiety disorder**

If you are depressed and/or have anxiety disorder you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks, but sometimes longer. You may be more likely to think like this:

- if you have previously had thoughts about killing or harming yourself

- if you are taking this medicine for disorders other than depression
  - if you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant
- If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

**You may find it helpful to tell a relative or close friend** that you are depressed or have an anxiety disorder, and ask them to read this leaflet.

You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

**Taking other medicines**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Please inform your doctor if you are taking or have previously taken any of the following medicines:

- other medicines used to treat depression including monoamine oxidase inhibitors (MAOIs) such as phenelzine or you have taken MAOIs within the last 14 days
- other medicines used to treat depression, including the herbal remedy St John’s Wort
- medicines used to lower the blood pressure (e.g. guanethidine, debrisoquine, bethanidine, methyl dopa and clonidine or diuretics “water” tablets)
- drugs that depress the central nervous system including barbiturates (e.g. phenobarbitone)
- ethchlorvynol drugs are used to treat sleeping problems
- sedatives (medicines that relieve anxiety and have a calming effect)
- thyroid hormone therapy
- Apraclonidine and brimonidine (to treat glaucoma; a condition characterized by increased intraocular pressure)
- fluconazole (to treat fungal infections)
- terfenadine (antihistamine) to treat allergies or hay fever
- methylphenidate (to treat attention deficit/hyperactivity disorder in children (ADHD) and sleeping problems)
- medicines used to treat Parkinson’s disease, including entacapone and selegiline
- disulfiram (a medicine used to treat alcohol addiction)
- cimetidine (a medicine used to treat ulcers)
- medicines used to relieve: asthma, gastrointestinal upset (e.g. vomiting or cramps)
- medicines such as adrenaline (epinephrine), isoprenaline, noradrenaline (norepinephrine), ephedrine, phenylephrine or phenylpropanolamine. These may be present in many medicines for colds and nasal stuffiness. Tell your pharmacist that you are taking Amitriptyline before buying such products
- chlorphenamine, dicyclomine (anticholinergic drugs)
- ritonavir, a drug used for HIV infection
- sibutramine, a medicine used for weight loss
- altretamine, a drug used for the treatment of advanced ovarian cancer
- certain painkillers, including nefopam and tramadol, codeine, dihydrocodeine
- medicines used to treat irregular heart rhythm, including amiodarone, disopyramide, procainamide, propafenone, quinidine, sotalol, diltiazem, and verapamil
- rifampicin or linezolid (an antibiotic to treat infection)
- medicines (carbamazepine or phenobarbital) used to treat epilepsy
- medicines used to treat mental illness, including thioridazine, pimozide, clozapine, chlorpromazine, haloperidol, prochlorperazine and sulpiride
- baclofen, a drug used for muscle spasm resulting from disorders such as multiple sclerosis
- levacetylmethadol (used to treat drug dependence)
- medicines used in the treatment of angina that you spray or dissolve under your tongue (e.g. glyceryl trinitrate “GTN”, isosorbide dinitrate)
- electroconvulsive therapy (ECT)
- oral contraceptives (“the pill”)

**Pregnancy and breast-feeding**

- Amitriptyline tablets should not be taken in the first three months and the last three months of pregnancy.
- If taken in the last three months, the new born baby may have withdrawal symptoms. (see section 4 possible side effects)
- Do not take Amitriptyline tablets if you are breast-feeding.
- If you are pregnant or planning to become pregnant, ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

- Amitriptyline tablets may cause abnormal muscle movements and it may affect your sight due to the possible side effect like blurred vision, eye problem, dilated pupil. This may affect your ability to drive (see section 4 possible side effects).
- If you feel dizzy or drowsy when you start taking this medicine, do not drive or operate machinery until these effects wear off.

**Taking Amitriptyline Tablets with food and drink**

Avoid alcohol while taking this medicine as it may affect you more than usual because it increases their sedative effect.

**Amitriptyline Tablet contain lactose, sucrose and colour sunset yellow (E110)**

- If you have been told by your doctor that you have an intolerance to some sugar, contact your doctor before taking this medicinal product.
- Sunset yellow (E110) may cause allergic-type reactions including asthma. Allergy is more common in people who are allergic to aspirin.

**Having operations and tests**

Tell your doctor or dentist that you’re taking amitriptyline, if you are going to have an anesthetic for surgery, dental treatment or for electroconvulsive therapy.

**3. How to take Amitriptyline**

Always take Amitriptyline exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Swallow the tablets with a glass of water. To be taken orally. The **usual dosage** is as below:

**For depression:**

- **Adults:**  
The usual dose is 75mg (3 tablets) in divided doses daily or as a single dose at bedtime. If necessary, your doctor may increase the dose to a total of 150mg (6 tablets) per day.
- **Elderly:**  
The usual dose is 10-25 mg three times a day initially, which may be gradually increased if necessary. The dosage may be taken as divided doses, or as a single dose, preferably in the evening or at bedtime. Your doctor will start you on a lower dose and gradually increase it as you may be more sensitive to the medicine.
- **Children:**  
Not recommended for treatment of depression in children under 16 years of age.

**For night bedwetting: Children only**

- **6-10 years:** One tablet 30 minutes before bedtime
  - **11-16 years:** One or two tablets 30 minutes before bedtime.
- This medicine should be used initially for up to 3 months to treat night bedwetting. If a repeated course is required, a medical review should be conducted every 3 months. The dose should be increased gradually and when stopping treatment should be withdrawn gradually.

**Amitriptyline tablets are not suitable for children under 6 years.**

- You should keep taking your medicine until your doctor tells you to stop. This medicine may take up to four weeks to be fully effective.

**If you take more medicine than you should**

If you or anyone else has swallowed a lot of the tablets all together contact your nearest hospital casualty department or doctor immediately. Symptoms of an overdose include fast or irregular heartbeat, low blood pressure, hot dry skin, dry mouth and tongue, dilated pupils, dilated pupils, problems passing water, difficulty in controlling movements, involuntary eye movement, drowsiness, low body temperature, breathing problems, fits, coma, agitation, muscle rigidity, being sick or fever.

**If you forget to take medicine**

If you forget to take a dose, take another as soon as you remember, unless it is nearly time to take the next one and then take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking medicine**

You may not notice any improvement for up to 4 weeks. Do not stop taking your medicine suddenly, unless your doctor tells you to. Withdrawal symptoms which may occur if you stop taking the tablets suddenly include feeling sick, headache and generally feeling unwell. Gradual withdrawal is associated with reports of symptoms including irritability, restlessness, excitement, and hyperactivity, as well as dream and sleep disturbances during the first two weeks of dosage reduction. Feeling elated or over-excited has been rarely reported when stopping long term treatment with this type of drug. These symptoms are transient and are not a sign of addiction.

**If you have any further questions on the use of this product, ask your doctor or pharmacist.**

**4. Possible side effects**

Like all the medicines, Amitriptyline tablets can cause side effects, although not everybody gets them.

**STOP TAKING this medicine and contact your doctor straight away if you have:**

- **skin rash or itching**, sensitivity to the sun or sun lamps, puffy, swelling of your lips, face, throat, or tongue, which may be severe causing shortness of breath, swelling, shock and collapse
- serious **effect on your blood**, such as low sodium levels, signs may include fever or chills, sore throat, ulcers in your mouth or throat, unusual tiredness or weakness, unusual bleeding or unexplained bruises
- **serious side effects:** if you feel more depressed, including thinking about suicide

**Tell your doctor if you notice any of the following side effects or notice any other effects not listed**

- **Effect on your blood:** bone marrow depression or reduction in some blood cells (you may experience a sore throat, mouth ulcers and recurring infections, bleeding or bruising easily)
- **Effect on your hormone system:** impotence and other sexual problems, breast swelling in men and women, swollen testicles, over secretion or secretion of breast milk, increased perspiration or hot

flushes, high or low blood sugar levels, weight loss or gain, loss or gain of appetite, inappropriate secretion of the hormone ADH (anti diuretic hormone), which may make you urinate more frequently

- **Effect on your brain and central nervous system:** fatigue, tiredness, dizziness, drowsiness, headache or confusion, weakness, difficulty concentrating, epileptic fits or convulsions, coma, sleeping problems, nightmares, slight hyperactivity, excitement, feeling anxious, hallucinations (seeing things that are not there), delusion, disorientation (not knowing where you are), restlessness, numbness, tingling or pins and needles (particularly in the hands and feet), lack of co-ordination, shaky movements, tremor, fits, unconsciousness, coma, slow or slurred speech
- **Effect on your heart:** commonly a heart problem called “prolonged QT interval” (which is shown on your electrocardiogram, ECG). High doses or an over dosage may lead to heart problems, change in blood pressure, fast / racing heart, palpitation, heart attack, stroke
- **Effect on your stomach and intestines:** part of the intestine may become paralyzed and this may lead to constipation, a swollen stomach, fever, nausea (feeling sick), vomiting, diarrhoea, irritation, a nasty taste in your mouth, swollen saliva glands, abdominal pain, black tongue, swelling of the area around the ear, soreness of the mouth, dry mouth, bowel problems and blockage of your small intestine
- **Effect on your liver:** hepatitis, including changes in liver function (as seen in blood tests), jaundice (yellowing of the skin and /or whites of the eyes)
- **Effect on your ears:** buzzing or a ringing in the ears
- **Effect on your eyesight:** dilated pupils, increased pressure in the eye, blurred vision, changes in eyesight, eye problems and sensitivity to light
- **General effect:** difficulty in passing water (urine), hair loss, speech impairment, abnormal muscle movements or twitching, unsteadiness.
- **Effect on the skin:** itching, skin rash due to sunlight
- an increased risk of bone fractures have been observed in patients taking this type of medicine
- **Children:** changes in behaviour
- mood changes after stopping treatment have been reported rarely
- There have also been reports of breathing problems and agitation in babies whose mothers took this type of drug
- **If you are elderly**, you are more likely to experience effects of agitation, confusion, low blood pressure on standing causing dizziness, light-headedness or fainting, or to develop low blood levels of sodium, which can cause tiredness, confusion, muscle twitching and fits

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Amitriptyline**

- **Keep all the medicines out of the sight and reach of children**
- Do not use this medicine after the expiry date which is stated on the label after ‘EXP’. The expiry date refers to the last day of that month.

**Container pack:**

- Do not store above 25°C.
- Store in the original container.
- Keep the Container tightly closed.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

**6. Contents of the pack and other information**

**What Amitriptyline tablets contain:**

- **The active substance** is Amitriptyline Hydrochloride. Each tablet contains 25mg of the amitriptyline hydrochloride.
- **The other ingredients** are lactose monohydrate, maize starch, povidone, magnesium stearate, stearic acid, calcium carbonate, talc, acacia, sucrose, polyvinyl acetate phthalate, yellow carnauba wax, white beeswax, shellac and the colours titanium dioxide (E171), quinoline yellow aluminium lake (E104) and sunset yellow aluminium lake (E110). The sugar coat contains the preservative sodium benzoate (E211).

**What Amitriptyline tablets look like and contents of the pack:**

- Amitriptyline 25mg tablets are pale yellow, circular, sugar coated tablets.
- Pack sizes: 7, 14, 28, 56, 84, 50, 100, 250 and 500 tablets. Not all pack sizes may be marketed.

**Marketing Authorization holder and Manufacturer:**

Pharmvit Ltd, 177 Bilton Road, Perivale, Greenford, Middlesex UB6 7HQ.

**Telephone: 0208 997 5444**

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