

Amitriptyline 10mg, 25mg and 50mg tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms 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.

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1 What Amitriptyline tablets are and what they are used for

Amitriptyline belongs to a group of medicines called tricyclic antidepressant drugs. These medicines alter the levels of chemicals in the brain to relieve the symptoms of depression. Amitriptyline is used:

- to treat the symptoms of depression.
- for the relief of bed-wetting at night by children aged 6 years and above.

2 What you need to know before you take Amitriptyline tablets

- Do not take** Amitriptyline tablets if you or your child (if they are the patient):
- are **allergic** to amitriptyline, other tricyclic antidepressants or any of the other ingredients (listed in section 6). The 25mg tablets contain sunset yellow (E110), which may cause allergic-type reaction.
 - have **heart disease** such as irregular heart beats, heart block or failure, coronary artery disease or have recently had a heart attack
 - suffer from periods of increased and exaggerated behaviour (**mania**)
 - have **severe liver** disease
 - are taking monoamine oxidase inhibitors (**MAOI**) or you have taken MAOIs within the previous 14 days for depression
 - are **breast-feeding**
 - if the **child is under 6** years old.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders 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 a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) 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.

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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Amitriptyline tablets if you or your child (if they are the patient):

- have any **blood disorders** (you may bruise easily, frequently suffer from infections or be anaemic)
- have any **psychiatric disorder** (eg schizophrenia or manic depression)
- have **liver** or cardiovascular disease
- are **not able to pass water** 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**
- are being given electroconvulsive therapy (**ECT**)
- have increased pressure in the eye (**glaucoma**)
- are due to have **any surgery**, including dental, that **involves an anaesthetic**
- are **elderly**.

Other medicines and Amitriptyline tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially:

- alitretamine (to treat some types of cancer)
- apraclonidine and brominidine (to treat glaucoma)
- baclofen (a muscle relaxant)
- disulfiram (to treat alcohol addiction)
- painkillers such as nefopam, tramadol, codeine, dihydrocodeine
- medicines to treat some heart conditions such as amiodarone, diltiazem, disopyramide, procainamide, propafenone, quinidine, sotalol, verapamil
- medicines to treat angina that you spray or dissolve under your tongue (eg glyceryl trinitrate "GTN", isosorbide dinitrate)
- rifampicin or linezolid (to treat infections), fluconazole (to treat fungal infections)
- carbamazepine or phenobarbital (to treat epilepsy)
- terfenadine (to treat allergies or hayfever)
- methylphenidate (to treat attention deficit/hyperactivity disorder (ADHD))
- any medicines to treat high blood pressure such as guanethidine, debrisoquine, bethanidine or clonidine or diuretics ("water" tablets),
- medicines to treat some mental illnesses such as clozapine, pimozide, thioridazine chlorpromazine, haloperidol, prochlorperazine, sulphiride
- cimetidine (to treat ulcers)
- ethchlorvynol (to help you sleep)
- entacapone or selegiline (to treat Parkinson's disease)
- oral contraceptives ("the pill")
- sibutramine (to suppress appetite)
- sympathomimetic medicines such as adrenaline (epinephrine), ephedrine, isoprenaline, noradrenaline (norepinephrine), phenylephrine and phenylpropanolamine (these may be present in many cough and cold remedies)
- ritonavir (to treat HIV)
- anaesthetics (used in surgery)
- anticholinergic medicines e.g. atropine, benztropine, dicyclomine or doxylamine
- antidepressants

Amitriptyline tablets and alcohol

Do not drink alcohol with this medicine.

Pregnancy and breast-feeding

Amitriptyline tablets should not be taken in the first 3 months and last 3 months of pregnancy. If taken in the last three months, the newborn may have withdrawal symptoms. Do not take Amitriptyline tablets if you are breast-feeding. If you are pregnant or breastfeeding, think you may be pregnant or

are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Amitriptyline may impair your alertness. Make sure you are not affected before you drive or operate machinery.

Amitriptyline tablets contain lactose and sunset yellow

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a type of sugar called lactose. The 25mg tablets also contain a colour called 'sunset yellow' which may cause allergic reactions.

3 How to take Amitriptyline tablets

Always take Amitriptyline tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets with a **glass of water**.

You may not notice any improvement in your symptoms for up to 4 weeks after starting treatment.

The recommended dose is

Depression:

Adults - 50-75mg a day either in divided doses or as a single night time dose increasing to 150-200mg a day. A maintenance dose of 50-100mg at night should be given to lessen the chances of relapse.

Adolescents and elderly - 25-50mg a day either in divided doses or as a single night time dose. A maintenance dose of 25-50mg may be sufficient.

Nightly bedwetting:

Children only (for no longer than 3 months)

11-16 years - 25-50mg at night.

6-10 years - 10-20mg at night.

Under 6 years - Not recommended.

If you take more Amitriptyline tablets than you should

If you or the patient (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include fast regular heart beat, dilated pupils, drowsiness, coma, difficulty breathing, jerky movements, hot dry skin, dry mouth and tongue, difficulty passing water, intestinal blockage, uncontrolled eye movement.

If you forget to take Amitriptyline tablets

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

If you stop taking Amitriptyline tablets

Talk to your doctor before you stop taking the tablets and follow their advice as you may experience withdrawal symptoms (see section 4).

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

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Amitriptyline tablets and contact your doctor at once if you have:

- an allergic reaction signs may include a skin rash, which may be itchy, sensitivity to the sun or sun lamps, puffy, swollen face or tongue, which may be severe causing shortness of breath, swelling, shock and collapse.
- a 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.
- bone marrow depression or reduction in some blood cells (you may experience a sore throat, mouth ulcers and recurring infections, bleeding or bruising easily)
- thoughts of suicide (see section 1)
- anticholinergic effects (dry mouth, fever, constipation, blurred or double vision, difficulty or lack of control when urinating, dilation of the pupil of the eye, glaucoma and blockage of the small intestine)
- stroke
- hepatitis

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

Common (may affect up to 1 in 10 people):

- a heart problem called prolonged QT interval (which is shown on your electrocardiogram, ECG).

Not known (frequency cannot be estimated from the available data):

- rash of purple spots (purpura).
- disturbances in sexual function or sex drive, breast swelling in men and women, swelling of the testicles, production or over-production of breast milk, changes in blood sugar levels, increased appetite and weight gain. Inappropriate secretion of the hormone ADH (antidiuretic hormone), which may make you urinate more frequently.
- dizziness, tiredness or sleepiness, weakness, headache, difficulty concentrating, confusion, difficulty sleeping, nightmares, slight hyperactivity, exaggerated behaviour, delusions, seeing things that are not there, anxiety, excitement, disorientation (not knowing where you are), restlessness, nerve damage, pins and needles, lack of co-ordination, loss of control of or shaky movements, tremor, fits.
- feeling faint when getting up (postural hypotension), increased blood pressure, fast/racing heart, palpitations, heart attack, irregular or slow heart-beats and very low blood pressure, other changes in ECGs
- feeling or being sick, diarrhoea, loss of appetite, inflammation of the mucus membranes in the mouth, swollen saliva glands, abdominal pains, black tongue, impairment of taste
- including changes in liver function (as seen in blood tests), jaundice (yellowing of the skin and/or whites of the eyes)
- increased sweating, hair loss, ringing in the ears, increased need to urinate. An increased risk of bone fractures has been observed in patients taking this type of medicine.

Withdrawal symptoms: feeling sick, malaise and headache, dream and sleep disturbances, irritability and restlessness. Mania or hypomania (exaggerated mood and/or elation) may occur. 2-7 days after stopping the tablets.

If taken to treat bed-wetting: drowsiness, mild sweating, itching, changes in behaviour and "Anticholinergic effects" (as described above).

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

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

5 How to store Amitriptyline tablets

Keep this medicine out of the sight and reach of children.

Store below 25°C in a dry place, protected from light.

Do not use Amitriptyline tablets after the expiry date stated on the carton. The expiry date refers to the last day of that month.

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

6 Contents of the pack and other information

What Amitriptyline tablets contain

- The active substance is amitriptyline hydrochloride. Each tablet contains either 10mg, 25mg or 50mg of the active ingredient.
- The other ingredients are lactose monohydrate, microcrystalline cellulose (E460), maize starch, colloidal anhydrous silica, magnesium stearate, hypromellose (E464), titanium dioxide (E171), macrogol. The 10mg tablet also contains: indigo carmine (E132). The 25mg tablet also contains: talc (E553b), quinoline yellow (E104), iron oxide (E172), sunset yellow (E110), indigo carmine (E132). The 50mg tablet also contains: talc (E553b), quinoline yellow (E104), iron oxide (E172).

What Amitriptyline tablets look like and contents of the pack

Amitriptyline tablets are circular, biconvex, film-coated tablets in the following colours:

10mg - blue, 25mg - yellow, 50mg - tan

Pack sizes are 28 tablets

Marketing Authorisation Holder and Manufacturer:

Actavis, Barnstaple, EX32 8NS, UK.

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