

Amitriptyline 10mg, 25mg and 50mg tablets

Read all of this leaflet carefully before you start taking this medicine.

- 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.

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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.

2 Before you take

Do not take Amitriptyline tablets and **tell** your doctor if you or your child (if they are the patient):

- are **allergic** (hypersensitive) to amitriptyline, other tricyclic antidepressants or any of the other ingredients (see section 6). The 25mg tablets contain sunset yellow (E110), which may cause allergic-type reactions including asthma. Allergy is more common in those people who are allergic to aspirin.
- 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 7** 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.

Check with 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**.

Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- altretamine (to treat some types of cancer)
- apraclonidine and brimonidine (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)
- 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, sulpiride
- 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)
- fluconazole (to treat fungal infections)

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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.

Driving and using machines

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

Important information about some of the ingredients

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

Always take Amitriptyline tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

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

You are advised **not to drink alcohol** with this medicine.

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

Doses

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.

7-10 years - 10-20mg at night.

Under 7 years - Not recommended.

If you take more 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 the 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 the tablets

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

4 Possible side effects

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

Stop taking Amitriptyline tablets and contact your doctor at once

if you experience the following: allergic reaction, 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.

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

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)

Endocrine system and metabolism: 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

Brain and central nervous system: 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, pins and needles, lack of co-ordination, shaky movements, tremor, fits. Anticholinergic effects (dry mouth, fever, constipation, blurred or double vision, difficulty passing water (urine), dilation of the pupil of the eye, glaucoma and blockage of the small intestine)

Heart: feeling faint when getting up (postural hypotension), increased blood pressure, fast/racing heart, palpitations, heart attack, stroke, irregular or slow heart-beats and very low blood pressure

Stomach and intestines: 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

Liver: hepatitis, including changes in liver function (as seen in blood tests), jaundice (yellowing of the skin and/or whites of the eyes)

Other: 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).

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

5 How to store

Keep out of the reach and sight 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 label/carton/bottle. The expiry date refers to the last day of that month.

Return any unused medicines to your pharmacist for safe disposal.

6 Further information

What Amitriptyline tablets contain

- The active substance (the ingredient that makes the tablets work) 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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Pharmaceutical
Position

 **actavis**

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