Side effects listed below have been reported in the following frequencies:

- **Very common:** may affect more than 1 in 10 people
- **Common:** may affect up to 1 in 10 people
- **Uncommon:** may affect up to 1 in 100 people
- **Rare:** may affect up to 1 in 1,000 people

- **breast enlargement, changes in sex drive or function, ADH secretion changes**
- **itching**
- **An increased risk of bone fractures has been observed in patients taking this type of medicine.**

When used for the treatment of bed wetting in children, the side effects are less frequent. The most common side effects are drowsiness, blurred vision, dilated pupils, constipation, sweating, itching and dry mouth. Changes in behaviour have also occurred in children receiving amitriptyline.

**Reporting of side effects**

If you get any side effect, talk to your doctor, pharmacist or nurse. This includes any possible side effect 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) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

**How to store Amitriptyline tablets**

Keep this medicine out of the sight and reach of children. This tablet contains lactose monohydrate (E125), sucrose (E152), calcium carbonate, a combination of iron and calcium in the form of its phospates, sodium chloride, titanium dioxide (E171), macrogol, talc, lactose monohydrate (E150) and sodium hydrogen carbonate.

**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), starch, colloid, 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**

Accord Barnstable, EX32 8NS, UK.

This leaflet was last revised in April 2019.

Amitriptyline All Strengths 28 Tablets PIL - UK

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**What is in this leaflet**

1. **What Amitriptyline tablets are and what they are 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**

**What Amitriptyline tablets are and what they are for**

Amitriptyline belongs to a group of medicines called tricyclic antidepressant drugs. This medicine is used to:

- Depression in adults (major depressive episodes)
- Neuropathic pain in adults
- Migraine prophylaxis in adults
- Bed-wetting at night in children aged 6 years and above, only when organic causes, such as spina bifida and related disorders, have been excluded and no response has been achieved to all other non-drug and drug treatments, including muscle relaxants and desmopressin. This medicine should only be prescribed by doctors with expertise in treating patients with persistent bed-wetting.

**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 of this medicine (listed in section 6)
- recently have had a heart attack (myocardial infarction)
- have heart problems such as disturbances in heart rhythm which are seen on an electrocardiogram (ECG), heart block, or coronary artery disease
- are taking medicines known as monoamine oxidase inhibitors (MAOIs)
- have taken MAOIs within the last 14 days. If you are treated with Amitriptyline tablet you have to stop taking this medicine and wait for 14 days before you start treatment in a MAOI
- have taken moclobemide the day before
- have a severe liver disease
- have porphyria (a disease of blood proteins affecting the skin, gut and nervous system).

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Amitriptyline tablets.

Heart rhythm disorders and hypotension may occur if you receive a high dosage of amitriptyline. This might also occur in usual doses if you have pre-existing heart disease.

**Prolonged QT interval**

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 tablets. 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

- have a surgery planned as it might be necessary to stop the treatment with amitriptyline before you are given anaesthetics. In the case of acute surgery, the anaesthetist should be informed about the treatment of amitriptyline.

- have an over active thyroid gland or receive thyroid medication.

**Thoughts of suicide and worsening of your depression**

If you are depressed, you 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, 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.

**Episodes of mania**

Some patients with manic-depressive illness may enter into a manic phase. This is characterised by profuse sweating, inactivity, irritability, restlessness, changes in sleep pattern, agitation, and often an increase in self esteem, with delusions of grandeur.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away. You may need it helpful to tell a relative or close friend that you are depressed, 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.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away. You may need it helpful to tell a relative or close friend that you are depressed, 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.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away. You may need it helpful to tell a relative or close friend that you are depressed, 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.

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enlarged prostate  
thyroid disease  
biolar disorder  
schizophrenia  
severe heart disease  
severe liver disease  
pylorus stenosis (narrowing of the gastric outlet) and peptic ulcer (blocked intestine)  
diabetes as you might need an adjustment of your anti-diabetic medicine  
phaeochromocytoma (a rare tumour of the adrenal gland).

If you use antidepressants such as SSRIs, your doctor might consider changing the dose of your medicine (see also section 2 ‘Other medicines and Amitriptyline tablets’ and section 3).

Elderly are more likely to suffer from certain side effects, such as dizziness when you stand up due to low blood pressure (see also section 4 ‘Other side effects’).

Children and adolescents
Depression, neuropathic pain, chronic tension type headache and migraine prophylaxis

Do not give this medicine to children and adolescents aged below 18 years as long term safety and efficacy have not been established in this age group.

Bed-wetting at night
• An ECG should be performed prior to initiating therapy with amitriptyline to exclude long QT syndrome.

This medicine should not be taken at the same time as an anticholinergic drug (see also section 2 ‘Other medicines and Amitriptyline tablets’).

Suicidal thoughts and behaviours may also develop during early treatment with antidepressants for disorders other than depression; the same precautions observed when treating patients with depression should therefore be followed when treating patients with enuresis.

Other medicines and Amitriptyline tablets
Some medicines may affect the action of other medicines and this can sometimes cause serious side effects.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, such as:
• valproic acid  
• monoamine oxidase inhibitors (MAOIs) e.g. phenelzine, isocarboxazid, nialamide or tranylcypromine (used to treat depression) or selegiline (used to treat Parkinson’s disease)  
• adrenergic blockers and antiarrhythmics such as amiodarone, propafenone, disopyramide, propafenone (used to treat heart conditions)  
• anticonvulsants (e.g. valproate)  
• medicines for certain heart conditions (e.g. beta blockers and antiarrhythmics such as amiodarone, disopyramide, propafenone)  
• antidepressants (e.g. SSRIs (fluoxetine, paroxetine, fluvoxamine), and bupropion)  
• medicines for certain heart conditions (e.g. beta blockers and antiarrhythmics such as amiodarone, disopyramide, propafenone)  
• medicines used to treat other conditions (e.g. tricyclic antidepressants, monoamine oxidase inhibitors (MAOIs) e.g. phenelzine, isocarboxazid, nialamide or tranylcypromine).

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines that may affect the heart’s rhythm, e.g.:
• quinidine and sotalol  
• amiodarone and terfenadine (used to treat allergies and hayfever)  
• medicines used to treat some mental illnesses (e.g. pmipramine and sertraline)  
• cisapride (used to treat certain types of indigestion)  
• halofantrine (used to treat malaria)  
• azathioprine (used to treat certain immune system disorders)  
• medicine to treat nausea and vomiting (e.g. metoclopramide)  
• inhaled corticosteroids (e.g. fluticasone, budesonide)  
• medicine to treat certain mental disorders (e.g. valproic acid, lithium)  
• amitriptyline tablets  
• medicines for certain heart conditions (e.g. beta blockers and antiarrhythmics such as amiodarone, disopyramide, propafenone)  
• zopiclone (used to help you fall asleep)  

If you are taking any of these medicines, please let your doctor know what you are taking.

Amitriptyline tablets with alcohol
It is not advised to drink alcohol during treatment with this medicine as it may increase the sedative effect.

Pregnancy and breast-feeding
If you are pregnant or breast feeding please ask your doctor for advice before taking this medicine.

Amitriptyline is not recommended during pregnancy unless your doctor considers it clearly necessary and only after careful consideration of the possible benefits and risks. If you have taken this medicine during the last part of the pregnancy, the newborn may have withdrawal symptoms such as irritability, increased muscle tension, tremor, irregular breathing, poor drinking, loud crying, urinary retention, and constipation.

Your doctor will advise you whether to start/continue/stop breast-feeding, or stop using this medicine taking into account the benefit of breast-feeding for your child and the need for therapy for you.

Driving and using machines
This medicine may cause drowsiness and dizziness, especially in the beginning of the treatment. Do not drive or work with tools or machines if you are affected.

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. The 25mg tablets also contain a colour called sunset yellow which may cause allergic reactions.

How to take Amitriptyline tablets
Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Not all dosage schemes can be achieved with all the pharmaceutical forms/strengths. The appropriate formulation/strength should be selected for the starting doses and any subsequent dose increases.

Amitriptyline tablets

The recommended initial dose is 25mg two times daily.

Depending on the response to the medicine, your doctor may gradually increase the dose to 150mg per day divided in two doses.

Amitriptyline All Strengths 28 Tablets PIL - UK

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Supplier: Accord Barnstable

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1. Black
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Non Printing Colours
1. Profile
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