



- enlarged prostate
- thyroid disease
- bipolar disorder
- schizophrenia
- severe heart disease
- severe liver disease

- pylorus stenosis (narrowing of the gastric outlet) and paralytic ileus (blocked intestine)

- diabetes, as you might need an adjustment of your antidiabetic 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 'How to take Amitriptyline tablets')

The 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 'Possible 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 for these treatments, as 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, have recently taken or might take any other medicines, such as:

- monoamine oxidase inhibitors (MAOIs) e.g. phenelzine, iproniazid, isocarboxazid, nialamide or tranylcypromine (used to treat depression) or selegiline (used to treat Parkinson’s disease). These should not be taken at the same time as Amitriptyline tablets (see section 2 'Do not take Amitriptyline tablets')
- adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine (these may be present in cough or cold medicine, and in some anaesthetics)
- medicine to treat high blood pressure, for example calcium-channel blockers (e.g. diltiazem and verapamil), guanethidine, betanidine, clonidine, reserpine and methylidopa
- anticholinergic drugs such as certain medicines to treat Parkinson’s disease and gastrointestinal disorders (e.g. atropine, hyoscamine)
- thioridazine (used to treat schizophrenia)
- nefopam, tramadol and morphine (painkillers)
- buprenorphine (a drug used for severe pain or opioid drug addiction). This medicine may interact with amitriptyline and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms
- medicines to treat fungal infections (e.g. fluconazole, terbinafine, ketoconazole, and itraconazole)
- sedatives (e.g. barbiturates)
- antidepressants (e.g. SSRIs (fluoxetine, paroxetine, fluvoxamine), duloxetine, and bupropion)
- medicines for certain heart conditions (e.g. beta blockers and antiarrhythmics)
- cimetidine (used to treat stomach ulcers)
- methylphenidate (used to treat ADHD)
- ritonavir (used to treat HIV)

- oral contraceptives
- rifampicin (to treat infections)
- phenytoin and carbamazepine (used to treat epilepsy)
- St. John’s Wort (*Hypericum perforatum*) – a herbal remedy used for depression
- thyroid medication
- baclofen (muscle relaxant)
- nitrate tablets placed under the tongue, such as glyceryl trinitrate, used to treat angina
- valproic acid.

You should also tell your doctor if you take or have recently taken medicine that may affect the heart’s rhythm, such as:

- medicines to treat irregular heartbeats (e.g. quinidine and sotalol)
- astemizole and terfenadine (used to treat allergies and hayfever)
- medicines used to treat some mental illnesses (e.g. pimozide and sertindole)
- cisapride (used to treat certain types of indigestion)
- halofantrine (used to treat malaria)
- methadone (used to treat pain and for detoxification)
- diuretics (“water tablets” e.g. furosemide).

If you are going to have an operation and receive general or local anaesthetics, you should tell your doctor that you are taking this medicine.

Likewise, you should tell your dentist that you take this medicine if you are to receive a local anaesthetic.

### Amitriptyline tablets with alcohol

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

### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist 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 benefit and risk. 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 or stop breast-feeding, or stop using this medicine taking into account the benefit of breast-feeding for your child and the benefit of 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 machinery if you are affected.

### Amitriptyline tablets contain lactose and sunset yellow

If you have been told by your doctor that 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 or pharmacist 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.

### Depression

#### Adults

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.

#### Elderly (above 65 years of age) and patients with cardiovascular disease

The recommended initial dose is 10mg – 25mg daily.

Depending on your response to the medicine, your doctor may gradually increase the dose to a total daily dose of 100mg divided in two doses.

If you receive doses in the range of 100mg – 150mg, your doctor may need to do more frequent follow-ups with you.

### Use in children and adolescents

This medicine should not be given to children or adolescents for treatment of depression. For further information please see section 2 'Do not take Amitriptyline tablets.'

### Neuropathic pain, chronic tension type headache and migraine prophylaxis

Your doctor will adjust the medication according to your symptoms and your response to the treatment.

### Adults

The recommended initial dose is 10mg - 25mg in the evening.

The recommended daily dose is 25mg – 75mg.

Depending on your response to the medicine, your doctor may gradually increase the dose. If you receive doses above 100mg daily, your doctor may need to do more frequent follow-ups with you. Your doctor will instruct you whether to take the doses once daily or divide into two doses.

#### Elderly (above 65 years of age) and patients with cardiovascular disease

The recommended initial dose is 10mg – 25mg in the evening.

Depending on your response to the medicine, your doctor may gradually increase the dose. If you receive doses above 75mg daily, your doctor may need to do more frequent follow-ups with you.

### Use in children and adolescents

This medicine should not be given to children or adolescents for treatments of neuropathic pain, chronic tension type headache prophylaxis and migraine prophylaxis. For further information please see section 2 'Do not take Amitriptyline tablets.'

### Bed-wetting at night

#### Use in children and adolescents

The recommended doses for children:

- aged below 6 years: see section 2 'Do not take Amitriptyline tablets'
- aged 6 to 10 years: 10mg – 20mg daily. A suitable dosage form should be used for this age group.
- aged 11 years and above: 25mg – 50mg.

The dose should be increased gradually.

Take this medicine 1-1½ hours before bedtime.

Before starting treatment, your doctor will conduct an ECG of your heart to check for signs of an unusual heartbeat.

Your doctor will re-evaluate your treatment after 3 months and if needed perform a new ECG. Do not stop the treatment without consulting your doctor first.

### Patients with special risks

Patients with liver diseases or people known as “poor metabolisers” usually receive lower doses. Your doctor may take blood samples to determine the level of amitriptyline in the blood (see also section 2).

### How and when to take Amitriptyline tablets

This medicine can be taken with or without food.

Swallow the tablets with a drink of water. Do not chew them.

### Duration of treatment

Do not change the dose of the medicine or stop taking the medicine without consulting your doctor first.

### Depression

As with other medicines for the treatment of depression, it may take a few weeks before you feel any improvement.

In treating depression, the duration of treatment is individual, and is usually at least 6 months. The duration of treatment is decided by your doctor.

Continue to take this medicine for as long as your doctor recommends.

The underlying illness may persist for a long time. If you stop your treatment too soon, your symptoms may return.

### Neuropathic pain, chronic tension type headache and migraine prophylaxis

It might take a few weeks before you feel any improvement of your pain.

Talk to your doctor about the duration of your treatment and continue to take this medicine for as long as your doctor recommends.

### Bed-wetting at night

Your doctor will evaluate if the treatment should be continued after 3 months.

### If you take more Amitriptyline tablets than you should

Contact your doctor or nearest hospital casualty department immediately. Do this even if there are no signs of discomfort or poisoning. Take the container of this medicine with you if you go to a doctor or hospital.

Symptoms of overdose include dilated pupils, fast or irregular heartbeats, difficulties passing water, dry mouth and tongue, intestinal blockage, fits, fever, agitation, confusion, hallucinations, uncontrolled movements, low blood pressure, weak pulse, pallor, difficulty breathing, blue discolouration of the skin, decreased heart rate, drowsiness, loss of consciousness, coma, various cardiac symptoms such as heart block, heart failure, cardiogenic shock, metabolic acidosis, hypokalaemia.

Overdose with amitriptyline in children could have serious consequences. Children are especially susceptible to coma, cardiac symptoms, difficulty in breathing, seizures, low blood sodium level, lethargy, drowsiness, nausea, vomiting and high blood sugar level.

### If you forget to take Amitriptyline tablets

Take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

### If you stop taking Amitriptyline tablets

Your doctor will decide when and how to stop your treatment to avoid any unpleasant symptoms that might occur if it is stopped abruptly (e.g. headache, feeling unwell, sleeplessness and irritability).

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

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. **If you notice any of the following symptoms of serious side effects, you should stop using amitriptyline and seek medical attention immediately:**

- Signs of a severe allergic reaction (anaphylaxis), such as difficulty breathing or swelling of your face, lips, throat or tongue. Not known, frequency cannot be estimated from the available data.
- Attacks of intermittent blurring of vision, rainbow vision, and eye pain. You should immediately have an eye examination before the treatment with this medicine can be continued. This condition may be signs of acute glaucoma. Very rare, may affect up to 1 in 10,000 people.
- A heart problem called “prolonged QT interval” (which is shown on your electrocardiogram, ECG). Common, may affect up to 1 in 10 people.
- Bad constipation, a swollen stomach, fever and vomiting. These symptoms may be due to parts of the intestine becoming paralysed. Rare, may affect up to 1 in 1,000 people.
- Any yellowing of the skin and the white in the eyes (jaundice). Your liver may be affected. Rare, may affect up to 1 in 1,000 people.
- Bruising, bleeding, pallor or persistent sore throat and fever. These symptoms can be the first signs that your blood or bone marrow may be affected. Effects on the blood could be a decrease in the number of white cells (which help to fight infection) and platelets (which help with clotting). Rare, may affect up to 1 in 1,000 people.
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS or drug hypersensitivity syndrome). Not known, frequency cannot be estimated from the available data.

### Other side effects