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:** affects less than 1 in 1,000 people

### Common side effects
- **Sleepiness/sedation**
- ** Shakiness, trembling, diarrhoea, incontinence, nausea**
- **Changes in taste, feeling thirsty**
- **Numbness or tingling in the arms or legs**
- **Dilated pupils**
- **Heart block**
- **Fatigue**
- **Low sodium concentration in the blood**
- **Urination disorders**

### Uncommon side effects
- **Excitement, anxiety, difficulties sleeping, nightmares**
- **Convulsions**
- **Irritability**
- **Increased blood pressure**
- **Dizziness**
- **Abnormality in the heart’s rhythm, or heartbeat pattern**
- **Swelling of the salivary glands**
- **Difficulty in passing urine**
- **Skin rash, nettle rash (urticarial), swelling of the face and tongue**

### Rare side effects
- **Confusion, disturbance in attention, disturbed coordination, agitation**
- **Increased or reduced appetite**
- **Breast enlargement in men**
- **Increased sweating**
- **Weight loss**
- **Increased sensitivity to sunlight**
- **Decreased sodium concentration in the blood**
- **Increased frequency of heart attacks**
- **Weight gain**
- **Allergic inflammation of the lung alveoli and of the lung tissue**
- **Abnormal results of liver function tests**

### Very rare side effects
- **Dizziness**
- **Feeling of inner restlessness and a compelling need to move**
- **Disorder of the peripheral nerves**
- **Particular forms of abnormal heart rhythm (so-called torades de pointes)**
- **Allergic inflammation of the lung alveoli and of the lung tissue**

### Not known
- **Frequency cannot be estimated from the available data**
- **Former or increased sensation of appetite**
- **Excitement, anxiety, difficulties sleeping, nightmares**
- **Convulsions**
- **Irritability**
- **Increased blood pressure**
- **Abnormality in the heart’s rhythm, or heartbeat pattern**
- **Swelling of the salivary glands**
- **Difficulty in passing urine**
- **Skin rash, nettle rash (urticarial), swelling of the face and tongue**

### 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.

#### 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.

This leaflet was last revised in January 2019.

### If you would like a leaflet with larger text, please contact 01271 385257.
- enlarged prostate
- thyroid disease
- bipolar disorder
- schizophrenia
- severe heart disease
- severe liver disease
- pylorus stenosis (narrowing of the gastric outlet) and paraesophageal (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 or 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 Possible side effects).

Children and adolescents

Depression, bi- or unipolar depression, 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, 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 below section 2 ‘Do not take Amitriptyline tablets’).
- antihypertensive drugs such as certain medicines to treat Parkinson’s disease (e.g. entacapone) and gastrointestinal disorders (e.g. atropine, hyoscyamine) and medicines that should be used with caution in people with low blood pressure (such as diltiazem and verapamil), guanethidine, betablockers, clonidine and methyldopa.
- antibiotics such as those used to treat infections (e.g. fluoroquinolones, tetracycline, and trimethoprim).
- sedatives (e.g. buspirone, diazepam, clonazepam, and lorazepam).
- antidepressants (e.g. SSRIs (fluoxetine, paroxetine, sertraline), SNRIs (venlafaxine, duloxetine), or tetracyclic antidepressants (e.g. amitriptyline)).
- medicines for heart failure (e.g. digoxin, metoprolol, and enalapril).
- medicines for high blood pressure (e.g. calcium channel blockers (e.g. diltiazem and verapamil), guanethidine, betablockers, clonidine and methyldopa).
- medicines to treat fungal infections (e.g. fluconazole, terbinafine, ketoconazole, and itraconazole).
- medicines to treat viral infections (e.g. aciclovir, lamivudine, and efavirenz).
- medicines to treat infections (e.g. fluoroquinolones, tetracycline, and trimethoprim).
- medicines for certain heart conditions (e.g. beta blockers and antiarrhythmics such as amiodarone, disopyramide, and propafenone).
- medicines for the treatment of psychiatric conditions (e.g. antipsychotics, mood stabilizers, and antidepressants).
- medicines for the treatment of anxiety (e.g. benzodiazepines).
- medicines for the treatment of Parkinson’s disease (e.g. levodopa, entacapone, and rasagiline).
- medicines for the treatment of depression (e.g. selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), and tricyclic antidepressants).
- medicines for the treatment of pain (e.g. opioids, nonsteroidal anti-inflammatory drugs (NSAIDs), and corticosteroids).
- medicines for the treatment of heart failure (e.g. diuretics, angiotensin-converting enzyme (ACE) inhibitors, and angiotensin receptor blockers (ARBs)).
- medicines for the treatment of hypertension (e.g. calcium channel blockers, beta blockers, and angiotensin receptor blockers (ARBs)).
- medicines for the treatment of high blood pressure (e.g. diuretics, angiotensin-converting enzyme (ACE) inhibitors, and angiotensin receptor blockers (ARBs)).
- medicines for the treatment of angina (e.g. nitrates, beta blockers, and calcium channel blockers).
- medicines for the treatment of diabetes (e.g. sulfonylureas, metformin, and glitazones).
- medicines for the treatment of atrial fibrillation (e.g. flecainide, propafenone, and amiodarone).
- medicines for the treatment of asthma (e.g. inhaled corticosteroids, long-acting beta agonists, and leukotriene receptor antagonists).
- medicines for the treatment of cancer (e.g. anthracyclines, taxanes, and platinum complexes).
- medicines for the treatment of inflammatory bowel disease (e.g. corticosteroids, 5-aminosalicylates, and immunosuppressants).
- medicines for the treatment of neurological disorders (e.g. anticonvulsants, dopamine agonists, and anticholinergics).
- medicines for the treatment of psychiatric conditions (e.g. antipsychotics, mood stabilizers, and antidepressants).
- medicines for the treatment of infections (e.g. antibiotics, antifungal agents, and antiviral agents).
- medicines for the treatment of cardiovascular diseases (e.g. statins, angiotensin-converting enzyme (ACE) inhibitors, and angiotensin receptor blockers (ARBs)).

Each of these medicines may have a number of interactions with Amitriptyline tablets, and the dosage of the other medicine may need to be adjusted. If you are prescribed any of these medicines, please let your doctor or pharmacist know.

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 you have an intolerance to any of these 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.

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 to 50mg daily. Depending on the response to the medicine, your doctor may gradually increase the dose to a total daily dose of 100mg to 200mg. If you receive doses in the range of 100mg to 150mg, your doctor may need to do more frequent follow up 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.

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. 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 up with you.

Use in children and adolescents

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

Bed-wetting at night

Use in children and adolescents

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 100mg daily, your doctor may need to do more frequent follow up with you.

If you forget to take Amitriptyline tablets

You can 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 discuss with you how to stop your treatment to avoid any unpleasant symptoms that might occur if it is stopped suddenly (e.g. ‘breakback’, feeling unwell, sleeplessness and irritability).

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

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you get any of the following symptoms you should see your doctor immediately.

Common side effect: may affect up to 1 in 10 people

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

Rare side effect: may affect up to 1 in 1,000 people

- Bad constipation, a swollen stomach, fever and vomiting. These symptoms may be due to parts of the intestine becoming paralysed.
- Any yellowing of the skin and the white in the eyes (jaundice). Your liver may be affected.
- Blurring, bleeding, pallor or persistent sore throat and fever. These symptoms may be due to parts of your blood or bone marrow may be affected. Effects on the blood could be a decrease in the number of red cells (which carry oxygen around the body), white cells (which help to fight infection) and platelets (which help with bleeding and clotting).
- Suicidal thoughts or behaviour.

Very rare: may affect up to 1 in 10,000 people

- Attacks of intermittent blurring of vision, rainbow vision, and eye pain. You should immediately have an eye examination and the medicine be continued. This condition may be signs of acute glaucoma.

Amitriptyline Tablets

10,25 & 50mg x 28’s (UK)

JDE No.: 9255

Leaflet for Blisters

Technically Approved

296x210 Leaflet Reel Fed Bi Fold Profile (BST)

Dimensions:

296x210 (Reel Fed)

50960114

Leaflet for Blisters

9255

R.Wrey

17/10/18

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Accord UK

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