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.

What is in this leaflet

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

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 breast-feeding, think you may be pregnant or are the patient:

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

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 reactions
- 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 (MAOIs) or 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 harming or killing 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Amitriptyline tablets if you or your child (if they are the patient):
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:
- any allergic reaction signs may include a skin rash, which may be itchy, sensitivity to the sun or sunburn, puffy eyelids, face or tongue, which may be fast or slow. You should stop taking them immediately.
- a serious effect on your blood, such as low potassium levels. Signs may include fever or chills, sore throat, ulcers in your mouth or throat, unusual tiredness or weakness, unusual bleeding or unexplained bruising.
- bone marrow suppression; in some blood cells you may experience a soreness of the mouth or throat, unusual bleeding or bruising, unusual bleeding or unexplained bruising.
- a serious effect on the blood, which may be low. Signs may include fever or chills, sore throat, ulcers in your mouth or throat, unusual tiredness or weakness, unusual bleeding or unexplained bruising.
- thoughts of suicide (see section 4).
- anticholinergic effects (dry mouth, fever, constipation, blurred or double vision, difficulty or lack of control when urinating, dilatation 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).
- inappropriate secretion of 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, tremors, 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 mucous membranes in the mouth, swollen saliva glands, abdominal pain, black tongue, impotence of taste.
- increased 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.

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.

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.

Contents of the pack and other information

What Amitriptyline tablets contain

The active substance is amitriptyline hydrochloride. Each tablet contains 10mg, 25mg or 50mg of the active ingredient.

What Amitriptyline tablets look like and contents of the pack

Amitriptyline tablets are circular, biconvex, 8 mm-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 May 2017.