Package leaflet: Information for the user

Amitriptyline 10 mg, 25 mg, and 50 mg Film-Coated Tablets
(Amitriptyline Hydrochloride)

Warning – Thoughts of self- harm and suicidal behaviour – see section 2

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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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 Tablet is and what it is 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

1. What Amitriptyline Tablet is and what it is used for

Amitriptyline belongs to a group of medicines known as tricyclic antidepressants.

This medicine is used to treat:

- Depression in adults (major depressive episodes)
- Neuropathic pain in adults
- Chronic tension type headache prevention in adults
- Migraine prevention 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.

As with many other kinds of medications and treatments, we don't know for certain how antidepressants work. We do know that they affect the activity of certain chemicals in our brains. These are called neurotransmitters, and pass signals from one brain cell to another. The neurotransmitters most affected by antidepressants are serotonin and noradrenaline. However, research suggests that antidepressants work on the brain in multiple ways that go beyond simple chemical reactions. This research suggests that they:

- influence how the body responds to stress
- improve our negative thinking
- stop or even reverse damage to brain cells

2. What you need to know before you take Amitriptyline Tablets

Do not take Amitriptyline Tablets

- If you are allergic to amitriptyline or any of the other ingredients of this medicine (listed in section 6).
- if you recently have had a heart attack (myocardial infarction)
- if you have heart problems such as disturbances in heart rhythm which are seen on an electrocardiogram (ECG), heart block, or coronary artery disease
- if you are taking medicines known as monoamine oxidase inhibitors (MAOIs)
- if you have taken MAOIs within the last 14 days
- if you have taken moclobemide the day before
- if you have a severe liver disease.

If you are treated with Amitriptyline Tablets, you have to stop taking this medicine and wait for 14 days before you start treatment with a MAOI.

This medicine should not be used for children below 6 years of age.

Warnings and precautions
Talk to your doctor or pharmacist before taking Amitriptyline Tablets.

The use of Buprenorphine/opioids or antidepressants such as SSRIs together with Amitriptyline tablets can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and 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 or anxiety disorder

This medicine may be associated with thoughts of self-harm and suicidal behaviour in some people. Tell someone you trust, who can help you in an emergency, that you are taking this medicine and ask that they read this leaflet
Talk to your trusted person, prescriber or go to a hospital straight away, if after starting this medicine, you have new or worse:
- Feelings of anxiety or irritability
- Feelings of restlessness and agitation
- Extreme increases in activity and difficulty sleeping
- Thoughts of acting on dangerous impulses to harm yourself
- Thoughts about suicide or dying
- Changes in behaviour or mood you, or someone you trust, notices and is worried about

In some people, thoughts of self-harm and suicidal behaviour may be increased when first starting antidepressants. Antidepressants take time to work; and sometimes side effects occur before you or others notice improvements in your mood.

Never stop taking an antidepressant suddenly without first talking to a healthcare professional. Stopping an antidepressant medicine suddenly can cause other symptoms related to withdrawal to occur.

Information from clinical trials has shown the highest risk of thoughts of self-harm and suicidal behaviour, is in adults aged less than 25 years who were treated with an antidepressant but the risk applies to people of all ages treated with these medicines.

Call NHS 111 who can offer you support, until you can be with someone who can help you in person.

Episodes of mania
Some patients with manic-depressive illness may enter into a manic phase. This is characterized by profuse and rapidly changing ideas, exaggerated gaiety and excessive physical activity. In such cases, it is important to contact your doctor who probably will change your medication.

Tell your doctor if you, or have had in the past, any medical problems, especially if you have

- narrow angle glaucoma (loss of vision due to abnormally high pressure in the eye)
- epilepsy, a history of convulsions or fits
- difficulty in passing urine
- enlarged prostate
- thyroid disease
- bipolar disorder
- schizophrenia
- severe liver disease
- severe heart disease
- pylorus stenosis (narrowing of the gastric outlet) and paralytic ileus (blocked intestine)
- diabetes as you might need and adjustment of your antidiabetic medicine.

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)

Sexual dysfunction

Medicines like amitriptyline may cause symptoms of sexual dysfunction (see section 4). Rarely people can experience more persistent sexual side-effects after they have stopped taking SSRIs. The term ‘post SSRI sexual dysfunction’ (PSSD) has been used by some people to describe these symptoms. For these people, PSSD can have a significant and distressing impact on their lives. Research is needed to understand why this happens and how common it is. It is important that people experiencing ongoing sexual side-effects receive appropriate and timely support.

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).

Take special care with Amitriptyline
Serious cutaneous reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Amitriptyline treatment. Stop using Amitriptyline and seek medical attention immediately if you notice any of the symptoms related to these serious cutaneous reactions described in section 4.

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

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 medicines should not be taking 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 bed-wetting

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)
- medicines to treat high blood pressure for example calcium-channel blockers (e.g. diltiazem and verapamil), guanethidine, betanidine, clonidine reserpine and methyldopa
- Anticholinergic drugs such as certain medicines to treat Parkinsons disease and gastrointestinal disorders (e.g. atropine, hyoscyamine)
- thioridazine (used to treat schizophrenia)
- tramadol (painkiller)
- medicines to treat fungal infections (e.g. fluconazole, terbinafine, ketoconazole, and itraconazole)
- sedatives (e.g. babiturates)
- antidepressants for example moclobemide, tranylcypromine, citalopram, escitalopram, SSRIs (fluoxetine, paroxetine, fluvoxamine), duloxetine, bupropion, venlafaxine, doxepin, trimipramine, or certain opioids(e.ge. tramadol, Buprenorphine). These medicines may have interactions with Amitriptyline tablets and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including those in the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating (hyperhidrosis), tremor, exaggeration of reflexes (hyperreflexia), increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.
- 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.
- Valproic acid

You should also tell your doctor if you take or have recently taken medicine that may affect the heart´s rhythm. e.g.:

- 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 food, drink and alcohol
It is not advised to drink alcohol during treatment with this medicine as it might increase the sedative effect

Pregnancy, breast-feeding and fertility
If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, 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 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 (withholding/retaining urine), 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 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.

The medicine may impair your ability to drive a motor vehicle or perform tasks that require careful concentration. It is your own responsibility to assess whether you are able to perform these tasks while taking the medicine. The medicine effects and side effects are described in other sections. Read the full package leaflet for your guidance. Talk to your doctor or pharmacist if you are not sure.

Amitriptyline Tablets contain lactose monohydrate, sodium and sunset yellow FCF
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product, as it contains a type of sugar called lactose.

The 50mg tablets also contain a colour called 'sunset yellow FCF' which may cause allergic reactions.

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Amitriptyline Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Not all dosing guidelines can be achieved with all formulations/strengths. The appropriate formulation/strength should be selected for initial doses and all subsequent dose increases.

Depression
In adults
The recommended starting dose is 25 mg twice daily.
Depending on your response to the medicine, your doctor may gradually increase your dose up to 150 mg per day, divided into two doses.

Elderly (over 65 years of age) and patients with cardiovascular disease, the recommended starting dose is 10-25 mg per day.

Depending on your response to the medicine, your doctor may gradually increase your dose up to 100 mg per day in two divided doses. If you are taking doses of 100 to 150 mg per day, your doctor may need to monitor you more frequently.

Use in children and adolescents
This medicine should not be given to children or adolescents to treat depression. See section 2 for more information.

Neuropathic pain, prevention of chronic tension headaches and migraine prevention
Your doctor will adjust your medication based on your symptoms and response to treatment.

In adults
The recommended starting dose is 10–25 mg in the evening.

The recommended dose is 25–75 mg per day.

Depending on your response to the medicine, your doctor may gradually increase your dose. If you are taking doses higher than 100 mg per day, your doctor may need to monitor you more frequently. Your doctor will tell you whether you should take your dose once a day or divide it into two doses.

Elderly (over 65 years of age) and patients with cardiovascular disease, the recommended starting dose is 10–25 mg in the evening.

Depending on your response to the medicine, your doctor may gradually increase your dose. If you are taking doses higher than 75 mg daily, your doctor may need to monitor you more frequently.

Use in children and adolescents
This medicine should not be given to children or adolescents for the treatment of neuropathic pain, for the prevention of chronic tension headaches and for the prevention of migraines. See section 2 for further information.

Bedwetting
Use in children and adolescents
Recommended doses for children:
- under 6 years of age: see section 2 Do not take Amitriptyline tablets
- 6–10 years of age: 10 mg–20 mg daily. A more appropriate dose should be used for this age group
- Children 11 years and older: 25 mg–50 mg.

The dose should be increased gradually.

Take this medicine 1 to 1½ hours before bedtime.

Before starting treatment, your doctor will take an ECG to check for any abnormalities in your heart rhythm. Your doctor will re-evaluate your treatment after three months and take a new ECG if necessary. Do not stop treatment without first asking your doctor.

Patients at special risk
Patients with liver disease or who are known to be "poor metabolisers" will usually receive a lower dose.

Your doctor may take blood samples to check the amount of amitriptyline in your blood (see also section 2).

How and when to take Amitriptyline tablets
The 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 prevention
It might take a few weeks before your 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/seizures
- 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 (abnormal heart rhythm due to issue with the heart's electrical system), heart failure (failure in the functioning of the heart), hypotension (decrease in blood pressure), cardiogenic shock (a condition in which your heart suddenly can't pump enough blood to meet your body's needs), metabolic acidosis (a condition that occurs when the body produces excessive quantities of acid), hypokalemia (decrease in the potassium level in the blood).

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 the 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 get any of the following symptoms you should see your doctor immediately:

- 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 side effect, may affect up to 1 in 10,000 people.

- A heart problem called “prolonged QT interval” (which is shown on your electrocardiogram, ECG). Common side effect, 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 side effect, 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 side effect, 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 red cells (which carry oxygen around the body), white cells (which help to fight infection) and platelets (which help with clotting). Rare side effect, may affect up to 1 in 1,000 people.

- Suicidal thoughts or behaviour. Rare side effect, may affect up to 1 in 1,000 people.

- Signs of a severe allergic reaction (anaphylaxis) such as swelling of your tongue or face, or difficulty breathing.

- Stop using Amitriptyline and seek medical attention immediately if you notice any of the following symptoms: Widespread rash, high body temperature and enlarged lymph nodes (DRESS or drug hypersensitivity syndrome). Not known: frequency cannot be estimated from available data.

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

Very common: may affect more than 1 in 10 people
- sleepiness/drowsiness
- shakiness of hands or other body parts
- dizziness
- headache
- irregular, hard, or rapid heartbeat
- dizziness when you stand up due to low blood pressure (orthostatic hypotension)
- dry mouth
- constipation
- nausea
- excessive sweating
- weight gain
- slurred or slow speech
- aggression
- Problem with ability of the eye to change its focus from distant to near objects (and vice versa)
- congested nose.

Common: may affect up to 1 in 10 people
- Confusion
- sexual disturbances (decreased sex-drive, problems with erection)
- disturbance in attention
- changes in taste
- numbness or tingling in the arms or legs
- disturbed coordination
- dilated pupils
- heart block
- fatigue
- low sodium concentration in the blood
- agitation
- urination disorders
- feeling thirsty.

Uncommon: may affect up to 1 in 100 people
- excitement, anxiety, difficulties sleeping, nightmares
- convulsions
- tinnitus (ringing in the ears)
- increased blood pressure
- diarrhoea, vomiting
- skin rash, nettle rash (urticaria), swelling of the face and tongue
- difficulties passing urine
- increased production of breast milk or breast milk outflow without breast feeding
- increased pressure in the eye ball
- collapse conditions
- worsening of cardiac failure
- liver function impairment (e.g. cholestatic liver disease).

Rare: may affect up to 1 in 1000 people

- decreased appetite
- delirium (especially in elderly patients), hallucinations
- abnormality in the heart's rhythm, or heartbeat pattern
- swelling of the salivary glands
- hair loss
- increased sensitivity to sunlight
- breast enlargement in men
- fever
- weight loss
- abnormal results of liver function tests.

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

- heart muscle disease
- feeling of inner restlessness and a compelling need to be in constant motion
- disorder of the peripheral nerves
- acute increase of pressure in the eye (acute glaucoma)
- particular forms of abnormal heart rhythm (so called torsades de pointes)
- allergic inflammation of the lung alveoli and of the lung tissue.

Not known: frequency cannot be estimated from available data

- absent sensation of appetite
- elevation or lowering of blood sugar levels
- paranoia
- movement disorders (involuntary movements or decreased movements)
- hypersensitivity inflammation of heart muscle
- Hepatitis (inflammation of the liver) with signs such as dark urine, weight loss and jaundice
- hot flush
- Dry eyes

An increased risk of bone fractures has been observed in patients taking this type of medicines.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at Website: 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.

5. How to store Amitriptyline Tablets

Keep this medicine out of the sight and reach of children.
Store below 25 ºC.
Do not use this medicine after the expiry date which is stated on the label and the carton after EXP.
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.

6. Contents of the pack and other information

What Amitriptyline Tablets contains

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

• The other ingredients are

Tablet core: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate.

Film-coat:
Amitriptyline 10 mg Film-coated tablets: polyvinyl alcohol –partially hydrolysed (E1203), talc (E555b), titanium dioxide (E171), hypromellose (E464), indigo carmine (E132), macrogol (E1521)

Amitriptyline 25 mg Film-coated tablets: hypromellose (E464), Iron oxide red (E172), talc (E555b), titanium dioxide (E171)

Amitriptyline 50 mg Film-coated tablets : lactose monohydrate, titanium dioxide (E171), hypromellose (E464), macrogol (E1521), quinoline yellow (E104), sunset yellow (E110), indigo carmine (E132)

What Amitriptyline looks like and contents of the pack
Amitriptyline 10 mg Film-coated tablets are blue colored, round, biconvex, film–coated tablets with a breakline on one face and other face plain, approximately 5.10 mm in diameter.

The score line is only to facilitate breaking for ease swallowing and not to divide into equal dose.

Amitriptyline 25 mg Film-coated tablets are brown colored, round, biconvex, film–coated tablets plain on both faces, approximately 7.10 mm in diameter.

Amitriptyline 50 mg Film-coated tablets are yellow colored, round, biconvex, film–coated tablets plain on both faces, approximately 8.60 mm in diameter.

Amitriptyline Tablets are available blister packs containing 28, 30, 56, 60, 84, 90, 98, 100, 112, 120, 168, 180, 250, film-coated tablets

Not all pack sizes may be marketed.

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