

PACKAGE LEAFLET: INFORMATION FOR USER**AMITRIPTYLINE 10 MG , 25 MG AND 50 MG FILM-COATED TABLETS
(Amitriptyline Hydrochloride)****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 is and what it is used for
2. What you need to know before you take Amitriptyline
3. How to take Amitriptyline
4. Possible side effects
5. How to store Amitriptyline
6. Contents of the pack and other information

1. What Amitriptyline is and what it is used for

Amitriptyline belongs to a group of drugs called tricyclic antidepressants (TCADs). Amitriptyline may be used:

- to treat the symptoms of depression (major depressive episodes).
- Neuropathic pain in adults
- Chronic tension type headache prophylaxis 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.

2. What you need to know before you take Amitriptyline**Do not take Amitriptyline and tell your doctor if you or your child (if they are the patients):**

- are allergic (hypersensitive) to amitriptyline, other tricyclic antidepressants or any of the other ingredients in these tablets (listed in section 6).
- are taking monoamine oxidase inhibitors (MAOI), or you have stopped taking these medicines within the last 14 days.
- have heart disease including irregular heart beats, heart block, heart failure, coronary artery disease or have had a recent heart attack (myocardial infarction).
- suffer from periods of increased and exaggerated behaviour (mania).
- have severe liver disease.
- have taken moclobemide the day before

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.

If this medicine has been prescribed for a child under 6 years of age, tell your doctor as it may not be suitable for them.

Warnings and precautions

Talk to your doctor or pharmacist before taking medicines.

Heart rhythm disorders and hypotension may occur if you receive a high dose of Amitriptyline. This might also occur in usual doses if you have pre-existing heart disease. The use of buprenorphine together with amitriptyline can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and Amitriptyline Tablets”)

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

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 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 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.

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.

Take special care with Amitriptyline Tablets :

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.

Tell your doctor if you have, 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 ileu (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)

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).

You may not see an improvement in your depression during the first month of treatment. Your doctor may want to monitor you during this time.

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 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 enuresis.

Other medicines and Amitriptyline

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 tranlycypromine (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 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) nefopam, or opioid 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. habiturates)
- antidepressants (e.g. SSRIs (fluoxetine, paroxetine, fluvoxamine), duloxetine, and bupropion).
- medicines for certain heart conditions (e.g. beta blockers and antiarrhythmics such as amiodarone, disopyramide, propafenone)
- 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
- apraclonidine and brimonidine (to treat glaucoma)
- altretamine (to treat some types of cancer)
- disulfiram (to treat alcohol addiction)
- baclofen (muscle relaxant)
- medicines to treat angina that you spray or dissolve under your tongue (e.g. glyceryl trinitrate “GTN, isosorbide dinitrate)
- sibutramine (to suppress appetite)

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 with food, drink and alcohol

DO NOT drink alcohol with this medicine as it may increase the sedative effects of these tablets

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, 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.

Amitriptyline film-coated tablets contain Lactose

If you or your child has been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Amitriptyline

Always take this medicine exactly as your doctor or pharmacist has told you. You should 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 25 mg two times daily.

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

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

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

Depending on your response to the medicine, your doctor may gradually increase the dose to a total daily dose of 100 mg divided in two doses. If you receive doses in the range of 100 mg – 150 mg, 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 10 mg - 25 mg in the evening.

The recommended daily dose is 25 mg - 75 mg.

FLAT DIMENSION = 180 x 890 mm
FOLDED DIMENSION = 180 x 28mm

Depending on your response to the medicine, your doctor may gradually increase the dose. If you receive doses above 100 mg daily, your doctor may need to do more frequent follow-up 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 10 mg – 25 mg in the evening.

Depending on your response to the medicine, your doctor may gradually increase the dose. If you receive doses above 75 mg 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 treatments 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 doses for children:

- aged below 6 years: see section 2 Do not take Amitriptyline Tablets
- aged 6 to 10 years: 10 mg – 20 mg daily. A suitable dosage form should be used for this agegroup.
- aged 11 years and above: 25 mg – 50 mg. 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 sign of 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 than you should

If you (or somebody else) accidentally swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Take any remaining tablets and the container with you.

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

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

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take another as soon as you remember and then your next dose at the usual time.

If you stop taking Amitriptyline

You may not notice any improvement for up to 4 weeks. Do not stop taking the medicine unless your doctor tells you to as you may experience withdrawal symptoms (see section 4). 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.

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).

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

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

Very rare side effect, 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 before the treatment with this medicine can be continued. This condition may be signs of acute glaucoma.

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.
- 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).
- Suicidal thoughts or behaviour.

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

Very common: may affect more than 1 in 10 people

- sleepiness/drowsiness
- dizziness
- irregular, hard, or rapid heartbeat
- dizziness when you stand up due to low blood pressure (orthostatic hypotension)
- dry mouth
- nausea
- weight gain
- aggression
- shakiness of hands or other body parts
- headache
- constipation
- excessive sweating
- slurred or slow speech
- congested nose.

Common: may affect up to 1 in 10 people

- confusion
- sexual disturbances (decreased sex-drive, problems with erection)
- changes in taste
- numbness or tingling in the arms or legs
- dilated pupils
- fatigue
- agitation
- disturbance in attention
- disturbed coordination
- heart block
- low sodium concentration in the blood
- 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 (urticarial), 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 1,000 people

- decreased appetite
- delirium (especially in elderly patients), hallucinations (especially in patents with schizophrenia)
- abnormality in the heart’s rhythm, or heartbeat pattern

- swelling of the salivary glands
- hair loss
- breast enlargement in men
- abnormal results of liver function tests.

- increased sensitivity to sunlight
- fever
- weight loss

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
- 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 the available data

- absent sensation of appetite
- elevation or lowering of blood sugar levels
- weakness, poor concentration, disorientation, delusion, restlessness, pain, poor co-ordination, blurred vision, dry eyes
- paranoia
- movement disorders (involuntary movements or decreased movements)
- hypersensitivity inflammation of heart muscle, heart attack
- hepatitis
- stomach pain, sore mouth
- inflammation of the testicle
- inflammation of the mouth and lips
- breast enlargement, changes in sex drive or function, ADH secretion changes
- hot flush
- elevated body temperature
- black tongue
- stroke

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

Additional side effects in children

- Changes in behaviour

Reporting of side effects

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

5. How to store Amitriptyline

- Keep out of the sight and reach of children.
- Do not store above 30°C. Store in the original package (blister) in order to protect from moisture and light.
- Do not use this medicine after the expiry date which is stated on the carton (EXP.) The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Amitriptyline film-coated 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, crospovidone, maize starch, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate and talc.

The 10 mg tablet film coat contains: hypromellose, macrogol 6000, talc, titanium dioxide (E171), indigo carmine Al Lake (E132). The 25 mg tablet film coat contains: hypromellose, macrogol 6000, talc, titanium dioxide (E171), quinoline yellow (E104).

The 50 mg tablet film coat contains: hypromellose, macrogol 6000, talc, titanium dioxide (E171), ferric oxide red (E172), quinoline yellow (E104).

What Amitriptyline film-coated tablets look like and contents of the pack

Amitriptyline 10 mg film-coated tablets are pale blue coloured, circular biconvex film-coated tablets with “BL” debossed on one side and “10” on the other side.

Amitriptyline 25 mg film-coated tablets are yellow coloured, circular biconvex film-coated tablets with “BL” debossed on one side and plain on the other side.

Amitriptyline 50 mg film-coated tablets are buff coloured, circular biconvex film-coated tablets with “BL” debossed on one side and plain on the other side.

Amitriptyline film-coated tablets are available in a pack sizes of 7, 10, 14, 21, 28, 30, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160 or 168 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Bristol Laboratories Ltd,

Unit 3, Canalside, Northbridge Road, Berkhamsted, Hertfordshire, HP4 1EG, UK

Telephone: 0044 (0)1442 200922

E-mail: info@bristol-labs.co.uk

Manufacturer

Bristol Laboratories Limited

Laporte Way, Luton, LU4 8WL, United Kingdom

Bristol Laboratories Ltd,

Unit 5, Traynor Way, Whitehouse Business Park, Peterlee, SR8 2RU, United Kingdom.

Amitriptyline 10 mg film-coated tablets; PL 17907/0131

Amitriptyline 25 mg film-coated tablets; PL 17907/0132

Amitriptyline 50 mg film-coated tablets; PL 17907/0133

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