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Package leaflet: Information for the user

Amitriptyline Hydrochloride 25mg/5ml Oral Solution
Amitriptyline Hydrochloride 50mg/5ml Oral Solution

Read all of this leaflet carefully before you start to take 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, please 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 Oral Solution is and what it is used for
2. What you need to know before you take Amitriptyline Oral Solution
3. How to take Amitriptyline Oral Solution
4. Possible side effects
5. How to store Amitriptyline Oral Solution
6. Contents of the pack and other information

1. What Amitriptyline Oral Solution is and what it is used for

Amitriptyline Oral Solution 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 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 Oral Solution

Do not take Amitriptyline Oral Solution if you:
- are allergic to amitriptyline or to 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 Oral Solution, 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
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.
Talk to your doctor before taking Amitriptyline Oral Solution:
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 Oral Solution. 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
If you are depressed, 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, 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.
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 ileus (blocked intestine)
- diabetes as you might need an 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 Oral Solution 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, 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 Oral Solution)
- 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 Oral Solution
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:
- 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 Oral Solution (see section 2 Do not take Amitriptyline Oral Solution)
- 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 disorders gastrointestinal (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. 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
- 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 Oral Solution 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 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.

Oral Solution contains maltitol, ethanol (alcohol), propylene glycol and preservatives known as para hydroxybenzoates
- Maltitol; if you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicine
- Small amounts of ethanol (alcohol), less than 100mg per dose
- Preservatives known as para hydroxybenzoates; these ingredients may cause allergic reactions and could happen some time after starting the medicine.

3. How to take Amitriptyline Oral Solution

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. This medicine should be swallowed. The recommended doses are as follows:
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-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.
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-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 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-up with you.

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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 Oral Solution
- 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 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 Oral Solution
This medicine can be taken with or without food.

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 Oral Solution 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, hypotension, cardiogenic shock, metabolic acidosis, hypokalemia.

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 Oral Solution
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 Oral Solution
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).

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:
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS or drug hypersensitivity syndrome)
- 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.

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
- 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
- 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
- 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
- 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
- paranoia
- movement disorders (involuntary movements or decreased movements)
- hypersensitivity inflammation of heart muscle
- hepatitis
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card SchemeWebsite: 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 Oral Solution

- Keep out of the sight and reach of children
- Amitriptyline Oral Solution should not be stored above 25°C. Store in the original bottle and outer carton to protect from light; do not transfer to another container
- Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Once opened the product should be used within 1 month.
Do not throw medicines away 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 Oral Solution contains
The active ingredient is: amitriptyline hydrochloride.
Amitriptyline Hydrochloride 25mg/5ml oral solution contains 25mg of the active ingredient in 5ml.
Amitriptyline Hydrochloride 50mg/5ml oral solution contains 50mg of the active ingredient in 5ml.
The other ingredients are: methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), propylene glycol, ascorbic acid, orange flavour 10950-56 (contains ethanol), orange/tangerine flavour 10888-56 (contains ethanol), sucralose powder, liquid maltitol and purified water.

What Amitriptyline Oral Solution looks like and the contents of the pack
Amitriptyline Oral Solution is a clear colourless solution that becomes yellow over time. It has an orange/tangerine odour. The medicine is supplied in 150ml amber glass bottle, with a child resistant cap, in a cardboard outer carton.

Marketing Authorisation Holder: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only). Please be ready to give the following information:

Product name	UK Reference number
Amitriptyline 25mg/5ml Oral Solution Amitriptyline 50mg/5ml Oral Solution	PL 29831/0356 PL 29831/0439

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in 12/2024

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