

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

The name of your medicine is Amitriptyline Oral Solution. Amitriptyline belongs to a group of medicines known as tricyclic antidepressants. Everybody has substances called serotonin and noradrenaline in their brains. It is thought that people with depression (and some other conditions) have less of these substances compared to those without depression (or other conditions).

Amitriptyline works by increasing the amounts of these substances in the brain. Amitriptyline also effects the muscles in the bladder and reduces the need to pass urine. Amitriptyline Oral Solution is used in the treatment of:

- depression (especially when associated with sleep disturbance)
- night-time bed-wetting in children aged six years and above.

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)
- are taking drugs called Monoamine Oxidase Inhibitors (MAOIs) for depression
- are recovering from a heart attack
- have blockage of the coronary arteries or heart failure
- are taking drugs that increase the QT interval of the ECG (heart trace) e.g. amiodarone, terfenadine, astemizole, sertindole, pimozone, thioridazine, sotalol
- have an abnormal heart rhythm
- suffer from mania (feeling high or over-excited)
- have severe liver disease

- suffer from porphyria (a disease of blood proteins affecting the skin, gut and nervous system)
- are breast feeding.

Warnings and precautions

Talk to your doctor before taking Amitriptyline Oral Solution if you:

- suffer from epilepsy
- suffer from liver disease
- have problems passing water
- have an enlarged prostate
- have increased pressure in your eyes (e.g. glaucoma)
- suffer from heart disease
- have an overactive thyroid gland
- are taking medicines for thyroid disease
- suffer from schizophrenia
- receive electroconvulsive therapy (ECT)
- are due to have surgery in the near future
- have a blood disorder
- have diabetes
- have hiatus hernia (a weakness of the diaphragm causing heartburn)
- have phaeochromocytoma (a rare tumour of the adrenal gland)
- smoke.

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
- have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood.

When the medicine is given for bed-wetting:

1. you should not take amitriptyline with medicines known as anticholinergic such as atropine, oxybutynin or orphenadrine.
2. your doctor may monitor your heart with an ECG (electrocardiogram) test before giving this medicine
3. suicidal thoughts may occur when taking this medicine for bed-wetting. See the information in the following section for advice.

Special care should be taken with elderly patients.

Thoughts of suicide and worsening of your depression or anxiety disorder

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 have these kind of thoughts if:

- you have previously had thoughts about killing or harming yourself
- you are a young adult. Information from clinical trials has shown an increased risk in suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts about harming or killing yourself at any time, contact your doctor or go to hospital straight away. You may find it helpful to tell a close friend or relative 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.

Children and adolescents

Amitriptyline Oral Solution should not be used in children under 6 years.

Amitriptyline Oral Solution is not recommended for the treatment of depression in children under 16 years of age.

Other medicines and Amitriptyline Oral Solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. It is important you do this as some medicines when taken in combination with Amitriptyline Oral Solution can cause a very serious side effect called paralytic ileus (this is when the small bowel ceases to function for a time).

The following medicines can affect or be affected by treatment with Amitriptyline Oral Solution:

- antidepressants called monoamine oxidase inhibitors (MAOIs) – you should wait at least 14 days after stopping an MAOI before starting amitriptyline
- medicines used to treat high blood pressure (e.g. guanethidine, debrisoquine, betanidine, clonidine)
- medicines used as sedatives to treat sleep problems (e.g. ethchlorvynol)
- medicines used to maintain blood pressure in critically ill patients (e.g. ephedrine, isoprenaline, adrenaline, noradrenaline, phenylephrine, phenylpropanolamine)
- disulfiram (used to treat alcoholism)
- ritonavir and saquinavir (used to treat HIV infection)
- cimetidine (used to treat problems with stomach acid)
- sertindole, pimozide, thioridazine and phenothiazine (used to treat mental illness)
- St John's Wort (a herbal remedy often used for depression)
- astemizole and terfenadine (used in hayfever and other allergic conditions)
- drugs used to control irregular heart rhythm, such as amiodarone, disopyramide, procainamide, propafenone and quinidine
- anaesthetics
- nitrates, such as glyceryl trinitrate (used to treat angina)
- sotalol, a beta-blocker (used in heart disease)
- barbiturates and other drugs which slow down brain function
- carbamazepine and sodium valproate (used to treat epilepsy)
- methylphenidate (used to treat hyperactivity)
- anticholinergic drugs, such as trihexyphenidyl hydrochloride, benztropine mesylate, atropine, oxybutynin and orphenadrine when combined with amitriptyline for bed-

wetting therapy in children or when used in elderly patients. These medicines should not be given to patients treated for bed-wetting with amitriptyline

- selegiline and entacapone, used in the treatment of Parkinson's Disease
- nefopam, tramadol and morphine (used for pain relief)
- rifampicin, moxifloxacin and linezolid (used to treat bacterial infections)
- warfarin and other drugs used to thin the blood
- fluconazole (used to treat fungal infections)
- diuretics (water tablets)
- oral contraceptives ("the pill")
- thyroxine, used to treat an underactive thyroid gland
- fluoxetine and reboxetine (used to treat depression)
- baclofen (used as a muscle relaxant)
- decongestants such as phenylpropanolamine
- apraclonidine and brimonidine (used to treat glaucoma)
- moclobemide (used to treat depression and social anxiety). After stopping amitriptyline do not start moclobemide for at least one week

Amitriptyline Oral Solution with food, drink, and alcohol

As with all medicines that act on the central nervous system, it is advised that you do not drink alcohol while taking this medicine.

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 or pharmacist for advice before taking this medicine. You should not use this medicine if you are pregnant unless your doctor specifically recommends it. Tell your doctor straight away if you think you may be pregnant or wish to become pregnant.

You should not take Amitriptyline Oral Solution if you are breast feeding.

Driving and using machines

Amitriptyline oral solution may cause drowsiness and reduced alertness, do not drive or operate machinery while taking this medicine.

Oral Solution contains maltitol, ethanol (alcohol) and preservatives known as para hydroxybenzoates

This medicine contains:

- 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. Your doctor will decide the right dose for you; this will be on the pharmacist's label. Check this carefully, it will tell you how much of this medicine to take

and how often to take it. This medicine should be swallowed. The recommended doses are as follows:

Depression

Adults

- recommended starting dose is 75mg given twice or as one dose before bedtime
- this may be increased to 150mg a day, given as one dose in the evening or before bedtime
- when an improvement is seen in your condition, your doctor will reduce the dose.

Use in children

Bed-wetting (Enuresis)

Children only (for no longer than 3 months, if repeated treatment required then a medical review should be conducted every 3 months)

- children aged 6-10 years may receive 10-20mg a day
- children aged 11-16 years may need 25-50mg a day

If you take more Amitriptyline Oral Solution than you should

If you (or anybody else, including a child), takes more Amitriptyline Oral Solution than you should you should contact your doctor or nearest hospital casualty department immediately. Always take the bottle and leaflet with you.

If you forget to take Amitriptyline Oral Solution

If you forget a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. Do not take a double dose to make up for a forgotten dose.

If you stop taking Amitriptyline Oral Solution

Do not stop taking Amitriptyline Oral Solution unless you have been told to do so by your doctor. If you suddenly stop your treatment you may experience effects such as nausea, headache, chills, sweating, irritability, restlessness, anxiety, agitation, jerky uncontrollable movements, irregular heart rhythm, vivid dreams and sleep disturbances and a general feeling of being unwell.

Even with gradual withdrawal of treatment you may still experience some side effects in the first two weeks such as irritability, restlessness and dream and sleep disturbances.

Rarely, some patients develop mania (persistent extremely elevated mood and sometimes psychosis) and hypomania (mild form of mania) within 2-7 days of stopping long-term therapy of amitriptyline.

Withdrawal symptoms seem to be more common and more severe in children.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects seek medical help immediately:

- allergic reaction. Symptoms may include rash, itching, difficulty breathing
- neuroleptic malignant syndrome. Symptoms may include fever, muscle cramps, delirium.

If you experience the following side effect, carry on taking the tablets but seek medical advice as soon as possible:

- problems with bone marrow and blood cell production. Symptoms may include a sore throat, mouth ulcers and recurring infections, bleeding or bruising easily.

Side effects that have been reported with Amitriptyline Oral Solution are:

Heart and Blood Vessel disorders

- high blood pressure
- fainting
- low blood pressure (particularly on standing)
- heart attack
- stroke
- problems with heart rhythm
- a heart problem called “prolonged QT interval” (which is shown on your electrocardiogram, ECG) (frequency common)

Some of these side effects can be life-threatening.

Nervous System disorders

- confusion
- disorientation
- excitement
- delusions
- sleep disturbance
- involuntary movements
- fits
- headache
- problems with coordination and balance
- nightmares
- reduced concentration
- hallucinations
- persistent elevated mood
- anxiety/restlessness
- agitation
- coma
- dizziness
- ringing in the ears
- numbness and tingling of the extremities

Eye problems

- blurred vision
- enlarged pupils
- problems focussing eyes
- increased pressure in the eye

Gastrointestinal System

- dry mouth
- paralysis of the gut
- stomach pains
- black tongue
- liver disease
- weight gain
- unpleasant tastes in mouth
- constipation
- nausea and vomiting
- altered appetite
- diarrhoea
- weight loss
- inflammation of the mouth

Skin and Hair problems

- sensitivity to sunlight
- increased sweating
- hair loss
- itching
- rash

Kidney and Urinary complaints

- problems passing water
- increased urination

Muscle and Bone complaints

- painful joints
- weakness
- fatigue
- increased risk of bone fractures

Other complaints

- altered sex drive
- delayed ejaculation; delayed orgasm in women
- swelling of testicles
- milk production
- increase in breast tissue (in men and women)
- fever
- swelling of glands
- impotence
- hormonal disturbances
- alteration of blood sugar levels
- swelling of face and tongue
- delirium (particularly in the elderly)
- syndrome of inappropriate antidiuretic hormone (SIADH), symptoms of which may include hyponatraemia (drowsiness, confusion or fits)

Additional side effects in children

Changes in behaviour have occurred in children receiving amitriptyline for treatment of night-time bed-wetting.

Some babies born to mothers who have taken amitriptyline shortly before delivery have had heart problems, breathing difficulty, muscle spasm, irritability, agitation, fits or difficulty passing urine.

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 national reporting systems listed below:

United Kingdom:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland:

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

Malta:

ADR Reporting, The Medicines Authority, Post-Licensing Directorate,
203 Level 3, Rue D'Argens, GZR-1368 Gzira

Website: www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt

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.

These medicinal products are authorised in the Member States of the EEA under the following names:

UK: Amitriptyline Hydrochloride 25mg/5ml oral solution and Amitriptyline Hydrochloride 50mg/5ml oral solution

Ireland: Amitriptyline Hydrochloride 25mg/5ml oral solution and Amitriptyline Hydrochloride 50mg/5ml oral solution

Cyprus: Amitriptyline Hydrochloride Wockhardt 25mg/5ml oral solution and Amitriptyline Hydrochloride Wockhardt 50mg/5ml oral solution

Malta: Amitriptyline Hydrochloride 25mg/5ml oral solution and Amitriptyline Hydrochloride 50mg/5ml oral solution

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	Irish Reference number
Amitriptyline 25mg/5ml Oral Solution	PL 29831/0356	PA 1339/24/1
Amitriptyline 50mg/5ml Oral Solution	PL 29831/0439	PA 1339/24/2

This is a service provided by the Royal National Institute of Blind People.
For the Republic of Ireland please call +44 1978 669272

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