Amitriptyline hydrochloride 10mg/5ml Oral Solution

1. What Amitriptyline 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)
- young people with suicidal thoughts and behaviours
- chronic tension type headache prophylaxis in adults
- neuropathic pain
- bed-wetting in children aged 6 years and older, when normal bed-wetting has not occurred and
- heart rhythm disorders and hypotension may occur if you are taking this medicine and wait for 14 days before you start treatment with a MAOI.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Amitriptyline.

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 an electrocardiogram, ECG), and heart rhythm disorders (rapid or irregular heart beat) have been reported with Amitriptyline. Tell your doctor if you:

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

If you are treated with Amitriptyline, 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.

Cautions for use

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including over-the-counter medicines and herbal medicines.

Tell your doctor if you have, or have had in the past, any of the following conditions:

- Narrow angle glaucoma (loss of vision due to increased pressure in the eye)
- Epilepsy, a history of convulsions or fits
- Difficulty in passing urine
- Severe heart problems, or
- Severe heart disease
- Pylorus stenosis (narrowing of the gastric outlet) and paralytic ileus (blocked intestine)
- Diabetes as this medicine may need an adjustment of your antidiabetic medicine.

If you use antidepressants such as SSRIs, your doctor may consider changing the dose of your medicine (see also section 2 Other medicines and Amitriptyline and section 3). Elderly are more likely to suffer from certain side effects, such as dizziness, confusion, and low blood pressure (see also section 4 Possible side effects).

Children and adolescents

Depression, neuropathic pain, chronic tension type headache, or 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 the QT syndrome

This medicine should not be taken at the same time as an anticholinergic drug (see also section 2 Other medicines and Amitriptyline).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, including medicines obtained without a prescription, including herbal medicines, such as:

- Monoamine oxidase inhibitors (MAOIs) e.g. phenelzine, isocarboxazid, nialamide or tranylcypromine (used to treat depression) or selegiline (used to treat Parkinson’s disease).

- Anticoagulants such as warfarin may increase the risk of bleeding

- Antihistamines such as chlorpheniramine are used to treat hay fever and other forms of allergies

- Antidepressants such as SSRIs (fluoxetine, paroxetine, fluvoxamine, sertraline, citalopram, bupropion) are used to treat certain heart conditions (e.g. beta blockers and antiarrhythmics)

- Cimetidine (used to treat stomach ulcers) methylphenidate (used to treat ADHD)

- Fludrocortisone (used to treat Addison’s disease)

- Oral contraceptives

- Rifaximin (to treat infections)

- Phenytoin (used in the treatment of epilepsy)

- St. John’s Wort (Hypericum perforatum) – a herbal remedy used for depression

- Propranolol (used to treat high blood pressure)

- 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 digoxin)

- Antihistamines used to treat allergies and hayfever

- Medicines used to treat some mental illnesses (e.g. pimozide and sertindole)

- Ciapride (used to treat certain types of indigestion)

- Haldolamine (used to treat nausea and vomiting)

- Methadone (used to treat pain for detoxification)

- Water treatment for acute kidney failure.

If you are going to have a 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 alcohol

This 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 necessary and only after careful consideration of the benefit and risk. If you have taken this medicine during the pregnancy, the newborn may have withdrawal symptoms such as irritability, increased muscle tension, tremor, irregular breathing, poor sucking, loud crying, urination, 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 contains:

Methyl and propyl parahydroxybenzoate: an artificial fruit flavoring and coloring. E123: an artificial color, and E110: may cause allergic reactions (possibly delayed).

Sodium: This medicine contains less than 1mmol sodium (23mg) per 5ml dose, that is to say essentially ‘sodium-free’.

3. How to take Amitriptyline

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 medicines on the market.

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.

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 4.

Neuropathic pain, chronic tension type headache and migraine prophylaxis

Your doctor will prescribe medication according to your symptoms and your response to the treatment.

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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.

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:

► aged below 6 years: see section 2

► Do not take Amitriptyline

► aged 6 to 10 years: 10mg to 20mg daily. A suitable dosage form should be used for this age group

► aged 11 years and above: 25mg to 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 metabolizers” usually require 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

This medicine should be taken with or without food.

► use the double-ended spoon supplied with the pack to measure the exact quantity (see figure below)

► do not overfill the spoon

► swallow the solution

► wash the spoon with clean water after taking every dose.

Double-ended Spoon

2.5ml 5ml

(Small end) (Large end)

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

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, cardiac shock, metabolic acidosis, hypokalaemia.

Overdose with amitriptyline in children could have serious consequences. Children are especially susceptible to coma, cardiac symptoms, difficulty in breathing, seizures, low blood sugar level, lethargy, drowsiness, nausea, vomiting and high blood sugar level.

If you forget to take Amitriptyline

Take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

Stop or reduce treatment

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 everyone may not get 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, palor 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.

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

Very common: may affect more than 1 in 10 people

► sleeplessness/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 sleep

► 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

► excitation, 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 points)

► allergic inflammation of the lung alveoli and of the lungs.

Not known: frequency cannot be estimated from the available data

► absent sensation of appetite

► elevation or lowering of blood sugar levels

► paranoiac attacks

► 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 or any close family member experience any side effect you are not sure of, please contact 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 at: 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

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Discard 30 days after first opening.

Do not use this medicine if you notice that the solution has become discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Amitriptyline contains

The active substance is amitriptyline hydrochloride.

Each 5ml solution contains 10mg amitriptyline hydrochloride.

The other ingredients are ascorbic acid (E300), disodium edetate, saccharin sodium (E954), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and purified water.

What Amitriptyline looks like and contents of the pack

Amitriptyline is a clear, colourless to yellow coloured solution supplied in amber glass bottles with tamper-evident child-resistant polypropylene plastic screw cap and a 2.5-5ml double ended spoon for measuring the dose.

Amitriptyline is supplied in bottles containing 150ml, 200ml, 300ml and 500ml solution.

Not all pack sizes may be marketed.

POM

Marketing Authorisation Holder:

SynMed, Unit 4, Bradfield Road, Ruslip, Middlesex, HA4 0NU, UK.

Manufacturer:

Manifarm d.o.o., Marinikova ulica 24, Maribor, 2000, Slovenia

If this leaflet is hard to see or read, please call +44 208 515 3700 for help.

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