Read all of this leaflet carefully before you start taking this medicine because it contains important information about your treatment.

Keep this leaflet. You need to read it again if:
- You have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- You get any side effects, talk to your doctor or pharmacist. This includes possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Amitriptyline hydrochloride 10mg/5ml Oral Solution but it will be referred to as Amitriptyline throughout this leaflet.

What is this leaflet about?

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 medicines known as tricyclic antidepressants.

This medicine is used to treat:
- depression in adults (major depressive episodes)
- depression in children and adolescents
- chronic tension type headache prophylaxis in adults
- psychoneurotic depression in adults
- bed-wetting at night in children aged 6 years and above, only when organic causes, such as spina bifida and signs of spina bifida have been excluded and no response has been achieved to all other non-drug and drug treatments, including muscle relaxants and desipramine. The 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 if:
- you are allergic to amitriptyline or any of the other ingredients of this medicine (listed in section 6)
- you recently have had a heart attack (myocardial infarction)
- you have heart problems such as disturbances in heart rhythm which are seen on your electrocardiogram, ECG) and heart rhythm. e.g.:
  - prolonged QT interval
  - heart failure
  - severe heart failure
  - pylorus stenosis (narrowing of the gastric outlet) and paralytic ileus (blocked intestine)
  - diabetes and you 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 and section 3).

Elderly are more likely to suffer from certain side effects, such as dizziness when you stand up, changes in blood pressure (see also section 4 Possible side effects).

Children and adolescents
Depression, neuropsychiatric or chronic tension type headache and migraine prophylaxis
Do not give this medicine to children and adolescents aged below 10 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. The 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 such as depression. The 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 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, iproniazid, isocarboxazid, nialamide or tranylcypromine (used to treat depression) or selegiline (used to treat Parkinson’s disease).
- these medicines should be taken at the same time as Amitriptyline (see section 3.2 Do not take Amitriptyline) adenocarcinoma, a form of cancer
- other antihistamines and phenytoin and phenytoinlike medications (these may be present in cough or cold medicine, and in some antidepressants).
- these medicines will lower the blood pressure of calcium-channel blockers (e.g. diltiazem and verapamil) and may result in a pressure drop.
- these medicines and this can sometimes cause allergic reactions (possibly delayed).

Driving and using machines
This medicine may cause dizziness and dizziness, especially in the beginning of the treatment. Do not drive or work with tools or machinery if you are affected.

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.

Do 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 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 cardiac 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 treatment adjustments.

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:
<table>
<thead>
<tr>
<th>Age</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>aged 6 years and above</td>
<td>25mg</td>
</tr>
<tr>
<td>aged 6 to 10 years</td>
<td>10mg to 20mg</td>
</tr>
</tbody>
</table>

The dose should be increased gradually.

Take this medicine 1-1.5 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 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

This medicine can 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

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Spoon Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5ml</td>
<td>Small end</td>
</tr>
<tr>
<td>5ml</td>
<td>Large end</td>
</tr>
</tbody>
</table>

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 recur.

Neuropathic pain, chronic tension type headache and migraine prophylaxis

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 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 heart rate
- difficulties passing water
- dry mouth and tongue
- intestinal blockage
- fits
- fever
- Amnesia
- confusion
- hallucinations
- uncontrolled movements
- low blood pressure, weak pulse, pallor
- difficulty breathing
- blue discolouration of the skin

Rare: may affect up to 1 in 1,000 people
- decreased appetite
- delirium (especially in elderly patients), hallucinations (especially in patients with schizophrenia)
- 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
- absence of sensation
- e. elevation or lowering of blood sugar levels
- paranoia
- movement disorders ( involuntary movements or decreased movement)
- hypersensitivity inflammation of heart muscle
- hepatitis
- hot flush.

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 Scheme at www.mhra.gov.uk/yellowcard. 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 clearly marked 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 after 30 days of first opening.

Do not use this medicine if you notice that the solution becomes 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 dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Amitriptyline contains

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-ml 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.

Marketing Authorisation Holder and Manufacturer:

Thame Laboratories, Unit 4, Bradford Road, Rustlip, Middlesex, HA4 0NU, UK.

Tel: +44 (0) 208 515 3700

If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.

This leaflet was last revised in 05/2017.