

CONSUMER MEDICINE INFORMATION

ARROW - AMITRIPTYLINE

Amitriptyline hydrochloride 10 mg, 25 mg and 50 mg film-coated tablets

What is in this leaflet

This leaflet answers some common questions about ARROW - AMITRIPTYLINE. It does not contain all the information available on this medicine. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

Your doctor has weighed the risks of using ARROW – AMITRIPTYLINE against the benefits expected it will have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may want to read it again.

What ARROW - AMITRIPTYLINE is used for

Your ARROW - AMITRIPTYLINE tablets contain amitriptyline hydrochloride. It belongs to a group of medicines known as tricyclic antidepressants (TCAs).

ARROW - AMITRIPTYLINE is used to treat depression. Depression involves emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing.

Your doctor may, however, prescribe ARROW - AMITRIPTYLINE for another reason. Ask your doctor if you have any questions about why ARROW - AMITRIPTYLINE has been prescribed for you.

ARROW - AMITRIPTYLINE is not recommended for use in children 12 years of age and under. ARROW - AMITRIPTYLINE is not recommended for use in adolescents (13-18 years of age) for the treatment of depression, unless under the supervision of a specialist.

ARROW - AMITRIPTYLINE is available on prescription from your doctor.

Before you take ARROW - AMITRIPTYLINE

When you must not take it

Do not take ARROW - AMITRIPTYLINE if:

- You are allergic to amitriptyline, other tricyclic antidepressants or any other ingredients listed at the end of this leaflet
- **You are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking a MAOI within the last 14 days. Ask your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI**

- **You have recently had a heart attack.**

ARROW – AMITRIPTYLINE should not be used for the treatment of bedwetting.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Before you take it

Tell your doctor if:

- You have had an allergic reaction to any medicine that you have taken previously to treat your current condition
- You have heart or liver problems
- You have difficulty passing urine
- You have epilepsy, fits or convulsions (or a condition such as alcoholism, brain damage or a recent head injury which might make fits more likely to occur)
- You are having electrical shock treatment
- You suffer from an overactive thyroid gland (hyperthyroidism) or are receiving thyroid medication
- You suffer from raised pressure in the eye (glaucoma)
- You have suicidal thoughts or have attempted suicide in the past
- You suffer from mania (mood of excitement, over-activity and uninhibited behaviour) or bipolar disorder
- You have allergies to any other medicines, foods, preservatives or dyes.
- You are pregnant, plan to become pregnant or are breastfeeding

If you are pregnant or plan to become pregnant you need to discuss with your doctor the risks and benefits of taking amitriptyline during pregnancy. The general condition of your newborn baby might be affected by the medicine. There is some evidence that use during pregnancy may also result in a pre-term delivery. If your baby has been exposed to this medicine during the last three months of pregnancy it may suffer withdrawal symptoms such as trouble with breathing, fits, feeding difficulties, vomiting, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, constant crying, changes in blood pressure and sleepiness. If your newborn baby has any of these symptoms, please contact your doctor immediately.

Amitriptyline passes into breast milk. Use of amitriptyline is not recommended when breastfeeding.

Taking other medicines

If you are taking any other medicines, including any you get without a prescription from a pharmacy, supermarket or health food shop, tell your doctor or pharmacist.

Medicines that may interfere with ARROW - AMITRIPTYLINE include:

- **Monoamine Oxidase Inhibitors** (e.g. moclobemide, phenelzine, tranylcypromine)
- **Other antidepressants** (e.g. SSRIs and tricyclic antidepressants)
- **Opioids** (e.g. pethidine, tramadol)
- **Dextromethorphan** (a cough suppressant)
- **Guanethidine** (used to lower blood pressure)
- **Sympathomimetics**, such as nasal decongestants (used for colds or hay fever) and anticholinergic medicines
- **Cimetidine** (used to treat ulcers and other stomach complaints)
- **Central Nervous System Depressants** (e.g. barbiturates)
- **Disulfiram** (used in the treatment of chronic alcohol dependence).

These medicines may be affected by ARROW - AMITRIPTYLINE or may affect how well ARROW - AMITRIPTYLINE works. You may need different amounts of your medicines or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ARROW - AMITRIPTYLINE.

How to take ARROW - AMITRIPTYLINE

How much to take

Your doctor will tell you how much ARROW - AMITRIPTYLINE you need to take each day. It is important that you take ARROW - AMITRIPTYLINE as directed by your doctor. Do not take more than the recommended dose.

It may take up to 4 weeks before any response to ARROW - AMITRIPTYLINE is noticeable.

The usual dose for an adult is 75 mg of amitriptyline a day in divided doses. If necessary, your doctor may increase the dose up to a maximum of 150 mg a day. Alternatively, your doctor may start you on a daily dose of 50-100 mg and increase the dose by 25-50 mg, if necessary, up to a maximum of 150 mg a day. The usual maintenance dose is 50-100 mg per day.

Your doctor may tell you to take different doses to these. If so, follow their instructions.

The tablet(s) should be swallowed whole with a glass of water.

How long to take it

For depression, the treatment is usually continued for at least six months to prevent potential recurrence. You may not feel better immediately as most

antidepressants take time to work. Do not stop taking ARROW - AMITRIPTYLINE even if you begin to feel better, unless your doctor tells you to do so. Make sure you do not run out of tablets.

If you forget a dose

If you forget a dose, just take the next dose when it is due. Do not take more than one dose at a time to make up for missed doses.

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking ARROW - AMITRIPTYLINE

Tell all doctors, dentists and pharmacists who are treating you that you are taking ARROW - AMITRIPTYLINE.

Tell your doctor or pharmacist that you are taking ARROW - AMITRIPTYLINE before you start any new medicine.

Tell your doctor if you develop a skin rash or hives, or you become pregnant while taking ARROW - AMITRIPTYLINE.

Some people taking ARROW – AMITRIPTYLINE have experienced severe skin reactions, including drug reaction with eosinophilia and systemic symptoms (DRESS). These reactions can be very serious or even life-threatening. If you notice any signs of a severe skin reaction stop taking ARROW – AMITRIPTYLINE and tell your doctor immediately.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking ARROW - AMITRIPTYLINE.

If you are going to have any blood tests, tell your doctor that you are taking ARROW - AMITRIPTYLINE.

Keep all appointments you and your doctor have scheduled so that your progress can be followed.

Tell your doctor if you notice any of the following, especially if they are severe, abrupt in onset, or were not part of your presenting symptoms: anxiety, agitation, panic attacks, insomnia (difficulty sleeping), irritability, hostility (aggressiveness), impulsivity, akathisia (restlessness or difficulty sitting still), hypomania, mania (mood of excitement, over-activity and uninhibited behaviour), worsening of depression.

Tell your doctor immediately if you have any distressing thoughts (thought of suicide or self-harm) or experiences during this initial period or at any other time.

Do not take ARROW - AMITRIPTYLINE to treat any other complaints unless your doctor tells you to.

Do not stop taking ARROW - AMITRIPTYLINE or lower the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

ARROW - AMITRIPTYLINE may cause drowsiness in some people. Be careful when driving, operating machinery or performing jobs that need you to be alert, until you are certain that ARROW - AMITRIPTYLINE does not affect your performance.

Your doctor may suggest avoiding alcohol while you are being treated for depression.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking ARROW - AMITRIPTYLINE.

All medicines can have some unwanted effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Stomach or bowel problems (e.g. nausea, vomiting, diarrhoea, constipation)
- Drowsiness
- Dry mouth or taste change
- Increased sweating
- Loss of appetite
- Shakiness or tremor
- Ejaculation disorders or changes in your sex drive
- Dizziness
- Headache
- Weakness
- Impaired concentration or thought processes
- Trouble sleeping
- Vision problems
- Weight gain or loss
- Irregular heart beats, also called palpitations
- Difficulty passing urine or changes in urinary frequency
- Increased risk of bone fracture

These are the more common side effects of ARROW - AMITRIPTYLINE.

Tell your doctor immediately if you:

- Develop a rash or hives while taking ARROW - AMITRIPTYLINE.

- Experience severe skin reactions (rash, high body temperature and enlarged lymph nodes) and stop ARROW - AMITRIPTYLINE

This side effect is rare but serious. You may need urgent medical attention.

See your doctor if you experience any of the following when you stop ARROW - AMITRIPTYLINE treatment:

- Nausea
- Headache
- Malaise (a general feeling of being unwell)
- Trouble sleeping.

These symptoms are generally not serious and disappear within a few days.

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

In case of overdose

You should only take the number of tablets that you have been told.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any ARROW - AMITRIPTYLINE by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Take the pack of ARROW - AMITRIPTYLINE with you if you can.

Keep telephone numbers for these places handy.

Storage conditions

Do not take this medicine after the expiry date shown on the pack/blister strip or if the packaging shows signs of tampering.

Keep your ARROW - AMITRIPTYLINE tablets in the blister pack until it is time to take them.

Store below 25°C and out of reach of children. Avoid exposure to heat, light and moisture.

Do not store ARROW - AMITRIPTYLINE, or any other medicine, in the bathroom or near a sink.

Disposal

If your doctor tells you to stop taking ARROW - AMITRIPTYLINE or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Product Description

What ARROW - AMITRIPTYLINE tablets look like

ARROW - AMITRIPTYLINE 10mg tablets are blue coloured, circular biconvex film-coated tablets with "IA" embossed on one side and plain on the other side
10

ARROW - AMITRIPTYLINE 25mg tablets are yellow coloured, circular biconvex film-coated tablets with "IA" embossed on one side and plain on the other side.
25

ARROW - AMITRIPTYLINE 50mg tablets are brown coloured, circular biconvex film-coated tablets with "IA" embossed on one side and plain on the other side.
50

Ingredients

Tablet Core:

Lactose monohydrate, microcrystalline cellulose, crospovidone, maize starch, silica, talc, magnesium stearate.

Film coating:

Brilliant blue FCF aluminium lake E133 (10mg), quinoline yellow aluminium lake E104 (25mg), sunset yellow FCF aluminium lake E110, indigo carmine aluminium lake E132 (50mg), hypromellose, talc, titanium dioxide, macrogol 6000.

The tablets do not contain gluten.

Who supplies this medicine

Distributed in New Zealand by:

Teva Pharma (New Zealand) Limited
PO Box 128 244
Remuera
Auckland 1541
Telephone: 0800 800 097

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