

AMITRIP



Amitriptyline hydrochloride film coated tablets 25 mg & 50 mg

What is in this leaflet

This leaflet answers some common questions about AMITRIP. 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 AMITRIP 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 AMITRIP is used for and how it works

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

AMITRIP is used to treat depression. Depression is thought to be caused by a chemical imbalance in parts of the brain. This affects your whole body and can cause 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. AMITRIP works by correcting this chemical imbalance and may help relieve the symptoms of depression.

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

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

AMITRIP is available on prescription from your doctor.

Before you take AMITRIP

When you must not take it

Do not take AMITRIP 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.

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 are pregnant, plan to become pregnant or are breastfeeding
- 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.

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. 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, and sleepiness. If your newborn baby has any of these symptoms, please contact your doctor immediately.

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 AMITRIP include:

- **Monoamine Oxidase Inhibitors** (e.g. moclobemide, phenelzine, tranylcypromine)
- **Other antidepressants** (e.g. SSRIs and tricyclic antidepressants)
- **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 AMITRIP or may affect how well AMITRIP 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 AMITRIP.

How to take AMITRIP properly

How much to take

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

It may take up to 4 weeks before any response to AMITRIP is noticeable.

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

Tell all doctors, dentists and pharmacists who are treating you that you are taking AMITRIP.

Tell your doctor or pharmacist that you are taking AMITRIP before you start any new medicine.

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

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

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

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 AMITRIP to treat any other complaints unless your doctor tells you to.

Do not stop taking AMITRIP 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.

AMITRIP 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 AMITRIP 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 AMITRIP.

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, 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
- Irregular heart beats, also called palpitations.

These are the more common side effects of AMITRIP.

Tell your doctor immediately if you:

- Develop a rash or hives while taking AMITRIP.

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 AMITRIP 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 AMITRIP by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of AMITRIP 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 AMITRIP 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 AMITRIP, or any other medicine, in the bathroom or near a sink.

Disposal

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

Product Description

What AMITRIP tablets look like

AMITRIP 25mg tablets are yellow, film coated biconvex tablets. AMITRIP 50mg tablets are orange, film coated biconvex tablets.

AMITRIP tablets are available in blister packs of 100 tablets.

Ingredients

AMITRIP 25mg tablets contain 25mg of the active ingredient, amitriptyline hydrochloride. AMITRIP 50mg tablets contain 50mg of the active ingredient, amitriptyline hydrochloride.

Each tablet also contains lactose, maize starch, disodium edetate,

povidone, pregelatinised maize starch, colloidal silicon dioxide, magnesium stearate, contents of a film coat [diethyl phthalate, hypromellose, Opaspray yellow (25mg), Opaspray orange (50mg)] and carnauba wax.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

Date of information

22 July 2010
(Based on datasheet 18 June 2010)