

Approved Patient Information Leaflet for Medicines for Human Use:

Amitriptyline 10 mg Camox

SCHEDULING STATUS:

S5

Amitriptyline 10 mg Camox film-coated tablets.

Amitriptyline hydrochloride

Contains sugar (lactose monohydrate).

Read all of this leaflet carefully before you start taking Amitriptyline 10 mg Camox.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Amitriptyline 10 mg Camox has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Amitriptyline 10 mg Camox is and what it is used for
2. What you need to know before you take Amitriptyline 10 mg Camox
3. How to take Amitriptyline 10 mg Camox
4. Possible side effects
5. How to store Amitriptyline 10 mg Camox
6. Contents of the pack and other information

1. What Amitriptyline 10 mg Camox is and what it is used for

Amitriptyline 10 mg Camox belongs to a class of medicine called tricyclic antidepressants. It is used to treat depression in adults.

2. What you need to know before you take Amitriptyline 10 mg Camox

Do not take Amitriptyline 10 mg Camox

- If you are hypersensitive (allergic) to amitriptyline or any of the other ingredients of Amitriptyline 10 mg Camox (listed in section 6).
- If you are currently using a medication known as a monoamine oxidase inhibitor (these medicines are often used to treat depression or Parkinson's disease) or have taken this medication in the last 14 days.
- If you are taking Guanethidine (used to treat high blood pressure).
- If you have just had a heart attack and are still in recovery phase.
- If you have severe liver disease.
- If you suffer from mania (feeling high or over-excited).
- If you are breastfeeding.

If you are uncertain whether any of these apply to you, please discuss this with your doctor or pharmacist before taking Amitriptyline 10 mg Camox.

Amitriptyline 10 mg Camox is not for use in children under the age of 12.

Using Amitriptyline 10 mg Camox during the first trimester of pregnancy is not advised. The safety of Amitriptyline 10 mg Camox during pregnancy and while breastfeeding your baby has not been determined.

Amitriptyline 10 mg Camox should at all times be kept out of the reach of children, as even small doses may be fatal to them.

Warnings and precautions

Take special care with Amitriptyline 10 mg Camox. Talk to your doctor before taking or whilst taking Amitriptyline 10 mg Camox:

- If you suffer from manic depressive psychosis (bipolar disorder) inform your doctor if you start feeling in either a depressed mood, or in a manic mood.
- If you are depressed you can sometimes have thoughts of harming or killing yourself. If at any time you have these thoughts, contact your doctor or go to a hospital straight away.
- If you have a blood disorder called porphyria.
- If you suffer from a heart condition including heart-block (a problem with the heart's "electrical" system).
- If you suffer from hyperthyroidism (a problem with your thyroid gland), liver problems, epilepsy ("fits"), narrow-angle glaucoma (a problem with the pressure in your eyes), urinary retention (being unable to pass urine even though you need to), prostatic hypertrophy (swelling of the prostate gland) or constipation.
- If you are elderly, you are more prone to experiencing side effects and your doctor may start your treatment at a lower dose.

If while taking Amitriptyline 10 mg Camox you need to undergo a procedure during which a local anaesthetic will be used, you should inform your doctor or dentist of your current medicines.

Other medicines and Amitriptyline 10 mg Camox

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

If you are taking any medicines containing the following:

- Monoamine oxidase inhibitors (these are medicines used to treat depression and Parkinson's disease),
- medicines to treat your hypertension (high blood pressure),
- barbiturates (medicines used to treat some types of epilepsy),
- medicines that have also anticholinergic effects: this includes medicines such as biperiden (used to treat Parkinson's Disease); chlorpheniramine and diphenhydramine (anti-histamines, often in cold/flu preparations); oxybutynin and solifenacin (used to treat an overactive bladder).

Consult your doctor, pharmacist or other healthcare professional as these medicines may interact with Amitriptyline 10 mg Camox.

Amitriptyline 10 mg Camox with food, drink and alcohol

Take Amitriptyline 10 mg Camox tablets with a drink of water. You are advised to not drink alcohol with Amitriptyline 10 mg Camox.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

When starting therapy with Amitriptyline 10 mg Camox you may feel drowsy or notice an impairment in decision making skills. Do not drive or operate machinery until you know how Amitriptyline 10 mg Camox affects you.

Amitriptyline 10 mg Camox contains lactose

Amitriptyline 10 mg Camox contains lactose monohydrate which is a sugar. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take Amitriptyline 10 mg Camox.

3. How to take Amitriptyline 10 mg Camox

Do not share medicines prescribed for you with any other person.

Always take Amitriptyline 10 mg Camox exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that Amitriptyline 10 mg Camox is too strong or too weak, tell your doctor or pharmacist.

The usual dose for adults is:

Initially 75 mg to 150 mg daily in divided doses.

Your doctor will prescribe an appropriate dose according to your condition.

You are advised to not drink alcohol while using Amitriptyline 10 mg Camox.

Do not stop taking this medicine without discussing it with your doctor.

If you take more Amitriptyline 10 mg Camox than you should

If you have taken too much Amitriptyline 10 mg Camox you may experience: drowsiness, restlessness, fainting and passing out, pyrexia (fever), palpitations (being able to feel your heart beat), tachycardia (increased heart rate), seizures ("fits").

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take Amitriptyline 10 mg Camox

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

Amitriptyline 10 mg Camox can have side effects. Check with your doctor, pharmacist or health care provider if any of these side effects persist or become bothersome.

Not all side effects reported for Amitriptyline 10 mg Camox are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Amitriptyline 10 mg Camox, please consult your health care provider for advice.

If any of the following happens, stop taking Amitriptyline 10 mg Camox and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Having difficulty breathing with or without swelling of the throat and face, severe itching of the skin. These may be signs of an allergic reaction.
- Dark urine, yellowing of your skin or the whites of your eyes. These may be signs of a problem with your liver.

These are very serious side effects. If you have them, you may have had a serious reaction to Amitriptyline 10 mg Camox. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you feel like harming or killing yourself.
- Feeling confused or seeing or hearing things that are not there (delirious).
- If you have a "fit".
- Having difficulty moving, being unable to stop moving, or being unable to coordinate movements, jerky movements of the limbs.
- Having speech difficulties, inability to talk.
- Blurring of your vision, being unable to focus.
- Being able to feel your heart beat (palpitations) or feeling your heart beat fast.
- Constipation (being unable to pass stool). This may become problematic if it continues as it may cause paralytic ileus- this is when your bowel muscles stop working.
- Urinary retention (being unable to urinate even though you need to).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- For both males and females: Swelling of the breasts or noticing a discharge of fluid from the nipple.
- Noticing a change in your libido (sexual desire).
- Impotence in males (being unable to get or keep an erection).
- Recurrent infections or noticing that it takes longer for your blood to clot (these may be signs of a decrease in your blood cells).
- Lack of appetite with weight gain or weight loss.

- Feeling drowsy, or being unable to sleep.
- Tingling sensation in the skin.
- Hearing a ringing sound in the ear.
- Feeling dizzy when standing up after you have been sitting or lying down.
- Dry mouth, pain in the stomach with feeling sick (nausea) and being sick (vomiting).
- Feeling dizzy, sweating, or feeling weak and tired.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Amitriptyline 10 mg Camox.

5. How to store Amitriptyline 10 mg Camox

HDPE bottle pack and PVC/aluminium blister pack

- Store at or below 25 °C in well closed containers (in the case of HDPE bottle packs).
- Store in the original packaging until required for use.
- Store in a cool dry place.
- Do not store your medicine in the bathroom.
- Do not use Amitriptyline 10 mg Camox after the expiry date printed on the label or container.
- Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Store all medicines out of reach of children.

6. Contents of the pack and other information

What Amitriptyline 10 mg Camox contains

- The active substance is amitriptyline. Each film coated tablet contains 10 mg amitriptyline (as hydrochloride).
- The other ingredients are:

Tablet core

Lactose monohydrate

Microcrystalline cellulose

Crospovidone

Maize starch

Anhydrous colloidal silica

Purified talc

Magnesium stearate

Film coating

Hypromellose

Purified talc

Titanium dioxide (E171)

Macrogol 6000

Brilliant blue FCF CI42090

What Amitriptyline 10 mg Camox looks like and contents of the pack

Amitriptyline 10 mg Camox tablets are blue coloured, circular, biconvex, film coated tablets with “IA” over “10” debossed on one side and plain on the other.

Tablets are packed in:

- HDPE bottles in pack sizes of 100, 500 or 1000 tablets.
- White opaque PVC/aluminium blister packs of 28, 30, 56, 60 and 100 tablets.

Not all pack sizes are marketed.

Holder of Certificate of Registration

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

JOHANNESBURG

2193

South Africa

Tel: 0860287835

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2. Amitriptyline 10 mg Apex - 49/1.2/1018

3. Amitriptyline 10 mg Camox - 49/1.2/1019