

APO-Amitriptyline

Contains the active ingredient amitriptyline hydrochloride

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about amitriptyline. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Amitriptyline Tablets. It contains the active ingredient amitriptyline hydrochloride.

It is used to treat:

- depression - the 10 mg and 25 mg tablets can be used at any stage in treatment; however, the highest strength 50 mg tablets are approved only for maintenance treatment (i.e. after symptoms have improved).
- Bed wetting, provided there is no physical cause for the problem (e.g. problems with the bladder).

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

Amitriptyline belongs to a group of medicines called tricyclic antidepressants (TCAs). TCAs work by correcting the imbalance of certain chemicals in the brain. These chemicals, called amines, are involved in controlling mood. By correcting this imbalance, TCAs can help relieve the symptoms of depression.

There is no evidence that this medicine is addictive.

Use in children

Amitriptyline should not be used in children and adolescents aged less than 18 years for the treatment of depression.

The safe use and effectiveness of Amitriptyline in treating above condition, for this age group, has not been established.

Before you take this medicine

When you must not take it

Do not take this medicine if you are allergic to medicines containing amitriptyline (e.g. Tryptanol) or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: skin rash, itching or hives; swelling of the face or tongue which may cause difficulty swallowing or breathing; increased sensitivity of the skin to the sun.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Do not take this medicine if you are taking, or have taken within the last 14 days, another medicine for depression called a monoamine oxidase inhibitor (MAOI)

Check with your doctor whether you are, or have been, taking an MAOI, as the combination of amitriptyline with an MAOI or taking it too soon after stopping a MAOI may cause serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

Your doctor will tell you when it is safe to start taking Amitriptyline after stopping the MAOI.

Ask your doctor or pharmacist if you are unsure if you are taking, or have been taking a MAOI.

MAOIs are medicines used to treat depression and symptoms of Parkinson's disease. Examples of MAOIs are phenelzine (Nardil), tranylcypromine (Parnate), moclobemide (eg. Aurorix, Arima and selegiline (Eldepryl, Selgene).

Do not take Amitriptyline if you are taking cisapride (Prepulsid) a medicine used to treat stomach reflux.

Combining Amitriptyline with cisapride may cause serious side effects such as an abnormal heart rhythm.

Do not take Amitriptyline if you have recently had a heart attack.

Taking Amitriptyline could make your condition worse.

Do not take Amitriptyline if you are breastfeeding.

Amitriptyline passes into human breast milk and may harm your baby.

Do not take Amitriptyline if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take Amitriptyline if the packaging is torn, shows signs of tampering or it does not look quite right.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:
 - other mental illnesses other than depression, for example schizophrenia
 - seizures or fits
 - glaucoma, a condition characterised by an increased pressure in the eye
 - urinary problems such as difficulty in passing urine
 - heart or blood vessel problems
 - thyroid problems
 - liver problems.
3. You plan to undergo any type of surgery or if you are receiving electroshock therapy.
4. If you are currently pregnant or you plan to become pregnant.

There have been reports of some babies experiencing complications immediately after delivery.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
5. You are currently breastfeeding or you plan to breastfeed.

Do not take this medicine whilst breastfeeding.
6. You are planning to undergo any type of surgery or if you are undergoing electroshock therapy.
7. You are currently receiving or are planning to receive dental treatment.

Taking other medicines

Some medicines may interact with amitriptyline. These include:

- cisapride (Prepulsid), a medicine used to treat stomach reflux.
- Any monoamine oxidase inhibitors (MAOIs) such as, phenelzine (Nardil) and tranylcypromine (Parnate), moclobemide (eg Aurorix, Arima), used to treat depression and selegiline (Eldepryl, Selgene), used to treat symptoms of Parkinson's disease.

Wait at least 14 days after stopping your MAOI before starting amitriptyline.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor if you are taking or have recently taken any other medicines, such as valproic acid.

Some medicines may be affected by Amitriptyline or may affect how well Amitriptyline works. These include:

- selective serotonin reuptake inhibitors (SSRIs), a group of medicines used to treat depression and other mental illnesses, such as fluoxetine (eg. Prozac, Lovan), sertraline (eg. Zoloft) and paroxetine (eg. Aropax, Paxtine)
- other medicines used to treat mental disorders such as schizophrenia
- some medicines used to treat high blood pressure
- anticholinergics, found in some medicines used to relieve stomach cramps; travel sickness; hayfever and allergies; cough and colds

- medicines used to control an irregular heartbeat such as quinidine (Kinidin) and flecainide (Tambocor, Flecatab)
- cimetidine (eg. Tagamet, Magicul), a medicine used to treat reflux and ulcers
- sleeping tablets/sedatives, anti-anxiety medicines
- medicines for epilepsy
- thyroid medicines
- disulfiram (eg. Antabuse), a medicine used to deter alcohol consumption
- tramadol (eg. Tramal), a medicine used to relieve pain.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Amitriptyline.

How to take this medicine

Follow carefully all directions given to you by your doctor and pharmacist.

Their instructions may be different to the information in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

For depression, it is recommended that the dose is started at a low level and then, if necessary, increased depending on how your symptoms improve and how well you tolerate it. For depression, the usual starting dose is 75 mg to 150 mg per day in divided doses.

For people being treated in hospital for their depression, the usual starting dose is 100 mg to 200 mg per day.

For the elderly, lower doses are recommended, as Amitriptyline may not be well tolerated in this age group.

Your doctor may then reduce your dose to 50 mg to 100 mg per day when your depressive symptoms have improved, depending on your response to Amitriptyline.

Bed-wetting

Keep Amitriptyline out of the reach of children.

Do not give your child more Amitriptyline than what is recommended by your doctor.

For bed wetting, the doses recommended are low compared with those used to treat depression and usually depend on the person's age and weight. Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablet(s) whole with a glass of water.

When to take it

Amitriptyline can be taken with or without food.

Amitriptyline can be taken as a single dose (e.g. at bedtime) or as divided doses (e.g. three times a day), your doctor will advise you when to take it.

Take your dose(s) at the same time each day. This will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food

How long to take it for

Depression

Keep taking Amitriptyline for as long as your doctor recommends.

The length of treatment will depend on how quickly your symptoms improve.

Most medicines for depression take time to work, so do not be discouraged if you do not feel better right away. Some people notice an improvement in their depressive symptoms after 3 or 4 days.

However, it may take up to 4 weeks to feel the full benefits of Amitriptyline.

Even when you feel well, your doctor may ask you to continue taking Amitriptyline for 3 months or longer to make sure that the benefits last.

Bed-wetting

Most children respond to bed wetting treatment in the first few days. However, continued treatment is usually required to maintain the response until bed-wetting ends.

It is important you continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If you take more than one dose a day and it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

However, if you only take one dose a day at bedtime:

If you forget to take amitriptyline before going to bed and wake up late in night or early in the morning, do not take the missed dose until you have checked with your doctor.

You may have difficulty waking up or experience drowsiness in the morning or during the day, if you take amitriptyline at these times.

Do not try to make up the dose you missed by taking double dose.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much Amitriptyline, you may feel drowsy, cold, very dizzy or have a fast or irregular heartbeat.

You may also have fits, difficulty breathing or lose consciousness.

Keep Amitriptyline out of the reach of children.

Children are much more sensitive than adults to medicines such as Amitriptyline. An accidental overdose is especially dangerous in children.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you feel the tablets are not helping your condition. Keep all of your appointments with your doctor so that your progress can be checked.
- you become pregnant while taking Amitriptyline. Do not stop taking your tablets until you have spoken to your doctor.
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery including dental surgery.

Your doctor may ask you to temporarily stop taking Amitriptyline a few days before elective surgery.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Tell your doctor or dentist if your mouth continues to feel dry for more than 2 weeks.

Amitriptyline may cause dry mouth. Continuing dryness of the mouth may increase the chance of dental disease, including tooth decay and gum disease.

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

Occasionally, the symptoms of depression may include thoughts of harming yourself or committing suicide. These symptoms may continue or get worse during the first one to two months of treatment until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur in children, adolescents and young adults under 25 years of age.

Contact your doctor or a mental health professional right away or go to the nearest hospital for treatment if you or someone you know is showing any of the following warning signs of suicide:

- worsening of your depression
- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Amitriptyline may reduce your alertness, cause drowsiness or dizziness in some people. If you experience any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

For the same reasons, children should not ride a bike, climb trees or do anything else that could be dangerous if they are drowsy.

Do not stop taking Amitriptyline, or lower the dose, without checking with your doctor. Do not let yourself run out of your medicine over weekends or during holidays.

Stopping Amitriptyline suddenly may make you feel sick (nauseous), have headaches or feel generally unwell.

Your doctor will tell you how to gradually reduce the amount of Amitriptyline you are taking before stopping completely.

Do not use Amitriptyline to treat any other conditions unless your doctor tells you to.

Be careful drinking alcohol while taking Amitriptyline.

Combining amitriptyline with alcohol can make you more drowsy or dizzy. Your doctor may suggest you avoid alcohol while being treated for depression.

Be careful getting up from a sitting or lying position.

Dizziness, light-headedness or fainting may occur, especially when you get up quickly. Getting up slowly may help.

Tell your doctor or dentist if your mouth continues to feel dry for more than 2 weeks.

Amitriptyline may cause dry mouth. This can be relieved by frequent sips of water, sucking sugarless lollies or chewing sugarless gum. However, continuing dryness of the mouth may increase the chance of dental disease, including tooth decay and gum disease.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking amitriptyline or if you have any questions or concerns.

Amitriptyline helps most people, but it may have unwanted side effects in some people

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor if you notice any of the following:

- dry mouth, altered sense of taste
- nausea (feeling sick), vomiting
- diarrhoea, constipation
- blurred vision, difficulty in focussing
- drowsiness, tiredness, headache
- dizziness, light-headedness
- increased sweating
- weight gain or loss
- changes in sex drive.

The above list includes the milder side effects of Amitriptyline.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- fast or irregular heart beats
- larger breast than normal (in men and women)

- tingling or numbness of the hands or feet
- uncontrolled movements, including trembling and shaking of the hands and fingers, twisting movements of the body, shuffling walk and stiffness of the arms and legs
- difficulty in passing urine
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- yellowing of the eyes or skin (jaundice)
- unusual bruising or bleeding
- feeling anxious, restless or confused
- abnormal ideas, hallucinations
- sudden switch of mood to one of excitement, overactivity, talkativeness and uninhibited behaviour.

If you experience any of the following, contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

- Skin rash, itching, hives, swelling of the face or tongue, severe sunburn, blistering or swelling of the skin
- fainting or collapse
- chest pain
- seizures or fits.

The above side effects are very serious and may require urgent medical attention or even hospitalisation.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to amitriptyline, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sills or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your

pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Amitriptyline tablet looks like

10mg tablet: Blue colour, circular, biconvex, film coated tablets with "IA" over "10" debossed on one side and plain on the other side.

25mg tablet: Yellow colour, circular, biconvex, film coated tablets with "IA" over "25" debossed on one side and plain on the other side.

50mg tablet: Brown colour, circular, biconvex, film coated tablets with "IA" over "50" debossed on one side and plain on the other side

Blister pack of 20, 50 and 100

Bottles of 100

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 10, 25 or 50 mg of amitriptyline hydrochloride as the active ingredient.

It also contains the following inactive ingredients:

- Lactose monohydrate
- Cellulose-microcrystalline
- Crospovidone
- Starch-maize (Dried)
- Silica-colloidal anhydrous
- Talc-purified
- Magnesium stearate
- Hypromellose
- Titanium dioxide
- Macrogol 6000
- Quinoline yellow aluminium lake (only 25mg)
- Brilliant blue FCF aluminium lake (only 10mg)
- Sunset yellow FCF aluminium lake (only 50mg).
- Indigo carmine aluminium lake (only 50mg).

Tablet contains sugar s as lactose.

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Amitriptyline 10mg tablet (blister pack): AUST R 215351.

APO-Amitriptyline 25mg tablet (blister pack): AUST R 215380.

APO-Amitriptyline 50mg tablet (blister pack): AUST R 215367.

Sponsor

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