

APX-AMITRIPTYLINE

contains the active ingredient amitriptyline hydrochloride

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about APX-AMITRIPTYLINE.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking APX-AMITRIPTYLINE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Please read this leaflet carefully and keep it with your medicine.

You may need to read it again.

WHAT APX-AMITRIPTYLINE IS USED FOR

APX-AMITRIPTYLINE is used to treat depression.

APX-AMITRIPTYLINE 10 mg and 25 mg tablets can be used at any stage in the treatment of depression. However, the highest strength APX-AMITRIPTYLINE 50 mg, is approved only for the maintenance treatment of depression (after your symptoms have improved).

APX-AMITRIPTYLINE belongs to a group of medicines called tricyclic antidepressants (TCAs). TCA medicines 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.

APX-AMITRIPTYLINE can also be used to treat bed-wetting, provided that there is no physical cause for the problem (e.g. problems with the bladder).

Ask your doctor if you have any questions about why APX-AMITRIPTYLINE has been prescribed for you.

Your doctor may have prescribed APX-AMITRIPTYLINE for another reason.

APX-AMITRIPTYLINE is not approved for use in children and adolescents below 18 years of age for the treatment of depression.

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

APX-AMITRIPTYLINE is available only with a doctor's prescription.

BEFORE YOU TAKE APX-AMITRIPTYLINE

When you must not take it

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

Some of the 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.

Do not take APX-AMITRIPTYLINE if you have recently had a heart attack.

Taking APX-AMITRIPTYLINE could make your condition worse.

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

Taking APX-AMITRIPTYLINE with a MAOI or taking it too soon after stopping a MAOI may cause a 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 APX-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 APX-AMITRIPTYLINE if you are taking cisapride (Prepulsid), a medicine used to treat stomach reflux.

Combining APX-AMITRIPTYLINE with cisapride may cause serious side effects such as an abnormal heart rhythm.

Do not take APX-AMITRIPTYLINE if you are breastfeeding.

APX-AMITRIPTYLINE passes into breast milk and may harm your baby.

Do not take APX-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 APX-AMITRIPTYLINE if the packaging shows signs of tampering or the tablets do 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

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

There have been reports of some babies experiencing complications immediately after delivery. Your doctor will discuss the possible risks and benefits of taking APX-AMITRIPTYLINE during pregnancy.

Tell your doctor if you have, or have had, any other medical conditions, especially the following:

- heart or blood vessel problems
- liver problems
- glaucoma, a condition characterised by an increased pressure in the eye
- urinary problems such as difficulty in passing urine
- thyroid problems
- seizures or fits
- any mental illness other than depression, for example schizophrenia or manic depression (alternating periods of

elation/overactivity and depressed mood)

- Family history of suicide or mania.

Tell your doctor if you plan to undergo any type of surgery or if you are undergoing electroshock therapy.

If you have not told your doctor about any of the above, tell him/her before you start taking APX-AMITRIPTYLINE.

Taking other medicines

Do not take APX-AMITRIPTYLINE if you are taking:

- cisapride (Prepulsid), a medicine used to treat stomach reflux
 - any monoamine oxidase inhibitor (MAOI) such as:
 - phenelzine (Nardil) and tranylcypromine (Parnate), moclobemide (eg. Aurorix, Arima), used to treat depression
 - selegiline (Eldepryl, Selgene), used to treat symptoms of Parkinson's disease.
- Wait at least 14 days after stopping your MAOI before starting APX-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 APX-AMITRIPTYLINE or may affect how well APX-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). This could result in "serotonin syndrome". This condition may include feeling agitated or restless, confused, loss of muscle coordination or twitching muscles and shivering.
- 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. This could result in high fever, particularly during hot weather. If you take these medicines together, you may feel drowsier and experience dry mouth, constipation, and dizziness for a longer period of time. Also, you may be more at risk of developing seizures and neuroleptic malignant syndrome. Neuroleptic malignant syndrome may include sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness, high blood pressure and convulsions
- medicines used to treat mental disorders such as schizophrenia
- quinidine (Kinidin) and flecainide (Tambacor, Flecatag), medicines used to control an irregular heart beat

- 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 APX-AMITRIPTYLINE.

HOW TO TAKE APX-AMITRIPTYLINE

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

They may differ from the information contained in this leaflet.

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

How much to take

The dose varies from person to person.

Your doctor will decide the right dose for you.

Follow the instructions provided and use this medicine until your doctor tells you to stop.

Depression

APX-AMITRIPTYLINE is usually started at a low dose 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 APX-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 APX-AMITRIPTYLINE.

Bed-wetting

Keep APX-AMITRIPTYLINE out of the reach of children.

Do not give your child more APX-AMITRIPTYLINE than what is recommended by your doctor.

The doses recommended for bed-wetting are lower than the doses used to treat depression and usually depend on the person's age and weight.

How to take it

Swallow the tablets whole with a glass of water.

When to take it

APX-AMITRIPTYLINE can be taken with or without food.

APX-AMITRIPTYLINE can be taken as a single dose (eg. at bedtime) or as divided doses (eg. three times a day). Your doctor will advise you.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it for

Depression

Keep taking APX-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 APX-AMITRIPTYLINE.

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

Bed-wetting

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

If you forget to take it

If you take one dose a day (at bedtime):

If you forget to take APX-AMITRIPTYLINE before going to bed and wake up late in the 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 APX-AMITRIPTYLINE at these times.

If you take more than one dose a day:

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Taking too much APX-AMITRIPTYLINE at once can be dangerous and may cause death.

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much APX-AMITRIPTYLINE.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much APX-AMITRIPTYLINE, you may feel drowsy, cold, very dizzy or have a fast or irregular heart beat.

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

Keep APX-AMITRIPTYLINE out of the reach of children.

Children are much more sensitive than adults to medicines such as APX-

AMITRIPTYLINE. An accidental overdose is especially dangerous in children.

They are especially susceptible to coma, cardiotoxicity, respiratory depression, seizures, hyponatraemia, lethargy, sinus tachycardia, drowsiness, nausea, vomiting and hyperglycaemia.

WHILE YOU ARE TAKING APX-AMITRIPTYLINE

Things you must do

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

Occasionally, the symptoms of depression or other psychiatric conditions 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.

Tell your doctor if you feel the tablets are not helping your condition.

Keep all of your appointments with your doctor so that your progress can be checked.

Tell your doctor immediately if you become pregnant while taking APX-AMITRIPTYLINE. Do not stop taking your tablets until you have spoken to your doctor.

Before starting any new medicine, tell your doctor or pharmacist that you are taking APX-AMITRIPTYLINE.

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

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking APX-AMITRIPTYLINE.

Your doctor may ask you to temporarily stop taking APX-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.

Things you must not do

Do not drive or operate machinery until you know how APX-AMITRIPTYLINE affects you.

APX-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 APX-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 APX-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 APX-AMITRIPTYLINE you are taking before stopping completely.

Do not use APX-AMITRIPTYLINE to treat any other conditions unless your doctor tells you to.

Do not give APX-AMITRIPTYLINE to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful drinking alcohol while taking APX-AMITRIPTYLINE.

Combining APX-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, lightheadedness 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.

APX-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.

SIDE EFFECTS

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

APX-AMITRIPTYLINE helps most people, but it may have unwanted side effects in some people.

All medicines can have side 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.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- dry mouth, altered sense of taste
- nausea (feeling sick), vomiting
- diarrhoea, constipation
- blurred vision, difficulty in focussing
- drowsiness, tiredness, headache
- dizziness, lightheadedness
- increased sweating

- weight gain or loss
- changes in sex drive

The above list includes the milder side effects of APX-AMITRIPTYLINE.

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

- 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.

The above side effects are serious and may require medical attention.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- 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 also occur in some people.

AFTER TAKING APX-AMITRIPTYLINE

Storage

Keep APX-AMITRIPTYLINE 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.

Keep your tablets in a cool dry and dark place where the temperature stays below 25°C.

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

Do not leave APX-AMITRIPTYLINE in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking APX-AMITRIPTYLINE, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

PRODUCT DESCRIPTION

What it looks like

APX-AMITRIPTYLINE is available in three strengths:

APX-AMITRIPTYLINE 10 mg: round blue coloured biconvex tablets debossed AM on one side and 10 on the other side.

APX-AMITRIPTYLINE 25 mg: round yellow coloured biconvex tablets debossed AM on one side and 25 on the other side.

APX-AMITRIPTYLINE 50 mg: round brown coloured biconvex tablets debossed AM on one side and 50 on the other side.

APX-AMITRIPTYLINE is available in blister packs of various pack sizes.

Not all pack sizes may be marketed.

Ingredients

The active ingredient in APX-AMITRIPTYLINE is amitriptyline hydrochloride.

Each APX-AMITRIPTYLINE tablet contains 10 mg, 25 mg or 50 mg of amitriptyline hydrochloride.

APX-AMITRIPTYLINE tablets also contain the following inactive ingredients:

- lactose monohydrate
- microcrystalline cellulose
- maize starch
- croscarmellose sodium
- colloidal anhydrous silica
- purified talc
- magnesium stearate
- hypromellose
- Macrogol 6000

The tablet coating contains:

OPADRY II complete film coating system

- 85F99075 BLUE [ARTG 109882 for 10 mg]
- 85F92349 YELLOW [ARTG 109879 for 25 mg]
- 85F565015 BROWN [ARTG 109885 for 50 mg].

Tablet contains sugars as lactose.

Sponsor

Arrotex Pharmaceutical Pty Ltd
15-17 Chapel Street
Cremorne Victoria 3121

Australian registration number:

APX-AMITRIPTYLINE 10 mg - AUST R 333508

APX-AMITRIPTYLINE 25 mg - AUST R 333509

APX-AMITRIPTYLINE 50 mg - AUST R 333510

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