

# APO-Amitriptyline

Contains the active ingredient amitriptyline (as 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](http://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:

- major depression - the 10 mg and 25 mg tablets can be used at any stage in treatment, however, the 50 mg tablets are approved only for maintenance treatment (i.e. after symptoms have improved).
- Bed wetting, provided there is no physical cause (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 safety and efficacy have not been satisfactorily established.

### Before you take this medicine

#### When you must not take it

##### Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, amitriptyline or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: 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; or hay fever-like symptoms.

**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.**

- **You are taking, or have taken within the last 14 days, a medicine called a monoamine oxidase inhibitor (MAOI), including selegiline.**

**Check with your doctor whether you are, or have been, taking an MAOI, as the combination of amitriptyline with an MAOI may cause serious side effects, such as extreme fever and severe convulsions.**

- **You are taking cisapride, which may cause serious side effects such as an abnormal heart rhythm.**
- **You have recently had a heart attack.**
- **You are breastfeeding. Amitriptyline may pass into human breast milk.**
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

### ***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, such as schizophrenia
  - seizures
  - glaucoma
  - urinary problems
  - heart or blood vessel problems
  - thyroid problems
  - liver problems.
3. You are receiving electroshock therapy.
4. You are currently pregnant or you plan to become pregnant.

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 have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.
8. You are taking or are planning to take any other medicines.

This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with amitriptyline. These include:

- cisapride, a medicine used to treat stomach reflux.

**You must not take amitriptyline whilst taking cisapride.**

- monoamine oxidase inhibitors (MAOIs), used to treat depression (e.g. phenelzine, tranylcypromine, moclobemide) and Parkinson's disease (e.g. selegiline).

**You must not take amitriptyline whilst taking MAOIs. Wait at least 14 days after stopping your MAOI before starting amitriptyline.**

- selective serotonin reuptake inhibitors (SSRIs), a group of medicines used to treat depression and other mental illnesses, such as fluoxetine, sertraline and paroxetine
- other medicines used to treat depression and other mental illnesses (e.g. schizophrenia)
- some medicines used to treat high blood pressure, such as guanethidine
- 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 and flecainide
- cimetidine, a medicine used to treat reflux and ulcers
- sleeping tablets/sedatives, anti-anxiety medicines
- medicines for epilepsy
- thyroid medicines
- disulfiram, a medicine used to deter alcohol consumption
- central nervous system (CNS) depressants such as barbiturates and alcohol
- tramadol, a medicine used to relieve pain.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with amitriptyline.

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## **How to take this medicine**

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Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

### ***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 increased gradually. When satisfactory improvement has been reached, the dose should be reduced to the lowest amount that will maintain relief of symptoms.

For bed wetting, the doses recommended are low compared with those used for depression.

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 may 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**

Some people notice an improvement in their depressive symptoms after 3 or 4 days however it may take up to 4 weeks.

Most children respond to bed wetting treatment in the first few days.

Please note your doctor may ask you to continue taking amitriptyline even after your symptoms have improved. 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 missed dose and take your next dose at the usual time.

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, ask your doctor for advice regarding missed doses, as taking it another time when you remember may mean you have difficulty waking up in the morning or experience drowsiness in the day.

**Do not take a double dose to make up for missed doses.**

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.**

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## **While you are taking this medicine**

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### **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 are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

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

Amitriptyline may cause dry mouth. Tell your doctor or dentist if your mouth continues to feel dry for more

than 2 weeks. 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.

**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.

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.

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## Possible side effects

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

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.

### **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.

### **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, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

- severe sunburn, blistering or swelling of the skin
- fainting or collapse
- chest pain
- seizures or fits.

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.

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## Storage and disposal

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### **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 sill 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.

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## Product description

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### **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).

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**

Apotex Pty Ltd

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