

APO-AMITRIPTYLINE TABLET

Amitriptyline Hydrochloride (10mg, 25mg)

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What Apo-Amitriptyline is used for

APO-AMITRIPTYLINE is a prescription medication containing the active ingredient, amitriptyline hydrochloride. APO-AMITRIPTYLINE is intended for the relief of symptoms of depression. Treatment with these types of medications is mostly safe and effective when you and your doctor have good communication about how you are feeling.

This medication can be used for bedwetting as well for certain cases.

How Apo-Amitriptyline works

APO-AMITRIPTYLINE is a form of tricyclic antidepressant (TCA). It works by increasing the amounts of certain natural substances in the brain that are needed to maintain mental balance.

Before you use

- When you must not use it

Do not use this medicine if:

- you have any known hypersensitivity to amitriptyline or to any ingredients listed at the end of this leaflet

- you have had heart attack
- you have acute congestive heart failure

- Before you start to use it

Your doctor needs to know:

- Any other medical condition that you may have including heart, liver, or kidney diseases, unusual eye conditions, seizures, difficulties in urinating ;
- How much alcohol you consume;
- Whether you are planning to get pregnant, are currently pregnant or are nursing an infant;
- If you are going to undergo any operation, including dental surgery;
- If you are a hyperthyroid (a condition where you produce too much thyroid hormone) patient or are receiving thyroid medication.

- Taking other medicines

Tell your doctor if you are taking any other prescription or over-the-counter medication that you are currently taking, such as:

- Monoamine oxidase inhibitors (MAOI). Amitriptyline should not be taken with or within at least 14 days after stopping MAOI. MAOI should not be started until at least 1 week after stopping amitriptyline.

- medicines to lower blood pressure eg. Guanethidine

- anticholinergic or sympathomimetic agents

- barbiturates

- ethchlorvynol

How to use Apo-Amitriptyline

- How much to use

Antidepressant:

The recommended initial adult dose of amitriptyline is 25mg 3 times a day. If necessary increase doses preferably in the late afternoon and/or bedtime to total of 150mg a day.

Lower dosages are recommended for adolescent and elderly, 10mg 3 times a day with 20mg at bedtime.

The maintenance dose is 25mg, 2 to 4 times a day.

It is not recommended for treatment of depression in children under 12 years old.

Establishing an effective dosage level will vary from one person to another. For this reason, your doctor may increase your dosage gradually during treatment. It is very important that you take APO-AMITRIPTYLINE exactly as your doctor has instructed.

Bedwetting:

Recommended dose is 10mg at bedtime for children under 6 years old.

Your doctor may increase dosage up to 25mg at bedtime for older children.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

APO-AMITRIPTYLINE should be taken according to the doctor's instructions or the label attached with this medication. Swallow the tablet(s) with water and without chewing.

- How long to use it

Never increase or decrease the amount of APO-AMITRIPTYLINE you, or those

in your care if you are a caregiver or guardian, are taking unless your doctor tells you to and do not stop taking this medication without consulting your doctor.

- If you forget to use it

As soon as you remember, take the missed dose. Unless it is almost time for your next scheduled dose, skip the missed dose. Do not take extra medicine to make up the missed dose.

- If you take too much (overdose)

High doses may cause temporary confusion, disturbed concentration, transient visual hallucinations, agitation, hyperactive reflexes, muscle rigidity, vomiting or anything in addition to anything listed under Side Effects.

Contact your doctor or nearest hospital emergency department even though you may not feel sick.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Apo-Amitriptyline.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

DO NOT take alcohol when using this medication

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

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

- Things to be careful of

Refrain from potentially hazardous tasks, such as driving a car or operating dangerous machines, until you are certain that this medication does not affect your mental alertness or physical coordination.

Contact your physician before stopping or reducing your dosage of APO-AMITRIPTYLINE.

If you are pregnant and taking amitriptyline, or other antidepressants, you should discuss the risks and benefits of the various treatment options with your doctor. Amitriptyline might affect the baby's growth upon birth. It is very important that you do NOT stop taking these medications without first consulting your doctor.

Side effects

As with all antidepressants, improvement with APO-AMITRIPTYLINE is gradual. You might experience some side effect such as:

- chest pain or heavy feeling, pain, pounding heartbeats or fluttering in your chest;
- nausea, sweating, numbness, burning pain, tingly feeling, or other general ill feeling;
- drowsiness;
- confusion, hallucinations, nightmares;
- restless muscle movements, or seizures;
- skin rash;
- urinating less than usual or not at all;
- constipation, diarrhoea;
- increased appetite;
- dry mouth, unpleasant taste

Some side effects may be temporary. Consult your doctor if you experience these or other side effects, as your doctor may adjust the dosage to alleviate the symptoms.

Particularly in the first few weeks or when doses are adjusted, a small number of patients taking

drugs of this type may feel worse instead of better; for example, they may experience unusual feelings of agitation, hostility or anxiety, or have impulsive or disturbing thoughts such as thoughts of self-harm or harm to others. Should this happen to you, or those in your care if you are a caregiver or guardian, consult your doctor immediately; do not discontinue your medication on your own.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public->Reporting Medicinal Problems/ Side Effects/ AEFI/ Vaccine Safety).

Storage and Disposal of Apo-Amitriptyline

- Storage

Remember to keep APO-AMITRIPTYLINE and all medications safely away from children.

Do not use this medicine after the month and year written after EXP on the container.

Store APO-AMITRIPTYLINE below 30°C.

- Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

The 10mg tablets are blue, round, biconvex, film-coated tablet,

engraved 10 one side, other side plain

The 25 mg tablets are yellow, round, biconvex, film-coated tablet, engraved 25 one side, other side plain

- Ingredients

The 10 mg tablets contain:

-Active Ingredient: 10 mg amitriptyline hydrochloride

- Inactive ingredients:

Microcrystalline cellulose, croscarmellose sodium, magnesium stearate, colloidal silicon dioxide, hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide, brilliant blue FC, aluminium lake 12% and carnauba wax.

The 25 mg tablets contain:

-Active Ingredient: 25 mg amitriptyline hydrochloride

- Inactive ingredients:

Microcrystalline cellulose, croscarmellose sodium, magnesium stearate, colloidal silicon dioxide, hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide, D&C yellow, aluminium lake and carnauba wax.

- MAL number:

Apo-Amitriptyline 10mg tab
(MAL19984714ARZ)

Apo-Amitriptyline 25mg tab
(MAL19984711ARZ)

Manufacturer

Apotex Inc.
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Product Registration Holder

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