

APO-Clomipramine Tablets

Contains the active ingredient, clomipramine (as clomipramine 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 clomipramine. 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-Clomipramine. It contains the active ingredient, clomipramine (as clomipramine hydrochloride).

It is used to treat:

- depression
- obsessive compulsive disorders and phobias in adults

- cataplexy associated with narcolepsy (sudden muscle weakness associated with an uncontrollable desire to sleep).

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

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

How it works

Clomipramine belongs to a group of medicines called tricyclic antidepressants.

These medicines are thought to work by their action on brain chemicals called amines which are involved in controlling mood.

Use in children

There is not enough information to recommend using this medicine in children and adolescents younger than 18 years.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- you are taking, or have taken within the past 2 weeks, a medicine called a monoamine oxidase inhibitor (MAOI). Taking this medicine with a MAOI may cause a serious

reaction with a sudden increase in body temperature, high blood pressure and convulsions. Examples of MAOIs include selegiline, phenelzine, tranylcypromine and moclobemide.

- you have recently had a heart attack. It may worsen your condition.
- you have a heart problem called congenital long QT syndrome
- you are taking any other tricyclic antidepressant
- it has passed the expiry date (EXP) printed on the pack.
- the packaging is torn, shows signs of tampering or it does not look quite right.
- **You are hypersensitive to, or have had an allergic reaction to, clomipramine, other tricyclic antidepressants, or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include 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 hayfever-like symptoms.

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **Do not take this medicine if you have any of the following:**
- galactose intolerance
- severe lactase deficiency
- glucose-galactose malabsorption.

These tablets contain lactose.

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, lactose, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- heart problems, especially an irregular heart beat
- liver or kidney problems
- glaucoma, or increased pressure in the eye
- difficulty in passing urine

- seizures/convulsions (fits) due to epilepsy or some other cause such as drug or alcohol withdrawal
- any mental illness, other than depression
- thyroid problems or taking thyroid tablets
- chronic constipation
- a tumour of the adrenal gland (e.g. phaeochromocytoma or neuroblastoma)
- low potassium levels in your blood
- blood disorders
- blood pressure which is either too high or too low
- Parkinson's disease.

Your doctor may not want you to take this medicine or may want to take special precautions if you have any of the above conditions.

3. You are currently pregnant or plan to become pregnant

This medicine may affect your baby if you take it while you are pregnant, especially during the last 7 weeks of pregnancy. Your baby may have some side effects from this medicine during the first month after birth.

4. You are currently breastfeeding plan to breast-feed.

Breast-feeding is not recommended while you are taking this medicine. The active ingredient, clomipramine, passes into the breast milk and could affect your baby.

- 5. You are planning to have surgery.**
- 6. You are currently receiving or are planning to receive dental treatment**
- 7. You are about to have electroconvulsive therapy**
- 8. You are a smoker**

Nicotine can affect the amount of clomipramine that is in your body. Sudden changes in your usual smoking habits can also change the effects of this medicine.

- 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 clomipramine. These include:

- MAOIs (you must not take clomipramine with a MAOI, or for 14 days after stopping most MAOIs, and you must not take a MAOI for 14 days after stopping clomipramine)
- any other medicines for depression such as: fluoxetine, fluvoxamine, paroxetine, sertraline, amitriptyline, nortriptyline, lithium). For fluoxetine, you must not take clomipramine within 3 weeks of taking it.

- sleeping tablets or medicines for anxiety, such as alprazolam
- medicines for other mental disorders, such as thioridazine
- St John's Wort, a herbal preparation for low mood
- certain medicines for high blood pressure or heart problems
- diuretic medicines, also called fluid or water tablets
- warfarin, used for preventing blood clots
- medicines for allergies
- phenytoin, carbamazepine and barbiturates, used to treat epilepsy or convulsions (fits)
- biperiden and other medicines for Parkinson's disease
- medicines for thyroid problems
- some medicines for cholesterol (cholestyramine or colestipol)
- some cough and cold preparations including nose drops or sprays
- nicotine in medicines used to help you quit smoking e.g. nicotine patches, inhalers or chewing gum
- medicines for stomach cramps, muscle spasms or travel sickness

- cimetidine, a medicine for stomach problems
- oestrogens, contained in some birth control pills and hormone replacement therapies
- methylphenidate, a medicine to treat narcolepsy or ADHD
- disulfiram, a medicine for alcoholism
- rifampicin, a medicine to treat infections
- medicines used during operations
- terbinafine, a medicine taken by mouth to treat fungal infections
- other medicines such as atropine, adrenaline and amphetamine.

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 clomipramine.

How to take this medicine

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

How much to take

Your doctor or pharmacist 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, obsessive compulsive disorders and phobias, treatment is usually started with a low dose of 2 or 3 tablets (50 to 75 mg) each day. The dose can be slowly raised to 4 to 6 tablets each day. Some people will need higher doses than others because each person's body chemistry is different. Once you are feeling better, your doctor may be able to slowly reduce the dose, usually down to 2 to 4 tablets each day.

For muscle weakness accompanying narcolepsy, the dose is usually from 1 to 3 tablets (25 to 75 mg) each day.

If you are older than 65 years, your doctor will probably start with a low dose (e.g. 1 tablet each day) to help avoid side effects. The dose is gradually increased over about ten days to 2 to 3 tablets each day and kept at that dose for the rest of your treatment.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

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

When to take it

Spread the tablets out over the day (for example, one tablet two or three times a day, depending on how many your doctor has told you to take).

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

If your stomach is upset after taking the tablets, then take your tablets with a meal or after a snack.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

The length of treatment will depend on your condition and how well the medicine works.

For depression, this will depend on how quickly your symptoms improve. Most medicines of this type take time to work, so don't be discouraged if you don't feel better right away.

Some of your symptoms may improve in 1-2 weeks, but it can take up to 4-6 weeks to feel any real improvement.

Even when you feel well, you will usually have to take this medicine for several months or even longer to make sure the benefits will last.

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

If you forget to take it

If it is almost time to take your next dose (e.g. it's due within 2-3 hours), 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.

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

This may increase the chance of unwanted side effects.

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

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.

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

If you take too much of your medicine, you may feel sleepy, restless or agitated. You may have stiffness or unusual muscle movements, fever, sweating, vomiting, difficulty breathing, a

drop in blood pressure, fast or irregular heartbeat, fits or other symptoms.

Children are much more sensitive than adults to tricyclic antidepressants. An accidental overdose is especially dangerous.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine or have been taking it within the last two weeks if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you become pregnant or plan to breastfeed. Your doctor can discuss with you the risks of taking this medicine while you are pregnant or breast-feeding
- you are about to have any blood tests
- you are going to have surgery. If possible clomipramine should be stopped before surgery to avoid unnecessary side effects

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 your doctor or dentist if your mouth feels dry and this lasts for more than 2 weeks.

This medicine may cause a dry mouth. Continuing dryness of the mouth may increase the chance of dental disease, including tooth decay and gum disease. You can relieve dry mouth by frequent sips of water, sucking sugarless lollies or chewing sugarless gum.

Be sure to have regular dental check-ups.

If you wear contact lenses and find that your eyes are dry, sticky and irritated, tell your doctor.

These side effects could damage your eyes.

Contact your doctor immediately if you or someone you know develop any of the following symptoms at any time while taking clomipramine:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- difficulty sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent

- acting on dangerous impulses
- an extreme increase in activity and talking
- other unusual changes in behaviour or mood.

Symptoms such as these may be associated with an increased risk of suicidal thinking and behaviour and must be taken seriously.

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.

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 or pharmacist tells you to
- stop taking your medicine, or change the dosage, without first checking with your doctor.

Do not run out of your medicine over weekends or public holidays.

If you stop taking it suddenly, your condition may get worse or you may have unwanted side effects such as nausea, vomiting, diarrhoea and nervousness.

If required, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert, until you know how this medicine affects you.

This medicine may cause drowsiness, dizziness, blurred vision or sleepiness and affect alertness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol or taking pain relievers, sleeping tablets or antihistamines (medicines for colds or allergies such as hay fever) while you are taking your medicine.

This medicine can increase the drowsiness caused by alcohol and by medicines that affect your nervous system.

If this medicine makes you feel lightheaded, be careful when getting up from a sitting or lying position.

You can usually prevent these symptoms by getting up slowly and flexing your leg muscles and toes to get blood flowing. When getting out of bed, dangle your legs over the side for a minute or two before standing up.

Be careful to stay out of direct sunlight as much as possible until you find out if your skin is more sensitive than usual. Wear protective clothing and use a sunscreen. Do not use a sunlamp.

This medicine makes some people more sensitive to sunlight.

After you have stopped taking clomipramine, you should still be careful for 1-2 weeks since some of the effects of the medicine will still be in your body.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking clomipramine 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, most of the time they are not.

If you are over 65 years of age you should be especially careful while taking this medicine. Tell your doctor immediately if you have any side effects.

As people grow older, they are more likely to get side effects from medicines.

This medicine may cause confusion or disorientation, especially in older people or those with Parkinson's disease. Your family or carer should be aware of this. Special care may be needed.

Tell your doctor or pharmacist if you notice any of the following side effects and they worry you.

- drowsiness, dizziness
- blurred vision or difficulty focusing, especially when treatment is started or the dose is increased
- dry or sticky eyes
- lightheadedness, especially when you get up too quickly from a sitting or lying position
- dry mouth
- difficulty urinating (passing water)
- sweating or hot flushes
- increased or decreased appetite
- weight gain or loss
- tired feeling and mental dullness
- feeling of unrest or anxiety
- problems getting to sleep, staying asleep or nightmares
- shakiness or trembling
- skin sensation of tingling or prickling
- nausea (feeling sick), vomiting, diarrhoea or constipation

- sores in the mouth or on the tongue
- headache
- changes in sexual desire or difficulty in reaching orgasm
- delayed or no ejaculation of semen if you are a male
- swelling of the breasts or discharge of milk
- swelling of the testicles
- increased sensitivity to the sun
- ringing in the ears
- hair loss
- change in sense of taste
- mild skin rashes.

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

These may be serious side effects. You may need medical attention.

- constant "flu-like" symptoms (chills, fever, sore throat, aching joints, swollen glands, tiredness or lack of energy)
- unusual bleeding or bruising
- frequent passing of large amounts of urine

- yellow colour to the skin or eyes

Most of these side effects are rare.

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.

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

- pain in the stomach, abdomen or chest that is severe or doesn't go away
- fast or irregular heart beat (pounding, racing, skipping beats)
- severe dizziness or drowsiness
- fainting spells or seizures (fits)
- difficulty in speaking or slurred speech
- weakness or loss of balance
- a sudden increase in body temperature, extremely high blood pressure and severe convulsions.
- swelling and/or pain following a fall, which may indicate that you have broken a bone
- unusually high energy, irritability or outbursts of anger, or feeling unusually withdrawn

- confusion or hallucinations (seeing, hearing or feeling things that are not there)
- muscle numbness, weakness, tingling or spasms, walking in an uncoordinated way
- eye pain

Other side effects not listed above may also occur in some people.

Allergic reactions

If you think you are having an allergic reaction to clomipramine, stop taking 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:

- 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
- hayfever-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 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 or pharmacist 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-Clomipramine looks like

Round, pale yellow, biconvex tablets engraved "25" on one side.

Blister packs of 50.

Ingredients

Each tablet contains 25 mg of clomipramine hydrochloride as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- anhydrous colloidal silica hypromellose
- macrogol
- titanium dioxide (E171)
- iron oxide yellow (CI77492).

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

Australian Registration Number

APO-Clomipramine 25 mg tablets

(PVC/ Aluminium blisters):

AUST R 73878.

Sponsor

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