

APO-Clomipramine Tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using APO-Clomipramine?

APO-Clomipramine contains the active ingredient clomipramine hydrochloride. APO-Clomipramine is used to treat: depression that is longer lasting and/or more severe than the "low moods" that everyone has from time to time due to the stress of everyday life; obsessive-compulsive disorders (OCD) and phobias in adults; and, muscle weakness in people with a sleep disorder called narcolepsy.

For more information, see Section [1. Why am I using APO-Clomipramine ?](#) in the full CMI.

2. What should I know before I use APO-Clomipramine?

Do not use if you have ever had an allergic reaction to APO-Clomipramine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use APO-Clomipramine ?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-Clomipramine and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use APO-Clomipramine?

- The dose, frequency and length of treatment will be determined by your doctor. Follow all directions given to you by your doctor or pharmacist carefully.
- Swallow the tablets with a full glass of water.

More instructions can be found in Section [4. How do I use APO-Clomipramine ?](#) in the full CMI.

5. What should I know while using APO-Clomipramine?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-Clomipramine.• Tell your doctor immediately if you become pregnant.• Call your doctor straight away if you or someone you know has thoughts about or attempts to commit suicide.• Call your doctor straight away if you or someone you know develops new or worse depression/anxiety, panic attacks, difficulty sleeping, or other unusual changes in behaviour or mood, for example: being angry or violent, acting on dangerous impulses, extreme increase in activity and talking.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not let yourself run out of medicine over the weekend or on holidays.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how APO-Clomipramine affects you.• APO-Clomipramine may cause tiredness, dizziness, drowsiness or blurred vision in some people.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.• APO-Clomipramine can increase the drowsiness caused by alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in the original container until it is time to take a dose.• Store it in a cool dry place at room temperature.

For more information, see Section [5. What should I know while using APO-Clomipramine?](#) in the full CMI.

6. Are there any side effects?

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

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. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APO-Clomipramine Tablets

Active ingredient(s): *clomipramine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-Clomipramine. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-Clomipramine.**

Where to find information in this leaflet:

- [1. Why am I using APO-Clomipramine?](#)
- [2. What should I know before I use APO-Clomipramine?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APO-Clomipramine?](#)
- [5. What should I know while using APO-Clomipramine?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using APO-Clomipramine?

APO-Clomipramine contains the active ingredient **clomipramine hydrochloride**. APO-Clomipramine belongs to a group of medicines called tricyclic antidepressants.

APO-Clomipramine is used to treat:

- depression that is longer lasting and/or more severe than the "low moods" that everyone has from time to time due to the stress of everyday life.**
Depression is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, loss of sex drive, lack of energy and feelings of guilt.
- obsessive-compulsive disorders (OCD) and phobias in adults.**
- muscle weakness in people with a sleep disorder called narcolepsy.**

The symptoms of these disorders vary from person to person. Your doctor can provide you with more information.

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 purpose.

2. What should I know before I use APO-Clomipramine?

Warnings

Do not use APO-Clomipramine if:

- you are allergic to clomipramine, any other tricyclic antidepressant, or any of the ingredients listed at the end of this leaflet.
- you are under 18 years of age.
- Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

- Do not start taking APO-Clomipramine if you are already taking another medicine called a monoamine oxidase inhibitor (MAOI) or you have been taking it within the past 2 weeks.**
Taking APO-Clomipramine together with a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and seizures (fits). Your doctor will know when it is safe to start APO-Clomipramine after the MAOI has been stopped.
- Do not take APO-Clomipramine if you are recovering from a recent heart attack.**
It may make your condition worse.
- Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**
In that case, return it to your pharmacist.

Check with your doctor if you have:

- an irregular heart beat or other problems with your heart
- an inherited heart problem called congenital long QT syndrome
- increased pressure in the eye from any cause (e.g. glaucoma)
- difficulty in passing urine (water), due to prostate trouble or any other cause
- seizures (fits)
- severe liver or kidney disease
- a low level of potassium in your blood (called hypokalaemia)
- a mental disorder other than the one being treated (e.g. schizophrenia, mania)
- problems with blood pressure (either too high or too low)
- a blood disorder
- a thyroid problem
- chronic constipation
- Parkinson's disease
- a tumour of the adrenal gland
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

APO-Clomipramine should not be taken if you are pregnant unless your doctor has told you to do so. 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 the medicine during the first month after birth. Newborn infants whose mothers had taken this medicine up until delivery may show symptoms such as shortness of breath, abnormal bluish discoloration of the skin and mucous membranes, lethargy, feeding difficulties, colic, irritability, convulsions, tremor, overactive muscle tone, poor muscle tone or spasms, during the first hours or days of life. If there is a need to take APO-Clomipramine when you are pregnant, your doctor will discuss the risks and benefits to you and the unborn baby. Your doctor may also recommend gradually stopping APO-Clomipramine in the 7 weeks before giving birth.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with APO-Clomipramine and affect how it works. These include:

- MAOI medicines. You must not take APO-Clomipramine together with a MAOI (see 2. What should I know before I use APO-Clomipramine?)
- medicines for high blood pressure or heart problems
- medicines to help you sleep or calm you down
- other medicines for depression called SSRIs or SNaRIs (e.g. fluoxetine, paroxetine, sertraline, fluvoxamine)
- medicines for other mental disorders
- medicines for seizures (fits)
- medicines to prevent blood clots (e.g. warfarin)
- diuretic medicines, also called fluid or water tablets
- some medicines for colds or allergies, including antihistamines and some nose drops
- anticholinergic medicines, which are used to relieve stomach cramps, spasms and travel sickness
- medicines for thyroid problems
- cimetidine, a medicine for stomach ulcers
- medicines for Parkinson's disease
- oestrogens (e.g. birth control pills, hormone replacement therapy)
- nicotine in medicines used to help you quit smoking, such as nicotine patches or chewing gum
- methylphenidate (Ritalin®)
- disulfiram, a medicine for alcoholism
- rifampicin, an antibiotic
- terbinafine, a medicine used to treat skin, hair or nail infections due to fungus
- medicines used to reduce fat in blood
- grapefruit/grapefruit juice or cranberry juice.

You may need to take different amounts of your medicines or you may need to take different medicines. Your doctor and pharmacist have more information.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-Clomipramine.

4. How do I use APO-Clomipramine?

How much to take

- 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 raised slowly up 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.
- Follow the instructions provided and use APO-Clomipramine until your doctor tells you to stop.

When to take APO-Clomipramine

- Take the tablets in 2 or 3 doses spread over the day unless your doctor advises you otherwise.
- If you have narcolepsy and you have trouble sleeping at night, take the last dose before evening to avoid making your insomnia worse.

How to take APO-Clomipramine

- Swallow the tablets with a full glass of water. If your stomach is upset after taking the tablets, take them with a meal or after a snack.

How long to take APO-Clomipramine

Take this medicine until your doctor tells you to stop treatment.

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

For depression, the length of treatment will depend on how quickly your symptoms improve. This type of medicine takes time to work, so don't be discouraged if you don't feel better right away. Some of your symptoms may improve in 1 or 2 weeks but it can take up to 4 to 6 weeks to feel any real improvement. Even when you feel well, you will usually have to take APO-Clomipramine for several months or even longer to make sure the benefits will last.

Do not stop taking APO-Clomipramine suddenly as you could suffer possible withdrawal symptoms.

If you forget to use APO-Clomipramine

If it is almost time for your next dose (e.g. within 2 or 3 hours), skip the dose you missed and take your next dose when you are meant to.

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

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

This may increase the chance of you getting an unwanted side effect.

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

If you take too much APO-Clomipramine

If you think that you have used too much APO-Clomipramine, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you take too much APO-Clomipramine, 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.

5. What should I know while using APO-Clomipramine?

Things you should do

If you become pregnant while taking APO-Clomipramine, tell your doctor immediately.

Your doctor can discuss with you the risks of taking it while you are pregnant.

Call your doctor straight away if you or someone you know develop any of the following:

- 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.

Before having any surgery or emergency treatment, even a minor procedure, tell the doctor or dentist in charge that you are taking APO-Clomipramine or have been taking it within the last two weeks or so.

If possible, this medicine should be stopped before surgery to avoid unnecessary side effects.

If this medicine causes your mouth to feel dry and this problem doesn't go away, tell your doctor or dentist. Be sure to have regular dental checkups.

Continuing dryness of the mouth may increase the chance of gum disease or cavities. You can relieve dry mouth by frequent sips of water, sucking sugarless lollies or chewing sugarless gum.

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

These side effects could damage your eyes.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want to take some blood tests and check your heart and blood pressure from time to time.

This helps to prevent unwanted side effects.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking APO-Clomipramine.

Remind any doctor, dentist or pharmacist you visit that you are using APO-Clomipramine.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not stop taking APO-Clomipramine or change the dose without first checking with your doctor.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not give this medicine to anyone else, even if their condition seems similar to yours.
- Do not use it to treat any other complaints unless your doctor tells you to.

If you stop taking this medicine suddenly, your condition may worsen or you may have unwanted side effects such as headache, nausea (feeling sick), vomiting, diarrhoea and nervousness. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Taking pain relievers, sleeping tablets or antihistamines

- **Be careful when taking pain relievers, sleeping tablets or antihistamines (medicines for colds or allergies such as hay fever) while you are taking APO-Clomipramine.**
- APO-Clomipramine can increase the drowsiness caused by medicines that affect your nervous system.

Lightheadedness

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 leg muscles and toes to get the blood flowing. When getting out of bed, dangle your legs over the side for a minute or two before standing up.

Exposure to sunlight or sunlamps

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 APO-Clomipramine, you should still be careful for 1 or 2 weeks since some of the effects of the medicine will still be in your body.

Smoking

Tell your doctor if you smoke.

Nicotine can affect the amount of APO-Clomipramine that is in your body. Sudden changes in your usual smoking habits can also change the effects of APO-Clomipramine.

Lactose intolerance

Tell your doctor if you are lactose intolerant.

This medicine contains lactose.

Allergies

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

Your doctor will want to know if you are prone to allergies.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-Clomipramine affects you.

APO-Clomipramine may cause tiredness, dizziness, drowsiness or blurred vision in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

APO-Clomipramine can increase the drowsiness caused by alcohol.

Looking after your medicine

- Keep your medicine in the original container until it is time to take a dose.

Follow the instructions on the carton as to how to take care of your medicine properly.

Store it in a cool dry place at room temperature away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

If you are over 65 years old, you should be especially careful while taking this medicine. Report any side effects promptly to your doctor.

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

APO-Clomipramine can 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.

Patients aged 50 years or older and taking a medicine of this group are more likely to experience bone fractures.

Patients with pre-existing heart conditions and the elderly should be monitored for heart health, as they are at an increased risk of heart attack, stroke and sudden death.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • drowsiness, dizziness, blurred vision or difficulty focusing your eyes, especially when treatment is started or the dose is increased. • lightheadedness, especially when you get up too quickly from a sitting or lying position. • dry mouth • difficulty urinating (passing water) • dry or sticky eyes if you wear contact lenses • constipation • sweating or hot flushes • increased appetite and weight gain • decreased appetite • tired feeling and mental dullness • feeling of unrest or anxiety • a compelling need to be in constant motion • repetitive, involuntary, purposeless movements • disturbed sleep or nightmares • shakiness or trembling • nausea (feeling sick), vomiting, diarrhoea • poor appetite or weight loss • sores in the mouth or on the tongue • headache • reduced sexual desire or difficulty in reaching orgasm • 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 • delayed or no ejaculation of semen if you are a male 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing or troubled breathing • constant "flu-like" symptoms (chills, fever, sore throat, aching joints, swollen glands, tiredness or lack of energy) • unusual bleeding or bruising • pain in the stomach or abdomen that is severe or doesn't go away • fast or irregular heart beat (pounding, racing, skipping beats) • muscle numbness, tingling or spasms • weakness or loss of balance • severe dizziness or drowsiness • fainting spells or seizures (fits) • difficulty in speaking or slurred speech • unusually high energy, irritability or outbursts of anger • confusion or hallucinations (seeing, hearing or feeling things that are not there) • frequent passing of large amounts of urine • yellow colour to the skin or eyes • eye pain • symptoms like agitation, confusion, diarrhoea, high temperature, increased blood pressure, excessive sweating and rapid heartbeat (syndrome caused due to increase in naturally occurring messenger, serotonin) • a sudden increase in body temperature, extremely high blood pressure and severe convulsions especially in conjunction with fast heart rate and sweating. This may be due to a very rare condition called neuroleptic malignant syndrome, which has been reported with various antipsychotic medicines. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What APO-Clomipramine contains

Active ingredient (main ingredient)	Clomipramine hydrochloride
Other ingredients (inactive ingredients)	lactose monohydrate microcrystalline cellulose croscarmellose sodium magnesium stearate colloidal anhydrous silica hypromellose macrogol 3350 titanium dioxide iron oxide yellow

Do not take this medicine if you are allergic to any of these ingredients.

This medicine does not contain gluten, tartrazine or any other azo dyes.

What APO-Clomipramine looks like

APO-Clomipramine 25 mg tablets are round, pale yellow, biconvex tablets engraved "25" on one side; supplied in packs of 50 tablets.

AUST R 73878

Who distributes APO-Clomipramine

Arrotex Pharmaceuticals Pty Ltd
15 - 17 Chapel Street
CREMORNE VIC 3121

www.arrotex.com.au

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