

CONSUMER MEDICINE INFORMATION

CLOMIPRAMINE-TEVA

Clomipramine hydrochloride 10 mg and 25 mg film-coated tablets

What is in this leaflet

This leaflet answers some common questions about Clomipramine-Teva. It does not contain all the information available on this medicine. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

Your doctor has weighed the risks of using Clomipramine-Teva against the benefits expected it will have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may want to read it again.

What Clomipramine-Teva is used for

Clomipramine-Teva is used to treat:

1. depression in adults, 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 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.
2. obsessive-compulsive disorders (OCD), phobias and panic attacks.
3. muscle weakness in people with a sleep disorder called narcolepsy.
4. chronic painful conditions.

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

Clomipramine-Teva belongs to a group of medicines called tricyclic antidepressants.

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.

Clomipramine-Teva is available on prescription from your doctor.

Before you take Clomipramine-Teva

When you must not take it

Do not take Clomipramine-Teva if you have an allergy to:

- clomipramine (the active ingredient) or any of the other ingredients of Clomipramine-Teva listed at the end of this leaflet
- any other tricyclic antidepressant

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 Clomipramine-Teva 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 Clomipramine-Teva 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 Clomipramine-Teva after the MAOI has been stopped.

Do not take Clomipramine-Teva if you are recovering from a recent heart attack. It may make your condition worse.

Clomipramine-Teva should not be taken to treat nocturnal enuresis (“bed-wetting”).

Do not give Clomipramine-Teva to a child under the age of 12 years for treatment of depression.

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.

Before you start to take it

Tell your doctor if you have any of the following health problems/medical conditions:

- 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

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.

Tell your doctor if you are pregnant or intend 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 the medicine during the first month after birth.

Tell your doctor if you are breastfeeding or plan to breast-feed.

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

Tell your doctor if you smoke.

Nicotine can affect the amount of Clomipramine-Teva that is in your body.

Sudden changes in your usual smoking habits can also change the effects of Clomipramine-Teva.

Tell your doctor if you are lactose intolerant.

This medicine contains lactose.

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

Taking other medicines

If you are taking any other medicines, including any you get without a prescription from a pharmacy, supermarket or health food shop, tell your doctor or pharmacist.

Some medicines and Clomipramine-Teva may interfere with each other. These include:

- MAOI medicines. You must not take Clomipramine-Teva together with a MAOI (see "When you must not take it")
- 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
- anticoagulants (blood thinning tablets)
- 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.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

How to take CLOMIPRAMINE - TEVA

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 label, ask your doctor or pharmacist for help.

How much to take

For depression, obsessive-compulsive disorders and phobias, treatment is usually started with a low dose of one 25 mg tablet 2 to 3 times daily. The dose can be raised slowly up to 4 to 6 tablets of 25 mg each day. In severe cases, this dosage can be increased up to a maximum of 250 mg daily.

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 of the 25 mg tablets.

For panic attacks/agoraphobia, the usual starting dose is one 10 mg tablet daily. The daily dosage varies from patient to patient and is usually between 25 mg and 100 mg. The maximum daily dose is 150 mg.

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

For chronic painful conditions, the dosage will be individualised (10 mg to 150 mg daily), taking into account any other pain relieving medication being taken at the same time.

If you are older than 65 years, your doctor will probably start with a low dose (e.g. one 10 mg tablet daily) to help avoid side effects. The dose is gradually increased over about ten days to a level of 30 mg to 50 mg daily and kept at that dose for the rest of your treatment.

Clomipramine-Teva is not recommended for the treatment of depression in adolescents (13-18 years of age).

Clomipramine-Teva should not be used for the treatment of depression in children 12 years of age and under.

When to take it

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 it

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 it

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 Clomipramine-Teva for several months or even longer to make sure the benefits will last.

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

If you forget to take it

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

While you are taking CLOMIPRAMINE - TEVA

Things you must do

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

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

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.

Contact your doctor immediately if you or someone you know develop any of the following symptoms at any time during treatment with Clomipramine-Teva:

- 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 Clomipramine-Teva 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.

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

Tell any other doctor, dentist or pharmacist who treats you that you are taking Clomipramine-Teva.

Things you must not do

Do not stop taking Clomipramine-Teva or change the dose without first checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

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.

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.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Clomipramine-Teva until you know how it affects you.

This medicine may cause tiredness, dizziness, drowsiness or blurred vision in some people.

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 Clomipramine-Teva.

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 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.

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

Side effects

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

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.

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.

Clomipramine-Teva 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.

Do not be alarmed by these lists 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 these side effects and they worry you:

- drowsiness, dizziness, blurred vision or difficulty focussing 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

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

- 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

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet.

In case of overdose

You should only take the number of tablets that you have been told.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any Clomipramine-Teva by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Take the pack of Clomipramine-Teva with you if you can.

Keep telephone numbers for these places handy.

If you take too much Clomipramine-Teva, 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.

Storage conditions

Do not take this medicine after the expiry date shown on the pack/blister strip or if the packaging shows signs of tampering.

Keep your Clomipramine-Teva tablets in the blister pack until it is time to take them.

Store below 25°C and out of reach of children. Avoid exposure to heat, light and moisture.

Do not store Clomipramine-Teva, or any other medicine, in the bathroom or near a sink.

Disposal

If your doctor tells you to stop taking Clomipramine-Teva or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Product Description

What Clomipramine-Teva tablets look like

Clomipramine-Teva 10 mg tablets are light yellow coloured, triangular shaped, biconvex, film coated tablets.

Clomipramine-Teva 25 mg tablets are light yellow coloured, round shaped, biconvex, film coated tablets.

Ingredients

Tablet Core:

10 mg: lactose monohydrate, corn starch, colloidal anhydrous silica, hypromellose, magnesium stearate.

25 mg: lactose monohydrate, corn starch, colloidal anhydrous silica, magnesium stearate, glycerol, stearic acid, talc.

Film coating & tablet polishing:

Hypromellose, macrogol 8000, talc, saccharose, copovidone, titanium dioxide E171, povidone K30, dispersed yellow 18014 Anstead, microcrystalline cellulose.

Who supplies this medicine

Distributed in New Zealand by:

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