

Tofranil®

10 mg and 25 mg tablets

Imipramine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tofranil. 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 final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Tofranil is used for

Tofranil is used to treat:

1. 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. It 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 feeling guilty over nothing.

2. Bed-wetting in people from the age of 5 years onwards if there is no physical cause for the problem (i.e. there is nothing wrong with the bladder itself).

Tofranil belongs to a group of medicines called tricyclic antidepressants (TCAs).

Tofranil corrects this chemical imbalance and may help relieve the symptoms of depression.

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.

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

Before you take Tofranil

When you must not take it

Do not take Tofranil if you have ever had an allergic reaction after taking:

- imipramine (the active ingredient in Tofranil)

- any of the other ingredients 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 Tofranil 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 this medicine together with a MAOI may cause a serious reaction (a condition called serotonin syndrome) with a sudden increase in body temperature, extremely high blood pressure, seizures (fits), hyperactivity, increase in muscle tone or stiffness of muscle and coma or death. Your doctor will know when it is safe to start Tofranil after the MAOI has been stopped.

Ask your doctor or pharmacist if you are not sure if you have been taking one of these medicines.

Do not take Tofranil if you are recovering from a recent heart attack.

It may make your condition worse.

Do not take Tofranil if you are under 18 years of age for the treatment of depression or other psychiatric disorders.

There is not enough information to recommend the use of this medicine to treat depression or other psychiatric disorders in children under 18 years of age.

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.

If you are not sure whether you should start taking Tofranil, talk to your doctor.

Before you start to take it

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

- heart problems, especially an irregular heartbeat
- 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
- mental disorders other than depression
- problems with blood pressure (either too high or too low)
- blood disorders
- thyroid problems
- chronic constipation
- a tumour of the adrenal gland.
- depression or other conditions that are treated with antidepressants.

The use of these medicines such as imipramine, selective serotonin reuptake inhibitors (SSRIs) and noradrenaline reuptake inhibitors together with Tofranil can lead to serotonin syndrome, a potentially life-threatening condition. Symptoms may include confusion, agitation, mood changes, diarrhoea, chills, increased body temperature, sweating, changes in blood pressures, nausea, vomiting, involuntary muscle jerk, overresponsive bodily reflexes, involuntary shaking or movement in one or more parts of body, difficult movement coordination, disturbances in mental abilities and coma. 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 breastfeed.

Breastfeeding is not recommended while you are taking Tofranil. 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 Tofranil that is in your body. Sudden changes in your usual smoking habits can also change the effects of Tofranil.

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.

Tell your doctor if you have an intolerance to lactose or sucrose.

This medicine contains lactose and sucrose.

Taking other medicines

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

Some medicines and Tofranil may interfere with each other. These include:

- MAOI medicines. You must not take Tofranil 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 (e.g. fluoxetine and paroxetine)
- medicines for other mental disorders
- medicines for seizures (fits)
- medicines to prevent blood clots (e.g. warfarin)
- some medicines for colds or allergies, including 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
- sulfamethoxazole and trimethoprim, medicines used to treat bacterial infections
- terbinafine, a medicine to treat fungal infections
- 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.

These medicines may be affected by Tofranil or they may affect how well it works. 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 on medicines to be careful with or avoid while you are taking Tofranil.

If you have not told your doctor about any of these things, tell them before you take Tofranil.

How to take Tofranil

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, treatment is usually started with a low dose (e.g. up to 75 mg each day). The dose can be increased slowly over the first week up to 150 to 200 mg each day.

If your symptoms are very severe, up to 300 mg each day may be prescribed.

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 50 to 100 mg each day.

For bed-wetting, the usual dose for children aged 5-8 years is 20 to 30 mg each day. For children aged 9-12 years the dose is 25 to 50 mg each day, and for children aged over 12 years, the dose is up to 75 mg each day.

The higher doses are usually used if bed-wetting does not improve after a week of treatment at a lower dose.

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

When to take it

For depression, take the tablets in 2 or 3 doses spread over the day unless your doctor advises you otherwise.

If the tablets make you sleepy, your doctor may suggest that you take

one dose at night to help you sleep well.

For bed-wetting, take the tablets as a single dose after the evening meal unless your doctor advises you otherwise.

If bed-wetting tends to happen early in the night, your doctor may advise you to take part of the dose earlier (e.g. at 4 p.m.).

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 Tofranil for several months or even longer to make sure the benefits will last.

Continue taking it until your doctor tells you to stop.

For bed-wetting, the treatment is usually continued for 1 to 3 months.

If you forget to take it

If you normally take the tablets 2 or 3 times a day and 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 it as soon as you remember, and then go back to taking the tablets as you would normally.

If you normally take the tablets only at bedtime and you miss a dose, do not take the missed dose the next morning until you check with your doctor.

The medicine may cause some side effects during the day if you take the whole dose in the morning.

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.

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Tofranil. Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

In children, accidental ingestion of any amount should be regarded as serious and potentially fatal. If you take too much Tofranil, you may feel sleepy, unresponsive, coma, impaired balance or coordination, restless or agitated, dilated pupils, overresponsive bodily reflexes, less wakeful or aware and symptoms of serotonin syndrome (refer section 4.4). You may also have stiffness or unusual muscle movements, fever, sweating, vomiting, difficulty breathing, a drop in blood pressure/shock, fast or irregular heartbeat, heart disorder including heart failure and cardiac arrest, bluish discoloration of the skin, unable to breath during sleep, fits or other symptoms including dry mouth, constipation, and low urine output.

If you are not sure what to do, contact your doctor or pharmacist.

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

While you are taking Tofranil

Things you must do

If you become pregnant while taking Tofranil, tell your doctor immediately.

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

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 your doctor if you feel the tablets are not helping your condition.

If you are being treated for depression, be sure to discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness or bursts of unusual energy or anger.

This will help your doctor to determine the best treatment for you.

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 Tofranil:

- 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. Talk to your doctor or mental health professional if you have thoughts or talk about death or suicide; or thoughts or talk about self-harm or doing harm to others.

Before having any surgery or emergency treatment, even a minor procedure, tell the doctor or dentist in charge that you are taking Tofranil 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 check-ups.

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 Tofranil.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Tofranil.

Things you must not do

Do not stop taking Tofranil 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, abdominal pain, chills, pain that affects bones, muscles and nerves, inability to sleep, irritability, tiredness, anxiety and nervousness. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Do not take Tofranil to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.

Things to be careful of

You must tell your doctor if you are pregnant or are intending to become pregnant.

There have been reports of some congenital abnormalities or an increase in pre-term delivery associated with taking antidepressants in pregnancy.

Some infants, exposed to antidepressants late in the third trimester, have shown drug withdrawal symptoms such as difficulty of breathing, sluggish, colic irritability, low or high blood pressure, and tremor or spasms. To avoid such symptoms, Tofranil should, if possible, be gradually withdrawn at least 7 weeks before the calculated date of confinement.

Your doctor will discuss the possible risks and benefits of taking Tofranil during pregnancy.

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Tofranil until you

know how it affects you. Children should take care when doing things like riding bicycles or climbing trees.

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 Tofranil.

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 Tofranil, you should still be careful for 1 or 2 weeks since some 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 Tofranil.

Tofranil helps most people with depression, but it may have unwanted side effects in some people. 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.

Tofranil can cause confusion or disorientation, especially in older people. Your family or carer should be aware of this. Special care may be needed.

Do not be alarmed by this list 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
- palpitations
- rash, hives
- light-headedness, especially when you get up too quickly from a sitting or lying position
- dry mouth
- altered sense of taste
- problems with urinating (passing water)
- dry or sticky eyes
- constipation or diarrhoea
- sweating or hot flushes
- weight gain
- tired feeling
- feeling of unrest or anxiety
- hallucinations, feeling very confused
- euphoria (strong feeling of happiness)
- disturbed sleep
- aggression
- suicidal thinking and behaviour
- mood swings

- prickly skin
- nausea (feeling sick), vomiting, loss of appetite or weight loss
- headache
- reduced sexual desire
- hairloss
- dark skin (hyperpigmentation)
- swelling (generalised or local)
- excessive breast tissue growth (Hypertrophy breast)
- milky nipple discharge unrelated to the normal milk production (galactorrhoea)
- abnormal liver function test.

These are the more common side effects of Tofranil.

An increased risk of bone fracture has been observed in patients over 50 years of age taking this type of medicine.

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
- pink or red skin rash with blotchy blisters, scaly patches (photosensitivity reactions)
- high fever, agitation, confusion, trembling and abrupt contractions of muscles
- constant "flu-like" symptoms (chills, fever, sore throat, aching joints, swollen glands, tiredness or lack of energy)
- unusual bleeding or bruising
- reduction in some blood cells (recurring infections)
- pain in the stomach or abdomen that is severe or doesn't go away
- fast or irregular heart beat (pounding, racing, skipping beats)
- heart failure
- muscle numbness, tingling or spasms

- stoke (trouble walking, speaking and understanding, as well as paralysis or numbness of the face, arm or leg.)
- uncontrolled, involuntary and jerky movements, including tremors and shaking of the hands, arms or legs
- 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
- high or unstable blood sugar levels
- abnormal Electrocardiogram (ECG)

Sudden deaths have occurred in patients taking this medicine.

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

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

Other side effects not listed here may happen in some people. Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using Tofranil

Storage

Keep your tablets in their container until it is time to take them.

If you take the tablets out of their container they may not keep well.

Store Tofranil in a cool dry place where the temperature stays below 30°C. Protect from moisture.

Do not store this or any other medicine in the bathroom or near a sink. Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep the tablets where children cannot reach them.

A locked cupboard at least 1½ metres above the ground is a good place to store medicines.

Disposal

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

Product Description

What it looks like

Tofranil 10 tablets - red-brown, triangular-shaped, convex sugar-coated tablets

Blister pack of 50 tablets.

Tofranil 25 tablets - reddish-brown, round, biconvex sugar-coated tablets

Blister pack of 50 tablets.

Ingredients

Tofranil tablets contain either 10 mg or 25 mg of imipramine hydrochloride as the active ingredient.

They also contain:

- colloidal anhydrous silica
- glycerol
- lactose monohydrate
- magnesium stearate
- maize starch
- stearic acid
- purified talc
- hypromellose
- microcrystalline cellulose
- macrogol 8000
- povidone
- copovidone
- sucrose
- titanium dioxide
- iron oxide red
- carnauba wax (Tofranil 25 mg tablets only)

Sponsor

Tofranil tablets are supplied in Australia by:

Amdipharm Mercury (Australia) Pty Ltd
Level 9, 76 Berry Street, North Sydney NSW 2060

Date of preparation

06 September 2022

Australian registration numbers

Tofranil 10 AUST R 11064

Tofranil 25 AUST R 60673

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