

Tofranil

Imipramine hydrochloride 10 mg and 25 mg coated tablets

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.

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 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 feelings of guilt.

Tofranil 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.

Tofranil is not recommended for use in children 12 years of age and under. Tofranil is not recommended for use in adolescents (13-18 years of age) for the treatment of depression, unless under the supervision of a specialist.

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 with a sudden increase in body temperature, extremely high blood pressure and seizures (fits). Your doctor will know when it is safe to start Tofranil after the MAOI has been stopped.

Do not take Tofranil for the treatment of bedwetting.

Do not take Tofranil 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.

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

Before you start to take Tofranil

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

- heart problems, especially an irregular heart beat
- 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 mental disorder other than depression
- 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
- blockage of the small intestine

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 breast-feeding or plan to breast-feed.

Breast-feeding 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.

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 (e.g. Amlodipine, Labetalol etc.)
- medicines to help you sleep or calm you down
- other medicines for depression called SSRIs (e.g. fluoxetine)
- 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
- 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 use 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.

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.

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.

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.

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.

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 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.

If you feel at any time that life is no longer worth living, seek medical help at once.

People who are seriously depressed may think of suicide.

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 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 Tofranil.

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 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 condition seems similar to yours.

Things to be careful of

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.

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.

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 or those with Parkinson's disease. 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.
- 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
- tired feeling and mental dullness
- feeling of unrest or anxiety

- disturbed sleep or nightmares
- shakiness or trembling
- nausea (feeling sick), vomiting, loss of 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
- increased sensitivity to the sun
- ringing in the ears
- hair loss
- dental caries
- small purple red spots in the skin'
- An increased risk of bone fractures has been observed in patients taking this type of medicines
- taste disturbance

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)
- suicidal ideation
- stroke in evolution
- frequent passing of large amounts of urine
- yellow colour to the skin or eyes
- eye pain

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.

Overdose

If you think you or somebody else has taken too much Tofranil, immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) or go to Accident and Emergency Department 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.

If you take too much Tofranil, 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.

Storage

- Keep your tablets in the container until it is time to take them.
- Store the tablets in a cool dry place at room temperature.
- 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.

Keep the tablets where children cannot reach them.

A locked cupboard at least one-and-a-half 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.

Other ingredients

Tofranil tablets also contain:

- silica-colloidal anhydrous
- glycerol
- lactose
- magnesium stearate
- starch-maize
- stearic acid
- talc
- hypromellose
- cellulose-microcrystalline
- polyethylene glycol (macrogol)
- povidone
- sucrose
- titanium dioxide
- iron oxide red CI 77491
- carnauba wax

If you want to know more

Talk to your doctor or pharmacist. They will be able to answer any questions you may have.

Distributor

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