CONSUMER MEDICINES INFORMATION LEAFLET

MELIPRAMINE
Imipramine Hydrochloride
(Boucher & Muir Pty Ltd)

WHAT IS IN THIS LEAFLET

This leaflet provides important information regarding Melipramine.

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

Keep this leaflet with the medicine.
You may need to read it again. If you have further questions, please ask your doctor or your pharmacist.

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

WHAT MELIPRAMINE IS USED FOR

Melipramine 25 mg coated tablets contains imipramine hydrochloride. It is a drug acting on the central nervous system and belongs to a group of drugs known as tricyclic antidepressants (TCAs). TCAs are medicines that work by correcting the imbalance of certain chemicals in the brain. These chemicals, called amines, are involved in controlling mood. By correcting this imbalance, TCAs can help relieve the symptoms of depression.

Melipramine is used to treat:
1. depression that is more severe and/or longer lasting.
2. bed wetting in people older than 5 years if there is nothing wrong with their bladder.

There is not enough evidence to recommend the use of this medicine in children under the age of 5 years.

Ask your doctor if you have any questions why Melipramine has been prescribed for you.

Your doctor may have prescribed Melipramine for another reason.

Melipramine is only available with a doctor’s prescription.

BEFORE YOU TAKE MELIPRAMINE

The responsibility for your health rests not only on your physician and the health care system but also on yourself. Read the following carefully.

When you must not take it
Do not take Melipramine if you are allergic to:
- imipramine.
- any ingredient of the preparation listed at the end of this leaflet.
- to any other tricyclic antidepressant.
Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face or tongue, shortness of breath, and wheezing or difficult breathing.

Do not take Melipramine if you recently have had a heart attack.

Do not take Melipramine if you are using a monoamine oxidase inhibitor (MAOI) type mood enhancer or if you have been taking it within the last 2 weeks.
Taking Melipramine with a MOAI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions. Examples of MAOI type of drugs include phenelzine (Nardil), tranylcypromine (Parnate), moclobemide (Aurorix, Arima) and selegiline (Eldepryl, Selgene). Your doctor will know when it is safe to start Melipramine after the MAOI has been stopped.

Ask your doctor or pharmacist if you are unsure if you are taking, or have been taking, a MAOI.

Do not take Melipramine if the expiry date printed on the pack has been passed or the pack has been tampered in any way.

Before you start to take it

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

Tell your doctor if you have, or had, any of the following medical conditions:
- severe liver and/or kidney disease.
- heart problems, especially an irregular heartbeat.
- seizure or fits or epilepsy.
- lactose intolerance, since each coated tablet contains 116 mg of lactose, which should be taken into account in your diet.
- saccharose intolerance since it is contained as an ingredient in each tablet.
- other mental disorders in addition to depression.
- difficulty in passing urine.
- glaucoma (raised pressure in the eye).
- problems with blood pressure (high or low).
- tumour of the adrenal gland.
- thyroid problems.
- chronic constipation.
- Parkinson’s disease.
- blood disorder.
Tell your doctor if you are pregnant or intend to become pregnant.
This medicine may affect your baby 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.

Tell your doctor if you are breast-feeding or intend to breast-feed
The active ingredient in Melipramine passes into breast milk and can affect your baby.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed. You should also inform your doctor if you would start using any new drug (especially those acting on the central nervous system) during Melipramine therapy or within 1 month after stopping Melipramine. Examples of drugs that have an effect on the central nervous system include medicines for depression and other mental health problems, medicines to help you calm down or to sleep and medicines for epilepsy (fits).

Some medicines cannot be taken together with Melipramine as they may be affected by Melipramine or they may affect how well Melipramine works. In some cases, other medicines will need to be used instead or different amounts may be taken. If you are not sure whether you are taking any of the following medicines, please talk to your doctor or pharmacist.
- MAOI medicines. You must not take Melipramine together with a MAOI (see “When you must not take it”).
- selective serotonin reuptake inhibitors (SSRIs), a group of medicines used to treat depression, such as fluoxetine (Prozac), sertraline (Zoloft) and paroxetine (Aropax).
- medicines to treat other mental problems.
- medicines used to treat high blood pressure or heart problems.
- anticholinergic medicines, used to relieve stomach cramps, travel sickness, hayfever and allergies, coughs and colds.
- sleeping tablets and medicines to make you calm.
- medicines for epilepsy (fits).
- medicines for thyroid problems.
- disulfiram (Antabuse), a medicine used to deter alcohol consumption.
- cimetidine, a medicine for stomach ulcers.
- medicines for Parkinson’s disease.
- oestrogens, a common ingredient in birth control pills and hormone replacement therapy.
- methylphenidate (Ritalin).

If you have not told your doctor about any of the above, tell them before you start taking Melipramine.

HOW TO TAKE MELIPRAMINE

Follow all advice 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 pack, seek the assistance of your doctor or pharmacist.

**How much to take**

The dose varies from person to person. Your doctor will decide the right dose for you.

For depression, treatment is usually started at a low dose and increased depending on how your symptoms improve and how well you tolerate it. The usual starting dose is up to 75mg each day, being slowly increased to 150mg to 200mg each day over the first week. If your symptoms are very severe, up to 300mg per day may be prescribed. Depending on your response to treatment, your doctor may then reduce your dose to 50mg to 100mg each day.

If you are over 65 years of age, your doctor will start treatment at the lowest dose possible, namely 10mg once daily. The starting dose may slowly be increased usually to 25-50 mg daily within a period of 10 days and this dose should be kept until the end of the therapy.

For bed-wetting, the usual dose for children aged 5-8 years is 25 mg each day. For children aged 9-12 years, the dose is 25-50 mg each day and for children aged over 12 years, the dose is up to 75mg each day. The higher doses are only used if no satisfactory response is seen after one week of treatment with lower doses.

As there is no evidence for the safe use of Melipramine in children and adolescents (<18 years), the use of Melipramine is not recommended in this age group for the treatment of depression or other mental problems.

**When to take it**

For depression, Melipramine can be taken as a single dose (e.g. at bedtime) or as divided doses (e.g. three times each day). Your doctor will advise you.

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 occur during the early hours of the morning, your doctor may advise you to take two separate doses, one late in the afternoon (e.g. at 4pm) and the second, at bedtime.

Take your medicine at about the same time each day.

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

**How to take it**

Swallow the tablets whole with a glass of water.

**How long to take it**

Keep taking Melipramine for as long as your doctor recommends.

The length of treatment will depend on how quickly your symptoms improve.
It will take some time for this medicine to work so you may not feel better straight away. Some people may notice an improvement in their depressive symptoms after 1 to 2 weeks. However, it may take 2 to 4 weeks (possibly 6 to 8 weeks) before you start to see the full benefits of treatment.

Even if you start to feel better, your doctor may ask you to keep taking this medicine for several months to make sure that the benefits last.

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

If you forget to take it

If you take this medicine 2 or 3 times each day, and it is almost time for your next dose (e.g. within 2 or 3 hours), do not take the missed dose and take the next dose as usual. Otherwise, take the missed dose as soon as you remember, and continue the next dose as normal.

If you take your dose once each day at bedtime and miss a dose, do not take the missed dose until you have checked with the doctor. The medicine may cause some side-effects during the day if you take the dose in the morning.

Do not try to make up the dose you missed by taking a double dose.

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

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

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Melipramine.

Do this even if there are no signs of discomfort or poisoning.

If you take too much Melipramine, you may feel drowsy, restless and agitated, and may lose consciousness. You may have stiff or rigid muscles, fast or irregular heartbeat, difficulty in breathing, low blood pressure, fits, vomiting, fever, sweating and other symptoms.

Keep Melipramine out of reach and sight of children.
Children are much more sensitive than adults to medicines such as Melipramine. An accidental overdose is particularly dangerous in children.

Even in older people, it is a situation which must be managed with extreme urgency.

WHILE YOU ARE TAKING MELIPRAMINE
Things you must do

Tell your doctor if you are having any problems while taking Melipramine, and especially how you feel. This is very important, particularly if any of the following symptoms develop whilst taking Melipramine:

- thoughts about suicide or dying.
- attempts to commit suicide.
- new or worsening depression.
- new or worsening anxiety.
- feeling agitated or restless.
- panic attacks.
- difficulty sleeping.
- new or worsening 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. Talking to your doctor immediately will help him/her determine the best treatment for you.

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

Before starting any new medicine, tell your doctor or pharmacist that you are taking Melipramine.

Tell all the doctors, pharmacists and dentists who are treating you that you are taking Melipramine.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking or have been taking Melipramine within the last two weeks or so. Your doctor may ask you to stop taking this medicine before any surgery to avoid side effects.

Visit your doctor regularly so that they can check on your progress. This is necessary so that your doctor can monitor you closely to manage any side effects you may be experiencing or likely to experience as your treatment progresses.

Tell your doctor if you are wearing contact lenses as Melipramine can reduce tear production and make your eyes dry and sticky.

Tell your doctor or dentist if your mouth feels dry and this problem does not go away. This medication can cause your mouth to become dry and increase the chances of getting gum disease and cavities. Your can relieve dry mouth by frequent sipping of water, sucking sugar-free lollies or chewing sugar-free gums. Frequent visits to the dentist are strongly recommended.
Things you must not do

Do not stop taking Melipramine, or lower the dose, without checking with your doctor.
Do not let yourself run out of your medicine over weekends or during holidays.
It is very important that treatment with Melipramine is not stopped suddenly at any time as this will make you feel sick and cause other side effects such as headache, stomach pain, vomiting, restlessness and anxiety.

Do not drive or operate machinery until you know how Melipramine affects you.
This medicine may make you less alert, drowsy and dizzy. If you find that you are experiencing any of these symptoms, do not drive or operate machinery or do any other tasks that require you to be mentally alert as it increases the chances of you having an accident.

For the same reason, children should take care while doing activities like riding and climbing.

Do not use Melipramine to treat any other condition unless your doctor tells you to.

Do not share your medicine with any other person, even if they have a similar condition as you.

Things to be careful of

Be careful drinking alcohol or taking pain relievers, sleeping tablets and medicines for colds and flu while taking Melipramine.
This medicine can increase the drowsiness caused by alcohol and other medicines that have an effect on the central nervous system.

Be careful getting up from a sitting or lying position.
Dizziness, light-headedness or fainting may occur, especially when you get up quickly. Getting up slowly may help. When getting up from a lying position, it will be preferable to first sit on the edge of the bed before standing up.

Avoid exposure to direct sunlight while taking Melipramine until you find out how well you can tolerate it.
Melipramine can make you more sensitive to sunlight and increase the chances of suffering sunburn. You will need to wear protective clothing and sunscreen.

After stopping your treatment with Melipramine, you will still need to be careful for up to two weeks as some medicine may still be in your body.

SIDE EFFECTS

Tell your doctor as soon as possible if you are not feeling well while you are taking Melipramine.
Melipramine can help you but like all medicines, it may have unwanted side effects in some people. While most side effects may not be serious, there are some that can be serious enough to warrant medical attention.
If you are over 65 years old, you should be especially careful while on this treatment and report any side effects immediately to your doctor. Older people are likely to experience more side effects from medicines. Melipramine can cause confusion and disorientation in older people, especially those with Parkinson’s disease. Special care may be required.

Do not be alarmed by the list of these side effects. You may not experience any of them.

Refer any questions you may have to your doctor or pharmacist.

Tell your doctor if you notice any of the following and they worry you:
- dry mouth.
- nausea (feeling sick), vomiting.
- constipation.
- blurred vision or difficulty in focusing.
- drowsiness, tiredness and headache.
- dizziness and light-headedness, especially when treatment is started or the dose is increased.
- dry and sticky eyes if you wear contact lenses.
- increased sweating.
- weight gain.
- changes in sex drive.
- sores in the mouth or on tongue.
- restlessness, anxiety and disturbed sleep.
- increased sensitivity to the sun.
- larger breast than normal (in men and women).
- difficulty in urinating (passing water).
- shakiness or trembling.

Tell your doctor immediately or go to the Accident and Emergency at the nearest hospital if you notice any of the following:
- skin rash, itching, hives; swelling of the face or tongue; severe sunburn, blistering or swelling of the skin.
- constant “flu-like” symptoms (chills, fever, sore throat, aching joints, swollen glands, tiredness or lack of energy).
- fainting or collapse.
- seizures or fits.
- fast or irregular heartbeats.
- abnormal ideas, hallucinations.
- sudden changes in mood to one of excitement, overactivity and uninhibited behaviour.
- unusual bruising or bleeding.
- yellowing of the eyes or skin (jaundice).
- severe pain in the stomach or abdomen.
- tingling or numbness of the hands or feet.
- painful eyes.
• frequent passing of large volumes of urine.

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.

AFTER TAKING MELIPRAMINE

Storage

Keep Melipramine out of reach of children.
A locked cupboard at least one and half metres above the ground is a good place to store medicines.

Keep your tablets in a cool and dry place where the temperature stays below 25°C.

Do not store Melipramine or any other medicine in the bathroom or near a sink.

Do not leave Melipramine in the car or on window sills.

Disposal

If your doctor tells you to stop taking Melipramine, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

PRODUCT DESCRIPTION

What it looks like

Melipramine 25mg tablets are shiny, brown, bi-convex shaped, odourless or almost odourless coated tablets.

Ingredients

Each Melipramine tablet contains 25mg of imipramine hydrochloride as the active ingredient. It also contains the following inactive ingredients:

• glycerine
• titanium dioxide E171
• polyethylene glycol 25000
• cosmetic red brown E172
• gelatine
• magnesium stearate talc
• saccharose
• lactose

SPONSOR
Melipramine is supplied in Australia by:

BOUCHER & MUIR PTY LTD
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Crows Nest NSW 2065
Telephone: (02) 9431 6333

Australian Registration No: 10037

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