

LUDIOMIL[®]

25mg & 75mg Tablets

Maprotiline Hydrochloride

What is in this leaflet

This leaflet answers some common questions about Ludiomil.

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 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 Ludiomil is used for

Ludiomil helps to relieve the symptoms of depression such as anxiety, sadness, loss of interest, difficulty in performing everyday tasks, nervousness and feelings of failure or guilt. It also improves physical symptoms caused by depression such as lack of energy, fatigue, poor sleep, dizziness, headache, indigestion and pain.

Ludiomil belongs to a group of medicines called tetracyclic antidepressants. These medicines correct the chemical imbalance and help to relieve the physical and emotional symptoms of depression.

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

Your doctor may have prescribed it for another purpose.

Ludiomil is not recommended for use in children 12 years of age and under. Ludiomil 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 Ludiomil

When you must not take it

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

- maprotiline (the active ingredient in Ludiomil)
- any of the other ingredients listed at the end of this leaflet
- any other tetracyclic antidepressant

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

Do not take Ludiomil if you are taking another medicine to treat depression called a monoamine-oxidase inhibitor (MAOI) or you have been taking it recently (within the past 2 weeks).

Taking this medicine together with an 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 Ludiomil after the MAOI has been stopped.

Do not take Ludiomil for the treatment of bedwetting.

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

If you take Ludiomil, it may make your condition worse.

Do not take Ludiomil after the expiry date printed on the pack.

If you take it after the expiry date has passed, it may not work as well as it should.

Do not take Ludiomil 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 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 any of these health problems/medical conditions:

- heart problems, especially an irregular heart beat
- increased pressure in the eye (eg. glaucoma)
- difficulty in passing urine (water), often due to prostate trouble
- seizures (fits) from any cause
- severe liver or kidney disease
- a mental disorder other than the one being treated (eg. schizophrenia, mania)
- problems with blood pressure (high or low)
- a blood disorder
- thyroid problems
- chronic constipation
- excessive use of alcohol

Your doctor may want to take special precautions if you have any of these conditions.

Tell your doctor if you are pregnant or breastfeeding. Ask your doctor about the risks and benefits of taking Ludiomil in this case.

It 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.

Breastfeeding is not recommended while you are taking Ludiomil. The active ingredient passes into the breast milk and could affect your baby.

If you have not told your doctor about any of these things, tell him/her before you take Ludiomil.

Taking other medicines

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

Other medicines and Ludiomil may interfere with each other. These include:

- medicines for high blood pressure or heart problems
- medicines to help you sleep or calm you down
- other medicines for depression
- medicines for other mental disorders
- medicines for seizures (fits)
- medicines for asthma or allergies
- medicines for diabetes
- medicines for thyroid problems
- cimetidine, a medicine for stomach ulcers
- medicines for Parkinson's disease
- methylphenidate (Ritalin)
- excessive alcohol consumption
- medicines for thinning the blood

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 taking Ludiomil.

How to take Ludiomil

Follow the directions given to you by your doctor and pharmacist carefully.

These directions 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

Your doctor will decide on the most suitable dosage, depending on your age and severity of your symptoms.

The daily dose will normally be between 25 mg and 150 mg daily.

Ludiomil should be taken as directed by your doctor. Do not take more of it, do not take it more often, or for longer than your doctor ordered.

The lowest effective dose is recommended for elderly patients. The normally daily dose will be between 25mg and 75mg daily.

When to take it

The tablets are usually taken in 1 to 3 doses spread over the day depending on the severity of symptoms and the patient response.

How to take it

The coated tablets should be swallowed whole with sufficient liquid. Ludiomil must usually be taken for a few weeks before you begin to feel better.

Do not stop taking it without first consulting your doctor. Your doctor may want you to reduce the dosage gradually before stopping completely. This is to prevent a possible worsening of your condition and reduce the risk of withdrawal symptoms such as headache, nausea, and general discomfort.

How long to take it

Take this medicine until your doctor tells you to stop.

The length of treatment will depend on your condition and on how well the medicine works. You may need to take it for a long time.

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

If you forget to take it

If you forget to take a dose of Ludiomil, take the missed dose as soon as possible. Then go back to your regular dosage schedule.

If it is almost time for your next dose, do not take the missed dose, but go back to your regular dosage schedule. If you have any questions about this, check with your doctor.

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 National Poisons Information Centre, Dunedin (telephone number 0800 POISON or 0800 764 766), or go to the Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Ludiomil. Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

The following symptoms of overdose usually appear within a few hours: severe drowsiness; poor concentration; fast, slow or irregular heartbeat; restlessness and agitation; loss of muscle co-ordination and muscle stiffness; shortness of breath; fits; vomiting; fever.

While you are taking Ludiomil

Things you must do

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

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

Take Ludiomil exactly as your doctor has prescribed.

If you do not follow your doctor's instructions, your condition may not improve or you may have unwanted side effects.

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 Ludiomil or have taken it recently (eg. in 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.

Constant dryness of the mouth may increase the chance of gum disease or cavities. Dry mouth can be relieved by frequent sips of water, sucking sugarless lollies or chewing sugarless gum. Be sure to have regular dental checkups.

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.

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

It is wise to carry an identification card in your wallet or wear a medical alert tag showing that you are taking this medicine and giving the name and phone number of your doctor. These are helpful if you are ill or in an accident and cannot speak.

Things you must not do

Do not take any other medicines (even such things as nose drops) while you are taking Ludiomil without first telling your doctor.

If you take other medicines together with Ludiomil, they may cause unwanted effects.

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

Your body will become used to Ludiomil and you may get unwanted side effects if you suddenly stop taking it. To prevent this, your doctor may want to gradually reduce the amount you take each day before stopping the medicine completely.

Do not use Ludiomil to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else even if their symptoms seem to be 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 Ludiomil until you know how it affects you.

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

If this medicine makes you feel light headed, be careful when getting up from a sitting or lying position.

It can usually be prevented 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 when drinking alcohol while you are taking Ludiomil.

The combination could make you more sleepy, dizzy or light headed than usual.

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 Ludiomil, 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 Ludiomil.

It helps most people, but it may have unwanted side effects in a few people. All medicines 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. Ludiomil 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.
- light headedness, 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, diarrhoea
- poor appetite or weight loss
- 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

Tell your doctor immediately 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
- 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

These side effects could be serious. You may need urgent medical attention.

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

Other side effects not listed above may happen in some people.

After using Ludiomil

Storage

- Keep your tablets in the original container until it is time to take them.
- Store the tablets in a cool dry place (room temperature).
- Do not store Ludiomil or any other medicine in the bathroom or near a sink.
- Do not leave the tablets in the car or on window sills.

Heat and dampness can destroy some medicines. Ludiomil will keep well if it is cool and dry.

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 using this medicine or you find that it has passed the expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

What it looks like

Ludiomil 25 mg: round, grey/orange coloured, tablet, marked CG on one side and DP on the other; packs of 100 tablets.

Ludiomil 75 mg: round, brown/red coloured, marked with CG on one side and FS with score on the other; packs of 30 tablets

Ingredients

Ludiomil tablets contain 25 mg or 75 mg of maprotiline hydrochloride as the active ingredient. They also contain:

- silica-aerogel
- calcium phosphate
- lactose
- magnesium stearate
- stearic acid
- hydroxypropyl methylcellulose
- iron oxide yellow
- polysorbate 80
- titanium dioxide
- talc
- wheat starch
- iron oxide red

Sponsor

Ludiomil is supplied in New Zealand by:
AFT Pharmaceuticals Ltd
PO Box 33.203
Takapuna
AUCKLAND

Date of preparation: 8 August 2008