

Nardil®

Phenelzine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the more common questions about Nardil. It does not contain all of the available information.

Check with your doctor or pharmacist to see if you need special care when taking Nardil or if you need further information.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Nardil against the benefits Nardil will have for you.

What Nardil is used for

The name of your medicine is Nardil. It contains the active ingredient phenelzine.

Nardil is used for the treatment of major depression.

Nardil belongs to a group of medicines called Monoamine Oxidase Inhibitors (MAOI's). These medicines are thought to work by acting on brain chemicals called amines, which are involved in controlling mood.

Your doctor, however, may prescribe Nardil for another purpose.

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

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

Before you take Nardil

Do not take Nardil if:

- You have ever had an allergic reaction to Nardil, other Monoamine Oxidase Inhibitors or any of the ingredients listed at the end of this leaflet. Allergic symptoms may include difficulty breathing, closing of your throat, swelling of your lips, tongue or face; hives, headaches, dizziness, drowsiness, tremors, weakness, or muscle twitches.
- You have a history of liver disease.
- You are currently taking other antidepressants or have taken other antidepressants within the last ten days.

Do not give Nardil to children and adolescents under 18 years of age. The safety of Nardil in this age group has not been established.

Do not take Nardil after the expiry date (EXP) printed on the pack. If you take it after the expiry date has passed, it may not work as well.

Do not take Nardil if the packaging is torn or shows signs of tampering, or if the tablets do not look quite right.

Before you start to take it:

You must tell your doctor if:

- You are allergic to other medicines, foods, dyes, or preservatives.
- you have any other health problems including:
 - Heart disease
 - Tumours of the adrenal gland
 - Diabetes
 - Epilepsy
 - Liver disease

- You are pregnant or are intending to become pregnant.
- You are breastfeeding or wish to breastfeed.

How to take Nardil

Use Nardil exactly as your doctor has prescribed.

How much to take

The usual oral dose of Nardil is one tablet (15 mg) three times a day. Your dose may vary depending on your medical condition.

Your doctor will instruct you on how much Nardil to take each day and how long to take it.

You may have some water to help you swallow the tablet.

How long to take it

Most antidepressants take time to work, so do not be discouraged if you do not feel better straight away. It may take up to two weeks to feel the full benefit of Nardil. You may need to take Nardil for several months or longer.

Continue taking it until your doctor tells you to stop.

If you forget to take it.

Do not take an extra dose. Wait until the next day and take your normal dose then.

Do not try to make up for the dose you have missed by taking more than one dose at a time.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone in

Australia-13 11 26; telephone in New Zealand - 0800 POISON or 0800 764 766) for advice or go to Casualty at your nearest hospital, if you think that you or anyone else may have taken too much Nardil. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

Signs and symptoms of overdosage may include, alone or in combination, any of the following: drowsiness, dizziness, faintness, irritability, hyperactivity, agitation, severe headache, hallucinations, spasm of jaw or of whole body, rigidity, convulsions and coma, rapid and irregular pulse, hypertension, hypotension and vascular collapse, chest pain, respiratory depression and failure, facial blushing, excessive sweating and cool, clammy skin.

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

While you are using Nardil

Things you must do

Before you have any elective surgery or dental work requiring anaesthesia, tell your doctor or dentist that you are taking Nardil or have used it within the last ten days.

Tell your doctor or pharmacist that you are taking Nardil if you are about to be started on any new medicines.

Tell your doctor if you become pregnant while taking Nardil.

Talk to your doctor about what foods you should avoid. Nardil reacts with certain foods that contain the chemical Tyramine. The following foods and drinks may react with Nardil:

Meat and fish:

- Pickled herring,
- Liver,
- Dry sausage (including hard salami, peperoni)

Vegetables:

- Broad bean pods
- Sauerkraut

Dairy products:

- Cheese (cottage cheese and cream cheese are allowed)
- Avoid items made from cheese eg. spreads, cheesecake, pizza, mornay sauce
- Yoghurt

Beverages:

- Home-brewed beer,
- Red wine,
- Alcohol-free and reduced alcohol beer and wine products (white wine, spirits and commercial beers are allowed, however see warning under “Things to be careful of”).

Miscellaneous:

- Yeast extract (including brewer's yeast in large quantities and yeast spreads such as Vegemite and Marmite),
- Meat extract (eg. Bovril, meat stock cubes, packet soup),
- Excessive amounts of caffeine and chocolate,
- Any spoiled or improperly refrigerated, handled or stored protein-rich foods such as meats, fish and dairy products,
- Soy sauce,
- Foods that may have undergone protein changes by ageing, pickling, fermentation or smoking to improve flavour.

The above foods should be avoided for two weeks even after you stop taking Nardil. The reaction between Nardil and the above foods may cause sudden high blood pressure, which may be experienced as severe headache, nausea, vomiting or rapid heart beat. If you have a

reaction after eating one of these foods, call your doctor.

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.

If you are taking Nardil, you should report the occurrence of headaches or other unusual symptoms.

Things you must not do.

Do not stop taking Nardil or lower the dose, without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays. Suddenly stopping Nardil has been shown on rare occasions to cause nightmares, restlessness, convulsions or abnormal thoughts.

Do not give this medicine to somebody else, even if their symptoms seem similar to yours.

Do not use Nardil to treat other complaints unless your doctor says to.

Things to be careful of

Watch carefully for signs that your depression or anxiety is getting worse, especially in the first few weeks of treatment.

Tell your doctor immediately if you experience any of the following symptoms, especially if they are severe, you have not had these symptoms before or they happen very suddenly:

- Anxiety or agitation
- Panic attacks
- Difficulty sleeping
- Hostility or impulsiveness
- Restlessness
- Overactivity or uninhibited behaviour
- Thoughts of suicide

Tell your doctor immediately if you have any thoughts about suicide or doing harm to yourself.

Warning signs of suicide:

All thoughts or talk about suicide or violence are serious. The risk is increased in young adults aged 18-24 years, as improvement may not occur during the initial treatment period (usually one to two months), If you or someone you know is showing the following warning signs, either contact your doctor or a mental health advisor right away or go to the nearest hospital for treatment:

- **Thoughts or talk about death or suicide**
- **Thoughts or talk about self-harm or doing harm to others**
- **Any recent attempts of self-harm**

An increase in aggressive behaviour, irritability or agitation.

Warnings for use in pregnancy:

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.

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

There are certain prescription and over the counter medications that should not be taken when you are taking Nardil. The medications to Avoid:

- Cold and cough preparations (including those containing dextromethorphan)

- Nasal decongestants (tablets, drops or spray)
- Hay-fever medications
- Sinus medications
- Asthma inhalant medications
- Anti-appetite medicines
- Weight-reducing preparations
- "Pep" pills
- Tryptophan, tyrosine and phenylalanine-containing preparations

Tell your doctor if you are taking any of the following medications before starting Nardil:

- Medication for high blood pressure (anti-hypertensives)
- Diuretics
- Beta-blockers

If you are under the care of another physician or dentist, you should inform him/her that you are taking Nardil.

Be careful driving or operating machinery until you know how Nardil affects you. Nardil may cause drowsiness or sleepiness in some people, and affect alertness. Make sure you know how you react to Nardil before you drive or operate machinery.

Avoid or reduce the amount of alcohol that you drink. Do not drink more than two of the allowed standard drinks (spirits, white wine or commercial beers). Alcohol may make you more sleepy, dizzy and light-headed than usual.

Avoid large amounts of caffeine-containing foods or drinks such as chocolate, coffee, tea or cola. This may trigger a migraine-like reaction in some people taking Nardil.

You should wait at least ten days after stopping Nardil before starting another antidepressant from the MAOI group.

Older people may be more sensitive to Nardil. Families and

carers should be aware of this. Special care may be needed.

Side Effects

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

Nardil 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.

Tell your doctor if you notice any of the following and they worry you:

- Weakness and tiredness, drowsiness,
- Dizziness,
- Dizziness on standing,
- Nausea and vomiting,
- Dry mouth,
- Constipation,
- Sleep problems,
- Blurred vision,
- Shaking,
- Muscle spasm,
- Enhanced reflexes,
- Indigestion,
- Signs of liver damage such as yellow skin / eyes,
- Weight gain,
- Swelling with fluid,
- Problems with orgasm or ejaculation, and
- Headache.

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

- Unsteady walking,
- Severe mental confusion,
- Excitability and mental instability,
- Fits,
- Severe anxiety,
- Disordered thinking,
- Slowing of heart rate and breathing following

- electro-convulsive therapy (ECT),
- Signs of liver damage,
 - High temperature,
 - Slowed heart rate and breathing,
 - Muscle stiffness,
 - Loss of consciousness,
 - Lack of oxygen,
 - High temperature with muscle stiffness,
 - Swelling of the tongue,
 - Disease of the skin and mucous membrane.

These are all serious side effects. You may need urgent medical attention.

All of these side effects are very rare.

If any of the following happen, stop taking Nardil and tell your doctor immediately or go to casualty at your nearest hospital.

- Headache at the back of the head which spreads to the front,
- Irregular heart beat,
- Neck stiffness or soreness,
- Sick feeling,
- Vomiting,
- Sweating with high temperature,
- Enlarged pupils and sensitivity to light,
- Increased or decreased heart rate,
- Chest pain.

These are all very serious side effects involving blood pressure changes. You may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

Remember that a number of foods and drinks including alcohol may react with Nardil. Your doctor and your pharmacist will tell you which foods may trigger off adverse events with NARDIL.

This is not a complete list of all possible side effects. Others may occur in some people and there

may be some side effects not yet known.

Check with your doctor as soon as possible if you have any problems while taking Nardil even if you do not think the problems are connected with Nardil or are not listed in this leaflet.

After using Nardil

Storage

Keep Nardil where your children cannot reach it.

Store between 2°C to 8°C in a refrigerator, unless unavoidable for short periods.

Heat and dampness can destroy some medicines.

Keep your tablets in their container until it is time to take them. If you take the tablets out of the container, they may not keep as well.

Disposal

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

Further information

If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Product Description

What it looks like

- tablets (orange)

Ingredients

Active ingredient:

- 15 mg phenelzine (as phenelzine sulfate)

Inactive ingredients:

Mannitol, povidone, maize starch, magnesium stearate, coating (Opadry 20A25096 Red)

Nardil does not contain gluten, lactose, tartrazine or any other azo dyes.

Supplier

Nardil is supplied in Australia by:

Link Medical Products Pty Ltd
Unit 18, 6A Prosperity Parade,
Warriewood NSW 2102
Australia

Nardil is supplied in New Zealand by:

Link Pharmaceuticals Ltd
Level 20, ASB Bank Centre
135 Albert Street
AUCKLAND, New Zealand

Australian Registration Number:

Nardil - AUST R 93600

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