

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Nardil?

Nardil contains the active ingredient phenelzine. Nardil is used to treat major depression.

For more information, see Section [1. Why am I using Nardil?](#) in the full CMI.

2. What should I know before I use Nardil?

Do not use if you have ever had an allergic reaction to phenelzine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. Also talk to your doctor about what foods and drinks you should avoid whilst taking Nardil.

For more information, see Section [2. What should I know before I use Nardil?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Nardil and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Nardil?

- Your doctor will instruct you on how much Nardil to take and how long to take it.
- The usual starting oral dose of Nardil is one tablet (15 mg) three times a day.

More instructions can be found in Section [4. How do I use Nardil?](#) in the full CMI.

5. What should I know while using Nardil?

Things you should do	<ul style="list-style-type: none"> Remind any doctor, dentist or pharmacist you visit that you are using Nardil, in particular before you have any surgery or emergency treatment, are about to start a new medicine or become pregnant. Watch carefully for signs that your depression or anxiety is getting worse. Tell your doctor immediately if you have any thoughts about suicide or doing harm to yourself.
Things you should not do	<ul style="list-style-type: none"> Do not stop using this medicine suddenly or lower the dose.
Driving or using machines	<ul style="list-style-type: none"> Be careful driving or operating machinery until you know how Nardil affects you.
Drinking alcohol	<ul style="list-style-type: none"> Avoid alcohol while taking Nardil. Also avoid drinking large amounts of caffeine-containing foods or drinks such as chocolate, coffee, tea or cola.
Looking after your medicine	<ul style="list-style-type: none"> Store Nardil between 2°C to 8°C in a refrigerator, unless unavoidable for short periods. Keep your tablets in their container until it is time to take them.

For more information, see Section [5. What should I know while using Nardil?](#) in the full CMI.

6. Are there any side effects?

If any of the following happen, stop taking Nardil and tell your doctor immediately or go to Accident and Emergency 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.

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. Unsteady walking, severe mental confusion and lethargy, coma, disordered thinking, excitability and mental instability, mistaken belief of being infested by parasites, fits, severe anxiety, episodes of delusions and hallucinations, uncontrollable muscle contractions, tingling and/or numbness of the hands or feet, involuntary inability to speak, slowing of the heart rate and breathing following electroconvulsive therapy (ECT), neuroleptic malignant syndrome, signs of liver damage (such as yellow skin/eyes), abnormality of the blood cells causing bleeding problems, weakness, pale skin colour or frequent infections, a disease affecting the immune system with flu-like symptoms and/or rash, an increase in water and a decrease in salt in the blood which may cause drowsiness, confusion or fits, increased metabolism, swollen glottis which is at the top of the wind pipe or a high temperature with muscle stiffness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Nardil. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Nardil.**

Where to find information in this leaflet:

1. [Why am I using Nardil?](#)
2. [What should I know before I use Nardil?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Nardil?](#)
5. [What should I know while using Nardil?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Nardil?

Nardil contains the active ingredient phenelzine.

Nardil belongs to a group of medicines called Monoamine Oxidase Inhibitors (MAOIs), which is a type of medicine used to treat depression. Antidepressants are thought to work by acting on brain chemicals called amines, which are involved in controlling mood.

Nardil is used to treat major depression.

Depression is longer lasting and/or more severe than the "low moods" 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, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing.

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.

2. What should I know before I use Nardil?

Warnings

Do not use Nardil if:

- you are allergic to phenelzine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. 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 are taking guanethidine (a medicine for controlling blood pressure).
- you have heart disease or heart failure.
- you have a disease affecting blood flow to your brain, such as stroke.
- you have a growth on the adrenal glands near your kidneys which is causing high blood pressure (phaeochromocytoma.)
- you are planning to undergo elective surgery requiring general anaesthesia, cocaine or certain local anaesthesia.
- you have a history of liver disease or abnormal liver function tests.
- you are in the manic phase of bipolar disorder.
- you are currently taking other antidepressants or have taken other antidepressants within the last ten days. Taking Nardil with other antidepressants may cause serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions. **Ask your doctor or pharmacist if you are not sure if you have been taking one of these medicines.**

Check with your doctor if you:

- are allergic to any other medicines, foods, dyes, or preservatives.
- have or have had any other health problems including:
 - heart disease
 - tumours of the adrenal gland
 - diabetes
 - epilepsy
 - liver disease
- are under 18 years of age. The safety of Nardil in children and adolescents has not been established.
- are elderly. Older people may be more sensitive to Nardil. Families and carers should be aware of this. Special care may be needed.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

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

Some medicines may interfere with Nardil and affect how it works.

There are certain medicines that should not be taken when you are taking Nardil.

The medicines to avoid are:

- 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:

- Other antidepressants
- Medication for high blood pressure and/or heart rate (anti-hypertensives or beta-blockers)
- Fluid tablets (diuretics)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Nardil.

4. How do I use Nardil?

How much to take / use

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

When to take / use Nardil

- Nardil should be used exactly as your doctor has prescribed. The directions from your doctor may differ from the information contained in this leaflet.
- Your doctor will instruct you on how much Nardil to take each day and how long to take it.
- If you do not understand the instructions, ask your doctor or pharmacist for help.

How to take Nardil

- Swallow Nardil with a glass of water.

How long to take Nardil for

- Most antidepressants take time to work, so do not be discouraged if you do not feel better straight away. It may take up to four weeks to feel the full benefit of

Nardil. You may need to take Nardil for several months or longer.

- Do not stop taking Nardil unless instructed by your doctor.

If you forget to take Nardil

Nardil should be taken regularly at the same time each day. If you miss your dose at the usual time, do not take an extra dose. Wait until the next dose and take your normal dose then.

Do not take a double dose to make up for the dose you missed.

If you take too much Nardil

If you think that you have taken too much Nardil, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre
(by calling Australia - 13 11 26;
New Zealand – 0800 POISON or 0800 764766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you take too much Nardil you may feel: drowsiness, dizziness, faintness, irritability, hyperactivity, agitation, severe headache, hallucinations, spasm of jaw resulting in reduced opening of the jaw, rigidity, whole body spasms and body arching, convulsions and coma, rapid and irregular pulse, high blood pressure, low blood pressure and vascular collapse, chest pain, breathing difficulties and failure, fever, excessive sweating, and cool, clammy skin.

5. What should I know while using Nardil?

Things you must do

Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking Nardil or have used it within the last ten days.

Carry an alert card or wear an SOS bracelet which tells the doctor you are taking Nardil. These are helpful if you are in an accident and cannot talk.

If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking Nardil.

Tell your doctor if you become pregnant while taking Nardil.

Talk to your doctor about what foods and drinks you should avoid. See "Food and drink".

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that your currently prescribed dose is not working as expected and change your treatment unnecessarily.

Be sure to keep all of your appointments with your doctor 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 prevent unwanted side effects.

Things to be careful of

Watch carefully for signs that your depression or anxiety is getting worse, especially in the first one to two months of treatment or when there is a change in dose. Tell your doctor immediately if you have any thoughts about suicide or doing harm to yourself.

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 during the initial treatment period (usually one to two months) and at the time of dose changes.

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.

Food and drink

Nardil reacts with alcohol and certain foods and drinks that contain the chemical Tyramine.

The following foods and beverages may react with Nardil:

Meat and fish:

- Pickled herring
- Liver
- Dry sausage (including salami, pepperoni and Lebanon bologna)

Vegetables:

- Broad bean pods
- Sauerkraut

Dairy products:

- Cheese (cottage cheese and cream cheese are allowed)
- Yoghurt

Beverages:

- Beer
- Red wine
- Alcohol-free and reduced alcohol beer and wine products (white wine, spirits and commercial beers are allowed, however see warning under "Drinking alcohol").

Miscellaneous:

- Yeast extract (including brewer's yeast in large quantities and yeast spreads such as Vegemite and Marmite)
- Meat extract (e.g. 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 list of foods and beverages should be avoided while taking Nardil, and for two weeks after discontinuing Nardil therapy.

Consuming foods and beverages outlined in this list may cause a severe increase in blood pressure. Symptoms include a headache, rapid heartbeat, nausea or vomiting. If you took a small amount of one of these foods one time, without a reaction, it does not mean you will not have a reaction the next time.

Call your doctor straight away if you:

- have a reaction after consuming one of these foods or beverages.
- have a headache or other unusual symptoms.

Remind any doctor, dentist or pharmacist you visit that you are using Nardil.

Things you should 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. You should wait at least ten days after stopping Nardil before starting another antidepressant from the MAOI group.
- Do not give this medicine to somebody else, even if their symptoms seem similar to yours or if they have the same condition as you.
- Do not use Nardil to treat other complaints unless your doctor says to.

Driving or using machines

Be careful before you drive or use any machines or tools 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 a car or operate machinery, or do anything else that could be dangerous if you are

drowsy, dizzy or not alert.

Drinking alcohol

Tell your doctor if you drink alcohol.

Avoid alcohol while taking Nardil.

Alcohol interacts with Nardil. Alcohol may also make you more sleepy, dizzy and light-headed than usual.

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Nervous system related: <ul style="list-style-type: none">• Dizziness• Drowsiness and excessive sleeping• Headache• Difficulty sleeping• Fatigue• Weakness• Involuntary movements including tremors, twitching, muscle spasms and enhanced reflexes Gut and digestion related: <ul style="list-style-type: none">• Constipation• Dry mouth• Nausea or feeling sick• Vomiting• Changes in the blood related to liver problems which may be detected in a blood test	Speak to your doctor if you have any of these less serious side effects and they worry you.

Metabolism related: <ul style="list-style-type: none">• Weight gain Heart related: <ul style="list-style-type: none">• Dizziness on standing• Fluid retention/swollen ankles Reproductive system related: <ul style="list-style-type: none">• Sexual disturbances (difficulty in achieving an orgasm or ejaculating) Special senses (sight) related: <ul style="list-style-type: none">• Blurred vision	
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Serious side effects

Serious side effects	What to do
Nervous system related: <ul style="list-style-type: none">• Unsteady walking• Severe mental confusion and lethargy, coma• Disordered thinking• Excitability and mental instability• Mistaken belief of being infested by parasites• Fits• Severe anxiety• Episodes of delusions and hallucinations• Uncontrollable muscle contractions• Tingling and/or numbness of the hands or feet• Involuntary inability to speak• Slowing of the heart rate and breathing following electroconvulsive therapy (ECT)• Neuroleptic malignant syndrome. Symptoms include high fever, sweating, unstable blood pressure, reduced consciousness, muscle stiffness and reduced automatic bodily functions. Gut and digestion related: <ul style="list-style-type: none">• Signs of liver damage, such as yellow skin/eyes Blood related: <ul style="list-style-type: none">• Abnormality of the blood cells causing bleeding problems, weakness, pale skin colour or frequent infections Immune system related: <ul style="list-style-type: none">• A disease affecting the immune system with flu-like symptoms and/or rash Metabolism related: <ul style="list-style-type: none">• An increase in water and a decrease in salt in the blood which may cause drowsiness, confusion or fits	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

<ul style="list-style-type: none"> Increased metabolism Breathing related: <ul style="list-style-type: none"> Swollen glottis which is at the top of the wind pipe Other: <ul style="list-style-type: none"> High temperature with muscle stiffness 	
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Very serious side effects

Very serious side effects	What to do
Signs of a sudden life-threatening reaction: <ul style="list-style-type: none"> 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 	<p>If any of the following happen, stop taking Nardil and tell your doctor immediately or go to Accident and Emergency at your nearest hospital.</p> <p>These are all very serious side effects involving blood pressure changes. You may need urgent medical attention or hospitalisation.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Nardil contains

Active ingredient (main ingredient)	15 mg phenelzine (as phenelzine sulfate)
Other ingredients (inactive ingredients)	Mannitol, povidone, maize, starch, magnesium stearate, coating (OPADRY AMB II High Performance Moisture Barrier Film Coating 88A250030 Orange)
Potential allergens	Nil

Do not take this medicine if you are allergic to any of these ingredients.

What Nardil looks like

Nardil is an orange, film coated biconvex tablet with round edges (AUST R 462329).

Who distributes Nardil

Nardil is supplied in Australia by:

Neon Healthcare Pty Ltd.
Level 10
171 Clarence Street
Sydney NSW 2000

Nardil is supplied in New Zealand by:

Neon Healthcare Ltd.
Monteck Carter, Level 1
Building 5, 15 Accent Drive
East Tamaki, Auckland, 2013

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