

Nardil®

Phenelzine

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you take Nardil.

This leaflet answers some common questions about Nardil. 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 Nardil 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 Nardil is used for

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

Nardil is used to treat major depression. There are many different types of medicines used to treat depression. Nardil belongs to a group of medicines called Monoamine Oxidase Inhibitors (MAOIs).

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.

Antidepressants 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

When you must not take it

Do not take Nardil if:

- You have an allergy to phenelzine, 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.
- If you are taking guanethidine (a medicine for controlling blood pressure)
- If 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 a 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.

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.

It may have no effect at all, or an entirely unexpected effect if you take it after the expiry date.

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

If you are not sure whether you should start taking Nardil, contact your doctor.

Before you start to take it:

You must tell your doctor if:

- You are allergic to any other medicines, foods, dyes, or preservatives.
- You have or have had 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.

Your doctor will discuss the risks and benefits of using Nardil when pregnant.

You are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of using Nardil when breastfeeding.

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

How to take Nardil

Use Nardil exactly as your doctor has prescribed.

The directions from your doctor may differ from the information contained in this leaflet.

How much to take

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.

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

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

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it

Swallow Nardil with a glass of water.

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 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 it.

Do not take an extra dose. Wait until the next dose 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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia – 13 11 26; New Zealand – 0800 POISON or 0800 764 766) for advice or go to Accident and Emergency 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.

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.

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 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.

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

Tell your doctor if you become pregnant while taking Nardil.

Talk to your doctor about what foods you should avoid.

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)

Vegetables:

- Broad bean pods
- Sauerkraut

Dairy products:

- Cheese (cottage cheese and cream cheese are allowed)
- Avoid items made from cheese eg. spreads, pizza, mornay sauce
- 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 “**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 (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 heart beat, nausea or vomiting.

If you have a reaction after consuming one of these foods or beverages, call your doctor or go to Accident and Emergency at your nearest hospital.

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.

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.

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 or if they have the same condition as you.

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 one to two months of treatment or when there is a change in dose.

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.

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 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:

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

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 a car or operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Avoid alcohol while taking Nardil.

Alcohol interacts with Nardil. Alcohol may also 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:

- Dizziness
- Dizziness on standing
- Drowsiness and excessive sleeping
- Headache
- Difficulty sleeping
- Blurred vision
- Fatigue
- Weakness
- Constipation
- Dry mouth
- Nausea or feeling sick
- Vomiting
- Involuntary movements including tremors, twitching, muscle spasms and enhanced reflexes
- Sexual disturbances (difficulty in achieving an orgasm or ejaculating)
- Fluid retention/swollen ankles
- Weight gain
- Changes in the blood related to liver problems which may be detected in a blood test

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

- 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.
- 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
- High temperature with muscle stiffness

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

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

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 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.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Nardil

Storage

Keep Nardil where 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.

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
5 Apollo Street,
Warriewood NSW 2102
Australia

Nardil is supplied in New Zealand by:

Link Pharmaceuticals Ltd
Level 31, Vero Centre
48 Shortland Street
Auckland, 1140
New Zealand

Australian Registration Number:

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