

PARNATE® TABLETS

(Tranlycypromine 10 mg)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about Parnate. 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 Parnate 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 PARNATE IS USED FOR

Parnate is used to treat symptoms of depression, especially if treatment with other types of antidepressants has failed. There are many different types of medicines used to treat depression. Parnate belongs to a group of medicines called monoamine oxidase inhibitor (MAOI) antidepressants. It contains the active ingredient tranlycypromine.

Depression is longer lasting or more severe than the 'low moods' that everyone has from time to time. It is thought to be caused by a chemical imbalance in parts of the brain. The imbalance affects your whole body and can cause emotional and physical symptoms. You may feel low in spirit, lose interest in usual activities, be unable to enjoy life, have poor appetite or overeat, have disturbed sleep, often waking up early, low energy and feel guilty over nothing.

Parnate corrects the chemical imbalance and helps relieve the symptoms of depression. It is not recommended for the 'low moods' that everyone has from time to time due to the stress or sadness of everyday life.

Your doctor may have prescribed Parnate for another use.

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

Parnate is available only with a doctor's prescription.

BEFORE YOU TAKE PARNATE

When you must not take it

Do not take Parnate if you have an allergy to:

- Parnate or any other medicine containing tranlycypromine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Parnate if you have taken it or any other MAOI medication (e.g. phenelzine, moclobemide, furazolidone, iproniazid, isocarboxazid, nialamide, pargyline, procarbazine hydrochloride) before and became unwell (you may experience changes

in blood pressure and fits). Tell your doctor or pharmacist before taking the first dose.

Do not take Parnate and talk to your doctor if you have taken any other medicines for the treatment of depression or anxiety within the last 5 weeks and have not discussed this with your doctor.

This includes:

- Selective Serotonin Reuptake Inhibitors (SSRIs), e.g. fluoxetine, paroxetine, sertraline
- Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs), e.g. venlafaxine
- tricyclic antidepressants, e.g. clomipramine, imipramine, amitriptyline, desipramine, dosulepin (dothiepin), nortriptyline, trimipramine or doxepin
- buspirone hydrochloride

You may experience symptoms of Serotonin Syndrome if Parnate is taken with other antidepressant drugs (e.g. MAOI, SSRIs, SNRIs and tricyclic antidepressants). Symptoms of serotonin syndrome may include confusion, extreme agitation, mood changes, diarrhoea, stiffness, increased body temperature, sweating, changes in blood pressures, nausea, vomiting, involuntary muscle jerk, involuntary shaking or movement in one or more parts of body, difficult movement coordination, disturbances in mental abilities and coma.

You may also experience a condition called neuroleptic malignant syndrome (muscles become stiff and the body no longer moves smoothly), elevated body temperature, fluctuations of vital signs (blood pressure, heart rate and breathing rate) and mental state from extreme agitation progressing to confusion and coma).

Do not take Parnate and talk to your doctor if:

- you are taking, or being treated with, any of the following:
 - appetite suppressants such as fenfluramine, dexfenfluramine, phentermine (e.g. Duromine), mazindol or diethylpropion for weight loss
 - amphetamines, phenylpropanolamine or other central nervous system stimulants
 - cold or hayfever medicines, including nose drops or sprays
 - dextromethorphan, contained in many cough and cold medicines you can buy without a prescription
 - methyl dopa, dopamine, ephedrine or any other medicine that affects blood pressure
 - strong pain killers, e.g. opioid analgesics, codeine, nefopam
 - levodopa (e.g. Madopar or Sinemet) for Parkinson's disease
 - carbamazepine, used to treat epilepsy, nerve pain, mania or bipolar disease
 - bupropion, used to help stop smoking
 - tryptophan, a dietary supplement to treat depression or anxiety or help you sleep
- you have or have had any of these medical conditions:
 - a stroke, poor blood flow to the brain, or frequent headaches
 - heart disease or high blood pressure

- liver disease
- hyperthyroidism (overactive thyroid gland)
- blood or bone marrow disorder
- porphyria, a rare blood pigment disorder
- pheochromocytoma, an adrenaline (epinephrine) producing tumour of the adrenal gland

- you are over 60 years of age.

Do not give Parnate to children and adolescents under 18 years of age.

The safety of Parnate in this age group has not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not give this medicine to anyone else.

Your doctor has prescribed it specifically for you and your condition.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- diabetes
- epilepsy (condition where you have repeated fits or convulsions)
- angina (chest pain)
- kidney problems
- addiction to drugs or alcohol
- angle-closure glaucoma (sudden rise in intra-ocular pressure)
- sugar intolerance.

Tell your doctor as soon as possible if you are planning to have any type of surgery.

Parnate may interfere with some medicines used during surgery.

Tell your doctor if you are pregnant or plan to become pregnant.

Parnate should not be used in pregnancy unless considered essential by doctor. Your doctor will discuss the risks and benefits of using Parnate if you are pregnant. If you take this medicine during the last three months of your pregnancy, the general condition of your newborn baby might be affected and baby may experience drug withdrawal symptoms such as difficulty in breathing, tiredness, unsettled crying and irritability, changes in blood pressure, fits (convulsions) and involuntary muscle jerk. Increased risk of congenital abnormalities and preterm birth has been observed with the use of this medicine.

Tell your doctor if you are breastfeeding or planning to breastfeed.

Your doctor will discuss the risks and benefits involved. It is not recommended that you breastfeed while taking Parnate as it passes into breast milk.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any

that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Parnate may interfere with each other.

Tell your doctor or pharmacist if you are taking any of the following:

- any medicine listed under 'When you must not take it'
- guanethidine, reserpine or any other medicine that affects blood pressure
- sedatives, medicines to help you sleep, reduce anxiety or induce anaesthesia
- anticholinergic medicines, e.g. atropine, which are used to treat a range of medical conditions
- medicines used to treat Parkinson's Disease
- medicines used to treat diabetes
- medicines used to treat epilepsy
- anticoagulants, used to treat blood clotting disorders
- antihistamines, used to treat allergies
- metrizamide, a contrast medium used in medical imaging.

These medicines may be affected by Parnate or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Parnate.

HOW TO TAKE PARNATE

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

They may differ from the information contained in this leaflet.

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

How much to take

The usual dose of Parnate is one 10 mg tablet taken twice a day.

How to take it

Swallow Parnate tablet(s) whole with a full glass of water or another liquid. Do not chew the tablets.

When to take it

Parnate tablets are usually taken in the morning and at midday. Take the last dose of the day not later than 3 pm. This will help avoid sleep disturbances.

How long to take it

For depression, the length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to work, so do not be discouraged if you do not feel better right away. Some of your symptoms may improve in 1 or 2 weeks, but it can take up to 4 or 6 weeks to feel any real improvement. Even when you feel well, you will usually have to take Parnate for several months or longer. Continue taking Parnate until the doctor tells you to stop.

If you forget to take it

Do not take a double dose to make up for the dose that you missed. Wait until the next dose and take your normal dose then.

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

time. This may increase the chance of you getting an unwanted side effect.

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 the Accident and Emergency Department at your nearest hospital, if you think that you or anyone else may have taken too much Parnate.

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

You may need urgent medical attention.

Symptoms of an overdose commonly include fast heartbeat, sweating, fever, restlessness and excitement. Tremors, depression, stupor or coma may also be present or develop. Blood pressure may increase but it also could drop lower than normal.

WHILE YOU ARE USING PARNATE

Things you must do

If you are about to be started on any new medicine, remind your doctor, pharmacist or dentist that you are taking Parnate or if you were taking it and stopped less than two weeks ago.

This applies to medicines that you buy without a prescription as well as prescription medicines.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery or emergency treatment, tell your doctor or dentist that you are taking Parnate or have used it in the last two weeks.

It may affect other medicines used during surgery.

Carry an alert card or wear an SOS bracelet, which tells the doctor, dentist or pharmacist you are taking Parnate.

These are helpful if you are in an accident and cannot talk.

You must avoid certain foods and drinks during treatment with Parnate and for at least a week after stopping therapy.

Avoid protein foods that have been aged or fermented to improve flavour. Also avoid any foods that have caused you unpleasant reactions previously.

While taking Parnate, you should avoid:

- matured cheese
- meat, fish, poultry, pate or yoghurt that is stale or smells "off"
- protein extracts such as Marmite, Vegemite, Bonox, Bovril, Promite
- pods of broad beans, sauerkraut
- smoked or pickled fish
- sour cream
- soy bean products, e.g. soy sauce, miso, tofu
- avocados
- yeast extracts
- banana skins
- red wines such as Chianti
- home brewed beers or liqueurs.

Parnate reacts with a chemical found in these foods. This reaction may cause sudden high blood pressure which may be experienced as severe headache, stiff or sore neck, nausea,

vomiting, fast or slow heartbeat, changes in vision, or sweating with initial paleness then sometimes followed by flushing of the skin.

Avoid large amounts of caffeine-containing foods or drinks such as chocolate, coffee, tea or cola during treatment with Parnate and for at least a week after ceasing therapy.

These may trigger off a migraine-like headache in some people taking Parnate.

Things you must not do

Do not take Parnate to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dose without checking with your doctor.

Some people may suffer symptoms such as dizziness or anxiety if Parnate is stopped suddenly. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

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
- overactive or uninhibited behaviour
- thoughts of suicide.

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

All thoughts or talk about suicide or violence are serious. The risk is increased in young adults aged 18 - 24 years. 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
- increase in aggressive behaviour, irritability or agitation.

Be careful driving or operating machinery until you know how Parnate affects you.

Parnate may cause drowsiness, dizziness or light-headedness in some people. Make sure you know how you react to Parnate before you drive a car or operate machinery.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, drowsiness, dizziness or light-headedness may be worse.

SIDE EFFECTS

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

This medicine 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 attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- rash
- dizziness or blurred vision
- drowsiness, weakness or fatigue
- feeling numbness or pins and needles
- difficulty sleeping
- chills, tremors
- nervousness
- dry mouth
- nausea, vomiting
- constipation, diarrhoea
- stomach pain, loss of appetite
- ringing in the ears
- swelling in ankles or limbs
- excess sweating
- sexual problems.

Tell your doctor immediately if you notice any of the following:

- thoughts of suicide
- severe dizziness or fainting on standing
- fever
- unusual bleeding or bruising
- reduction in some blood cells
- yellowing of the skin and eyes (jaundice)
- agitation, confusion or nervousness
- muscle spasms or twitches
- difficulty passing urine or unable to empty urine from bladder.

The above list includes serious side effects that may require medical attention.

Stop taking Parnate and contact your doctor or go to the Emergency Department of your nearest hospital if any of the following happens:

- serious allergic reaction (swelling of the face, lips, mouth or throat which may cause difficulty swallowing or breathing)
- chest palpitations, fast heartbeat or frequent headaches
- headache which may start at the back of the head and radiate forward, accompanied by chest pain, palpitations, neck stiffness or soreness, nausea, vomiting, either fast or slow heartbeat, sweating, with initial paleness sometimes followed by flushing of the skin, enlarged pupils and light sensitivity.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Some side effects (for example, changes in liver function or blood) can only be found when your doctor does tests from time to time to check your progress.

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

Other side effects not listed above may also occur in some people.

AFTER USING PARNATE

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep the pack in a cool dry place where the temperature stays at or below 25°C.

Do not store Parnate in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep Parnate where children cannot reach it.

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 taking Parnate or the expiry date has passed, ask your pharmacist what to do with any tablets that are left over.

PRODUCT DESCRIPTION

What it looks like

Parnate tablets are red, round, biconvex film coated tablets. Each Parnate tablet contains 10 mg of tranlycypromine (as sulfate).

Parnate comes in packs of 50 tablets.

Ingredients

Parnate contains 10 mg of tranlycypromine as the active ingredient. It also contains:

- calcium sulfate dihydrate
- maize starch
- sucrose
- magnesium stearate
- gelatin
- erythrosine aluminium lake
- Opadry complete film coating system 06H250000 Red PI (106298)
- carnauba wax.

Parnate tablets do not contain lactose, gluten or tartrazine.

Sponsor

Distributed in Australia by:

Amdipharm Mercury (Australia) Pty Ltd
Level 9, 76 Berry Street
North Sydney NSW 2060

Australian registration number: AUST R 174086

Distributed in New Zealand by:

Boucher & Muir (NZ) Ltd t/a Mercury
Pharma (NZ)
39 Anzac Road
Browns Bay
Auckland 0753

This leaflet was revised on 12 December 2022.

Amdipharm Mercury (Australia) Pty Ltd is licensed to use the trademark Parnate.