PARNATE TABLETS

(Tranylcypromine 10 mg)

Consumer Medicine Information

WHAT IS 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. Please read this leaflet before you start taking PARNATE. If you are helping someone else take PARNATE, please read this leaflet before you give the first dose.

All medicines have risks and benefits. Your doctor has weighed the possible risks of taking PARNATE against the expected benefits. Keep this leaflet with the medicine. You may want to read it again.

WHAT PARNATE IS USED FOR

The name of your medicine is PARNATE also known as tranylcypromine.

There are many different types of medicines used to treat depression. PARNATE belongs to a group of medicines called monoamine oxidase inhibitor (MAOI) antidepressants. Depression is longer lasting or more severe than the 'low moods' that every one 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, loss 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 so helps relieve the symptoms of depression. Your doctor may have prescribed PARNATE for another use. Ask your doctor if you have questions about why PARNATE has been prescribed for you.

BEFORE YOU START TAKING PARNATE TELL YOUR DOCTOR IF:

- You have had an allergic reaction to any medicine which you have taken previously to treat your current condition.
- You are pregnant or intend to become pregnant. Your doctor will discuss with you the possible risks and benefits of using PARNATE during breastfeeding.
- You have any of these medical conditions: - Diabetes - Epilepsy - Overactive thyroid gland - Angina or other heart problems - Kidney problems - You are planning to have any type of surgery

TAKING OTHER MEDICINES WITH PARNATE

Tell your doctor if you are taking any other medicines or have used other medicines until recently. This includes those that you buy without a prescription. In particular tell your doctor if you are taking any of the following medicines:

- Appetite suppressants fenfluramine (Ponderas Pacaps), dexfenfluramine (Adifax) phenteramine(Duromine), mazindol (Sanorex) or diethylpropion (Tenuate, Tenuate Dospan) for weight loss - Cold or hay fever medicines (including nose drops or sprays) - Cough suppressants e.g. Dextromethorphan - Blood pressure medicines - Strong pain killers eg Pethidine, Codeine - Levodopa (Madopar or Sinemet) for Parkinsons disease - Tryptophan

Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you which medicines are safe to take with PARNATE.

HOW TO TAKE PARNATE

Follow your doctor's instructions about how and when to take PARNATE.

Read the directions carefully, if you have any concerns about how to take PARNATE, talk to your doctor or pharmacist.

HOW MUCH TO TAKE

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

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 even longer to make sure the benefits will last. Continue taking PARNATE until the doctor tells you to stop.

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 that you missed by taking more than one dose at a time.

OVERDOSAGE

Immediately telephone your doctor or 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 Emergency Department at your nearest hospital, if you think that you or any one 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.

The most important reaction associated with PARNATE overdose is the occurrence of hypertensive crises, which are characterised by some or all of the following symptoms:

- Strong pain killers eg Pethidine, Codeine - Barbiturates eg amylobarbitone (Amytal, Neur-Amyl), butobarbitone (Soneryl), methyphenobarbitone (Prominal), pentobarbitone, phenobarbitone - Levodopa (Madopar or Sinemet) for Parkinsons disease - Tryptophan

PARNATE overdose is the occurrence of hypertensive crises, which are characterised by some or all of the following symptoms:

- Headache - Heart rate increase - Hypertension - Nausea - Convulsions - Tachypnoea - Non dreaming sleep

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THINGS TO BE CAREFUL OF

THINGS YOU MUST DO:

- Certain foods and drinks must be avoided during treatment with PARNATE and for two weeks after ceasing therapy.

PARNATE reacts with a chemical found in a variety of foods. This reaction may cause sudden high blood pressure which may be experienced as severe headache, nausea, vomiting or rapid heartbeat.

Avoid protein foods that have been aged or fermented to improve flavour. Avoid any foods that have caused you unpleasant reactions previously. Food and drink to be avoided while taking PARNATE include:
- Matured cheese
- Meat, fish, poultry, pate or yogurt that are stale or smell "off"
- Pots of beans, sauerkraut
- Smoked or pickled fish
- Sour cream
- Soy bean products eg soy sauce, miso, tofu
- Avocado
- Yeast extracts
- Banana skins
- Red wines such as chianti
- Home brewed beers or liqueurs

Check with your doctor, pharmacist or dentist before taking any other medicines. This applies to medicines that you buy without a prescription as well as prescribed medicines.

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. 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

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. Avoid large amounts of caffeine-containing foods or drinks such as chocolate, coffee, tea or cola. These may trigger off a migraine-like headache in some people taking PARNATE.

When your doctor decides that you should stop taking PARNATE they may decide to reduce your dose or the interval of your dose over 1 to 2 weeks. Some people may suffer symptoms such as dizziness or anxiety if PARNATE is stopped suddenly. Avoid or reduce the amount of alcohol you drink. Do not drink more than two of the allowed standard alcoholic drinks (spirits, white wine or commercial beers). Alcohol may make you more sleepy, dizzy and light-headed than usual.

After you stop taking PARNATE you must continue to follow the restrictions regarding food, alcohol and other medications for two weeks.

Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking PARNATE or have used it in the last two weeks. Carry an alert card or wear an SOS bracelet, which tells the doctor you are taking PARNATE. These are helpful if you are in an accident and cannot talk.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PARNATE. Like other medicines, PARNATE can cause some 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.

MILD EFFECTS

- Tell your doctor if you notice any of the following that are troublesome or ongoing:
  - Rash
  - Mild dizziness on standing, drowsiness, weakness, fatigue, difficulty sleeping, tremors, nervousness, blurred vision
  - Dry mouth, nausea, constipation, vomiting
  - Stomach pain, diarrhoea, loss of appetite
  - Ringing in the ears, chills
  - Swelling in ankles or limbs, weight gain, excess sweating
  - Sexual problems

MORE SERIOUS EFFECTS

- Tell your doctor immediately if you notice any of the following:
  - Severe dizziness or fainting on standing
  - Fast heart beat
  - Unusual bleeding or bruising
  - Yellowing of the skin and eyes (jaundice)
  - Agitation, confusion or nervousness
  - Muscle spasms or twitches
  - Difficulty passing urine

STOP taking PARNATE and contact your doctor or go to the emergency department of your nearest hospital if any of the following happens:
- Allergic reaction including fainting, swelling of limbs, face, lips, mouth or throat which may cause difficulty swallowing or breathing
- Sore or frequent headaches, chest pain, fast or slow heart beat, neck stiffness or soreness, sweating with initial paleness followed by flushing of the skin, enlarged pupils, nausea and vomiting

Other rare side effects that have been reported include disorders of the liver and blood.

This is not a complete list of all possible effects reported. Other events may occur in some people and there may be some unwanted effects not yet known. Remember to tell your doctor as soon as possible if you do not feel well when you are taking or soon after you have stopped taking PARNATE.

STORAGE

Keep your tablets in the blister pack until it is time to take them. Keep the pack in a cool dry place at or below 25°C. Do not leave it in the car on a hot day. Do not store medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines.

Store all medicines out of the reach of children such as in a locked cupboard.

If your doctor tells you to stop taking PARNATE, ask your pharmacist what to do with any tablets that are left over.

PRODUCT DESCRIPTION

WHAT IT LOOKS LIKE

PARNATE comes as a red, round, film-coated tablet containing 10 mg of tranylcypromine.

OTHER INGREDIENTS

PARNATE tablets also contain inactive ingredients including calcium sulfate, starch maize, sucrose, magnesium stearate, gelatin, erythrosine (red, 127), iron oxide yellow (yellow, 172), cochineal (red, 120), iron oxide red (red, 172), iron oxide black (black, 172), talc, carnauba wax, hypromellose and propylene glycol.

PARNATE tablets do not contain lactose, gluten or tartrazine.

FURTHER INFORMATION

PARNATE tablets are only available if prescribed by a doctor. PARNATE comes in packs of 50 tablets (AUST R 60821).

SPONSOR

Distributed in Australia by:
LINK Medical Products Pty Ltd
Level 1 Bridgepoint Centre
3 Brady Street
Mosman NSW 2088, Australia

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