

Package leaflet: Information for the patient

Parnate® 10mg Film Coated Tablets tranylcypromine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet (See section 4).

What is in this leaflet

1. What Parnate tablets are and what they are used for
2. What you need to know before you take Parnate
3. How to take Parnate Tablets
4. Possible side effects
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1. WHAT PARNATE TABLETS ARE AND WHAT THEY ARE USED FOR

Parnate 10mg Film Coated Tablets will be referred to as Parnate or Parnate Tablets throughout this leaflet.

Parnate Tablets contain the active substance called tranylcypromine which belongs to a group of antidepressant medicines known as monoamine oxidase inhibitors (MAOIs). It works by stopping the breakdown of two substances in the brain called serotonin and noradrenaline. Your medicine should help bring these substances back to normal levels.

Parnate tablets are used to treat moderate to severe depression in adults. These tablets are not suitable for use in situations which make someone feel slightly depressed or apprehensive. It can also help you if you are having feelings of fear (phobia) which sometimes occurs in depression. This medicine is often used when other types of antidepressant medicines have not worked.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARNATE

Do not take Parnate if

- you are allergic to tranylcypromine or any of the other ingredients of Parnate (listed in section 6)
- you are taking other MAOIs or have taken other MAOIs within the last two weeks
- you have taken clomipramine or imipramine within the last three weeks or are planning to take them within the next three weeks
- you suffer from porphyria which is an inherited disease affecting the nervous system and skin
- you have severe heart disease or any disease of the blood vessels of the brain
- you have pheochromocytoma which is a tumour of the adrenal glands (glands near the kidneys) causing high blood pressure
- you have been diagnosed with an overactive thyroid gland (a gland in the neck)
- you have problems with your liver or a disorder affecting the blood cells (your doctor will know)
- you are taking any of the medicines listed under “Do not take” in the “Other Medicines and Parnate”.

Please tell your doctor if any of the above apply to you, and do not take Parnate.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you:

- are elderly
- have cardiovascular disease (also known as heart disease)
- suffer from seizures/fits (epilepsy)
- have a history of dependence on drugs or alcohol
- are taking any of the medicines listed under: “Other Medicines and Parnate” section of this leaflet

Even though some of the above may be obvious, it is important that your doctor is aware if any of them apply to you.

Thoughts of suicide and worsening of your depression or anxiety disorder:

If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself (see section 4 ‘Possible side effects’). These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this if you:

- have previously had thoughts about killing or harming yourself
- are a young adult. Information from clinical trials have shown an increased risk of suicidal behavior in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself, at any time, *contact your doctor or go to a hospital straight away*. You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behavior.

Children and adolescents

Parnate is not recommended for children under 18 years old (see section 3 ‘Use in children and adolescents’).

Other medicines and Parnate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

DO NOT take Parnate with the following medicines

- medicines called sympathomimetic agents - these include ephedrine, pseudoephedrine, adrenaline and noradrenaline (these may be found in medicines used to treat heart problems and asthma as well as some decongestants and cough/cold remedies)
- bupropion, a medicine to help you stop smoking
- medicines to control appetite, e.g. amphetamine and fenfluramine
- medicines that treat Parkinson’s disease, e.g. levodopa
- dopamine, a medicine used to treat certain heart conditions
- the pain killers pethidine and nefopam
- general anaesthetics such as propofol, which are used in surgery
- other medicines used to treat depression (e.g. amitriptyline, imipramine, tryptophan)
- buspirone, used to treat anxiety

- metrizamide, used as a nonionic radiopaque contrast agent.

Parnate Tablets must be taken with caution if you are taking the following medicines

- other MAOIs such as Isocarboxazid
- strong pain killers e.g. codeine
- medicines to treat seizures/fits, e.g. carbamazepine
- barbiturates used to treat severe sleeping problems, e.g. amylobarbitone
- SSRIs such as fluoxetine or sertraline (for depression). Taking your medicine with these products may cause the following serious side effects: sweating, extreme agitation, confusion, muscle stiffness
- medicines for high blood pressure (e.g. guanethidine, reserpine, methyl dopa)
- medicines to treat diabetes (e.g. insulin, metformin)
- antihistamines used to treat allergies, e.g. cetirizine.

Parnate Tablets with food, drink and alcohol

You should NOT take alcohol (especially red wine) whilst you are taking Parnate Tablets. This includes non-alcoholic beer, lager or wine.

Parnate Tablets stops the breakdown of a substance called tyramine which is found in large amounts of certain foods. If this substance is not broken down, it can cause very high blood pressure (hypertensive crisis). See section 4 - Possible side effects of this leaflet. So, whilst you are taking Parnate Tablets, you should avoid the following foods:

- cheese – cooked or plain (e.g. cheddar or processed cheese made from mature cheese)
- yeast extracts (e.g. Bovril, Oxo, Marmite, brewer's yeast)
- meat, fish or poultry which is not fresh or has been pickled or aged e.g. hung game, pickled herrings
- broad bean pods
- banana skins.

Once you stop taking Parnate Tablets, your doctor will tell you when you can start to eat these foods again.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Parnate should NOT be used during pregnancy or breastfeeding unless your doctor thinks it is essential.

This medicine may pass into breast milk.

Your doctor will decide whether you should ab lactate (gradually reduce) or stop therapy with Tranlycypromine. Effects of Tranlycypromine on fertility are unknown.

Driving and using machines

Do not drive or use machines when you first start to take this medicine as it may make you feel drowsy or dizzy, or affect your concentration. Wait until you are certain that you are not getting these side effects. If in any doubt, speak to your doctor before you drive or use machines.

Parnate 10mg Tablets contains Sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on content of Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE PARNATE TABLETS

Always take this medicine exactly as your doctor or pharmacist has told you. Do **NOT** take more than your doctor tells you to.

Check with your doctor or pharmacist if you are not sure.

Swallow the tablets whole with a glass of water.

The recommended dose for adults is:

- one 10mg tablet in the morning and one 10mg tablet in the afternoon each day. Try to take the last dose before 3 o'clock in the afternoon
- this dose may be increased by your doctor to three tablets a day. Take the extra tablet at mid-day
- if you are elderly, your doctor will usually prescribe you a lower dose.

When you start to feel better, your doctor may change your dose to one 10mg tablet a day. Do **NOT** take more than three tablets each day unless your doctor tells you to. Your doctor will probably check your blood pressure while you are taking Parnate Tablets.

Use in children and adolescents:

Parnate Tablets are not recommended for children under 18 years of age. (see section 2 'Children and adolescents').

If you take more Parnate Tablets than you should

If you think that you, or any other person, have taken too many tablets, contact your doctor or hospital casualty department immediately. Take any remaining tablets and this leaflet with you so that the medical staff know exactly what you have taken.

If you forget to take Parnate tablets

If you miss a dose, wait until your next dose. Do not take the dose you have missed. You can then carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Parnate tablets

Continue to take Parnate even if you no longer feel ill. **DO NOT STOP** taking this medicine without talking with your doctor first, especially if you have taken large doses for a long time.

When the time comes to stop, your doctor will probably decrease your dose gradually as stopping the tablets suddenly may cause ill-effects such as nausea (feeling sick), vomiting (being sick), feeling unwell, vivid nightmares, fits, loss of contact with reality, usually including false beliefs about what is taking place or who one is (delusions) and seeing or hearing things that aren't there (hallucinations). Symptoms will usually start 24 to up 72 hours after you stop taking this medicine abruptly (see section 4 possible side effects).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- if you eat foods or take medicines which interact with the active ingredient tranylcypromine, you may get very high blood pressure (a hypertensive crisis).

If you notice any of the following symptoms please see your doctor immediately:

- frequent or throbbing headaches, painful or stiff neck, changes in heart rate, pain in the middle of the chest, feeling sick or being sick, sweating, paleness, or flushing of the skin and enlarged pupils which may make bright sunlight uncomfortable. Although very rare, there may be muscle weakness or paralysis (loss of movement) down one side of the body and there have been a few deaths from hypertensive crisis
- thoughts of suicide and suicidal behaviour early on in treatment or shortly after stopping treatment (see section 2 'Thoughts of suicide and worsening of your depression or anxiety disorder')
- sometimes patients feel anxious whilst taking this medicine and rarely some patients will become very agitated or irritable. Your doctor may reduce your dose if this happens
- some patients get low blood pressure and may feel dizzy on standing up. If this continues for a long time, your doctor may stop your medicine.
- Liver problems (symptoms include yellowing of the skin and the whites of the eyes), bruising and changes in blood have been reported. Therefore, if you get a bad sore throat or high fever or become very tired and pale or notice bruises and nose bleeds, tell your doctor.

Other side effects which may occur include:

Rare: may affect up to 1 in 1,000 people

- soreness in the hands and feet, which may be a sign of inflamed nerves
- A need to take increasingly higher doses to obtain the same effect (tolerance)
- seeing or hearing things that are not real (hallucinations)
- elated moods and excitability (hypomania)
- drug dependence (addiction)

Not known: frequency cannot be estimated from the available data

- difficulty in sleeping, mild headache, sleepiness, weakness, dizziness, fast heart beat (palpitations), restlessness, dry mouth, diarrhoea, vomiting (being sick), blurred vision, nausea (feeling sick), feeling of tiredness, water retention or swelling, weight gain, increased appetite, rash and difficulty in passing water.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects, not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PARNATE TABLETS

Keep this medicine out of the sight and reach of children.

Do not use Parnate Tablets after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the blister packs. Keep the blister packs in the outer carton in order to protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Parnate Tablets contain

The active substance is tranylcypromine (as tranylcypromine sulfate). Each film-coated tablet contains 10mg of the active substance.

The other ingredients are sucrose, maize starch, calcium sulfate dihydrate, erythrosine (E127), magnesium stearate and gelatin. The coating contains opadry red 06H250000 (PI 106298) & carnauba wax.

What Parnate Tablets look like and contents of the pack

Parnate are light red coloured, bi-convex, film coated tablets.

They are packed in PVC-PVDC/Aluminium blisters in a Carton containing 28 (7 tablets/blister x 4) and 50 (10 tablets/blister x 5) tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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