

## Patient Information Leaflet

# Parnate® 10mg Tablets / Tranylcypromine 10mg Tablets (tranylcypromine sulfate)

**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 or pharmacist.
- This medicine has been prescribed for you. 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 or pharmacist. This includes any possible side effects not listed in this leaflet.
- Your medicine is available using either of the above names but will be referred to as Parnate® 10mg Tablets throughout the remainder of this leaflet.

### What is in this leaflet:

- 1) What Parnate® 10mg Tablets are and what they are used for
- 2) What you need to know before you take Parnate® 10mg Tablets
- 3) How to take Parnate® 10mg Tablets
- 4) Possible side effects
- 5) How to store Parnate® 10mg Tablets
- 6) Contents of the pack and other information

## 1) WHAT PARNATE® 10MG TABLETS ARE AND WHAT THEY ARE USED FOR

Parnate® 10mg Tablets contain the active substance 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.

This medicine is used to treat moderate to severe depression in adults. 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® 10MG TABLETS

### Do not take Parnate® 10mg Tablets if:

- you are allergic to tranylcypromine or any of the other ingredients of this medicine (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 known liver damage 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® 10mg Tablets" section of this leaflet

Please tell your doctor if any of the above apply to you, and do not take Parnate® 10mg Tablets.

### Warnings and precautions

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

- are elderly
- have a mild heart problem which restricts your activity
- suffer from seizures/fits (epilepsy)
- are due to have surgery in the next few weeks
- have a history of dependence on drugs or alcohol.

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 has shown an increased risk of suicidal behaviour 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 behaviour.

### Children and adolescents

Parnate® 10mg Tablets are not recommended for children under 18 years old (see section 3 'Use in children and adolescents').

### Other medicines and Parnate® 10mg Tablets:

Please 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® 10mg Tablets 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.

### Parnate® 10mg 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.

Consult your doctor before you take Parnate® 10mg Tablets if you are taking or might be taking any of these.

### Parnate® 10mg Tablets with food, drink and alcohol

You should **NOT** take alcohol (especially red wine) whilst you are taking Parnate® 10mg Tablets. This includes non-alcoholic beer or lager.

Parnate® 10mg Tablets stop 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. So, whilst you are taking Parnate® 10mg Tablets, you should avoid the following foods:

- matured cheeses – (e.g. cheddar or processed cheese made from mature cheese)
- yeast extracts (e.g. Bovril or Marmite)
- meat, fish or poultry which is not fresh or has been pickled
- broad bean pods
- banana skins.

### Pregnancy and breast-feeding:

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

Parnate® 10mg Tablets should NOT be used during pregnancy or breast-feeding 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 Parnate® 10mg Tablets. Effects of Parnate® 10mg Tablets on fertility are unknown.

### Driving and using machines:

Parnate® 10mg Tablets may make you feel drowsy or dizzy or affect your concentration. You should not drive or use machines when you first start to take this medicine 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.

### Important information about some of the ingredients of Parnate® 10mg Tablets

This medicine also contains Ponceau 4R (E124) which may cause allergic reactions.

This medicine also contains sucrose (a sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## 3) HOW TO TAKE PARNATE® 10MG TABLETS

Always take this medicine exactly as your doctor 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 tablet in the morning and one 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 tablet a day.

Do **NOT** take more than three tablets each day unless your doctor tells you to.

### Use in children and adolescents:

Parnate® 10mg Tablets are not recommended for children under 18 years old (see section 2 'Children and adolescents').

### If you take more Parnate® 10mg 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 your Parnate® 10mg 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 more than one dose at a time.

**If you stop taking Parnate® 10mg Tablets:**

Continue to take Parnate® 10mg Tablets 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), sweating and difficulty in sleeping.

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

**4) POSSIBLE SIDE EFFECTS**

Like all medicines, Parnate® 10mg Tablets 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.

Other side effects which may occur include:

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

Rarely some patients experience soreness in the hands and feet, which may be a sign of inflamed nerves.

Rarely, some patients may find the relief of their depression decreases with time and higher doses of the active ingredient, tranylcypromine, are needed to get the same effect.

Very rarely, 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.

**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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

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

**5) HOW TO STORE PARNATE® 10MG TABLETS**

- Keep this medicine out of the sight and reach of children.
- Do not use Parnate® 10mg Tablets after the expiry date which is stated on the box. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Store in the original package in order to protect from light and moisture.
- If your tablets become discoloured or show any sign of deterioration, return them to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6) CONTENTS OF THE PACK AND OTHER INFORMATION****What Parnate® 10mg Tablets contain:**

Each sugar coated tablet contains 10 mg of the active substance, tranylcypromine as tranylcypromine sulfate.

The other ingredients are:

Tablet core – Sucrose, Maize starch, Calcium sulfate dihydrate, Carmellose sodium, Magnesium stearate.

Tablet coating – Gelatin, Sucrose, Docusate Sodium, Purified talc, Light kaolin, Calcium carbonate, Ethylcellulose, Acacia, Ponceau 4R (E124), Maize starch, Titanium dioxide (E171), Carnauba wax, Edible ink (shellac, iron oxide black (E172), soya lecithin (E322) and trace amounts of dimethyl siloxane)

**What Parnate® 10mg Tablets look like and the contents of the pack:**

Parnate® 10mg Tablets are geranium-red coloured, biconvex, sugar-coated tablets marked 'FW251' on one side only.

Parnate® 10mg Tablets are packed in plastic containers containing 28 tablets.

Manufactured by

Dales Pharmaceuticals Ltd., Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, UK

Procured from within the EU by Product Licence holder:

MPT Pharma Ltd, Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall, WS9 8ER, UK

Repackaged by: XXXXXXXXXXXXXXXX

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