

**Package leaflet: Information for the patient**  
**Parnate® 10mg tablets**  
(tranylcypromine sulphate)

**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 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

The name of your medicine is Parnate 10mg tablets but will be referred to as Parnate throughout this leaflet.

**What is in this leaflet:**

1. What Parnate is and what it is used for
2. What you need to know before you take Parnate
3. How to take Parnate
4. Possible side effects
5. How to store Parnate
6. Contents of the pack and other information

**1. What Parnate is and what it is used for**

Parnate contains 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**

**Do not take Parnate 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' section of this leaflet.
- 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 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 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 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 if you are taking or might be taking any of these.

**Parnate with food, drink and alcohol**

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

Parnate 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. So, whilst you are taking Parnate, 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, breast feeding and fertility**

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 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. Effects of Parnate on fertility are unknown.

**Driving and using machines**

Parnate 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.

Parnate contains

- Ponceau 4R (E124) which may cause allergic reactions.
- sucrose: 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

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 is not recommended for children under 18 years old (see section 2 'Children and adolescents').

#### If you take more Parnate 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

If you miss a dose, wait until your next dose. Do not take a double dose to make up for a forgotten tablet. You can then carry on as before. Do not take more than one dose at a time.

#### If you stop taking Parnate

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), 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 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:

#### 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.

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

- 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.
- Seeing or hearing things that are not real (hallucinations)
- Rarely some patients experience soreness in the hands and feet, which may be a sign of inflamed nerves.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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

Keep out of the sight and reach of children.

Do not store above 25°C.

Store in the original package in order to protect from light and moisture.

Do not take the tablets after the expiry date which is stated on the carton and blister labels after 'Exp'. The expiry date refers to the last day of that month.

Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.

If the tablets become discolored or show any signs of deterioration, seek the advice of 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 contains

The active ingredient in Parnate is 10mg tranylcypromine sulphate. Each film-coated tablet contains tranylcypromine sulphate equivalent to 10mg of tranylcypromine base.

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

#### What Parnate looks like and contents of the pack

Parnate is light red coloured, bi-convex, film-coated tablet. It is available in packs of 28 tablets.

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

**OR**

Genexi, 52, rue Marcel et Jacques Gaucher, Fontenay-sous-Bois, 94120, France.

**Procured from within the EU and repackaged by the Product Licence holder:** B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**Parnate® 10mg tablets; PL 18799/2448**

**Leaflet date:** 20.10.2023

**POM**

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**Blind or partially sighted?  
Is this leaflet hard to see or read?  
Call 0208 515 3763 to obtain the  
leaflet in a format suitable for you.**

**Package leaflet: Information for the patient**  
**Tranlycypromine 10mg tablets**  
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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 or pharmacist. This includes any possible side effects not listed in this leaflet.

The name of your medicine is Tranlycypromine 10mg tablets but will be referred to as Tranlycypromine throughout this leaflet.

**What is in this leaflet:**

1. What Tranlycypromine is and what it is used for
2. What you need to know before you take Tranlycypromine
3. How to take Tranlycypromine
4. Possible side effects
5. How to store Tranlycypromine
6. Contents of the pack and other information

**1. What Tranlycypromine is and what it is used for**

Tranlycypromine contains the active substance tranlycypromine 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 Tranlycypromine**

**Do not take Tranlycypromine if:**

- you are allergic to tranlycypromine 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 Tranlycypromine' section of this leaflet
- Please tell your doctor if any of the above apply to you, and do not take Tranlycypromine.

**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 behavior.

**Children and adolescents**

Tranlycypromine is not recommended for children under 18 years old (see section 3 'Use in children and adolescents').

**Other medicines and Tranlycypromine**

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 Tranlycypromine 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

**Tranlycypromine 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 Tranlycypromine if you are taking or might be taking any of these.

**Tranlycypromine with food, drink and alcohol**

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

Tranlycypromine 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. So, whilst you are taking Tranlycypromine, 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, breast feeding and fertility**

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.

Tranlycypromine 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 Tranlycypromine. Effects of Tranlycypromine on fertility are unknown.

**Driving and using machines**

Tranlycypromine 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.

Tranlycypromine contains

- Ponceau 4R (E124) which may cause allergic reactions.
- sucrose: 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 Tranlycypromine

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

Tranlycypromine is not recommended for children under 18 years old (see section 2 'Children and adolescents').

#### If you take more Tranlycypromine 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 Tranlycypromine

If you miss a dose, wait until your next dose. Do not take a double dose to make up for a forgotten tablet. You can then carry on as before. Do not take more than one dose at a time.

#### If you stop taking Tranlycypromine

Continue to take Tranlycypromine 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, Tranlycypromine can cause side effects, although not everybody gets them.

If you eat foods or take medicines which interact with the active ingredient tranlycypromine, 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').
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- 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:

#### 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.

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

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#### Reporting of side effects

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### 5. How to store Tranlycypromine

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If the tablets become discolored or show any signs of deterioration, seek the advice of 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 Tranlycypromine contains

The active ingredient in Tranlycypromine is 10mg of tranlycypromine sulphate.

Each film-coated tablet contains tranlycypromine sulphate equivalent to 10mg of tranlycypromine base.

The other ingredients are sucrose, maize starch, calcium sulphate dihydrate, erythrosine (E127), magnesium stearate and gelatin.

The coating contains opadry red 06H250000 (PI 106298) & carnauba wax.

#### What Tranlycypromine looks like and contents of the pack

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