

## Package leaflet: Information for the patient

### **PARNATE® 10MG FILM COATED TABLETS** (tranylcypromine sulphate)

Your medicine is available using the name Parnate 10mg Film Coated Tablets but will be referred to as Parnate throughout this leaflet.

#### **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.

#### **What is in this leaflet:**

- What Parnate tablets are and what they are used for
- What you need to know before you take Parnate
- How to take Parnate
- Possible side effects
- How to store Parnate
- Contents of the pack and other information

#### **1. What Parnate tablets are and what they are 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 behaviour.

##### **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**

- 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.

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

### **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 midday
- 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 Website: [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 use Parnate after the expiry date which is stated on the box. The expiry date refers to the last day of that month. If your tablets are out of date, take them to your pharmacist who will get rid of them safely.

Do not store above 25°C (normal room temperature).

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

If your tablets appear to be discoloured or show any other signs of deterioration, take them to your pharmacist who will advise you.

If your doctor decides to stop treatment, return any leftover tablets to the pharmacist. Only keep them if your doctor tells you to.

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

Each film coated tablet contains tranylcypromine sulphate equivalent to 10mg of tranylcypromine.

Parnate also contains the following inactive ingredients:

- Tablet core: sucrose, maize starch, calcium sulphate dihydrate, erythrosine (E127), magnesium stearate and gelatin.
- Tablet coating: opadry red 06H250000 (PI 106298) and carnauba wax.

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

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

Parnate is packed in PVC-PVDC/Aluminium blisters in a carton containing 28 (7 tablets/blister x 4) tablets or in white containers of 28 tablets.

**Manufacturer**

Manufactured by:  
Cenexi – Fontenay Sous Bois, 52,  
Rue Marcel et Jacques Gaucher, Fontenay-sous-Bois,  
94120, France.

Procured from within the EU and repackaged by:  
BModesto B.V., Minervaweg 2, 8239 DL, Lelystad,  
Netherlands.

Product Licence holder: Doncaster Pharma Limited,  
Crompton Road, Doncaster, DN2 4PW, UK.

PL No: 56830/0042

POM

Leaflet revision and issue date: 21.02.2024

Parnate® is a registered trademark of  
Mercury Pharma Group Limited.

Blind or partially sighted?  
Is this leaflet hard to see or  
read?  
Call +44 (0) 1302 365000  
(Regulatory)

Please be ready to give the  
following information:  
Product name:  
PARNATE 10MG FILM  
COATED TABLETS  
Reference No: 56830/0042

## Package leaflet: Information for the patient

### TRANLYCYPROMINE 10MG FILM COATED TABLETS

(tranylcypromine sulphate)

Your medicine is available using the name Tranylcypromine 10mg Film Coated Tablets but will be referred to as Tranylcypromine throughout this leaflet.

#### 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.

#### What is in this leaflet:

- What Tranylcypromine tablets are and what they are used for
- What you need to know before you take Tranylcypromine
- How to take Tranylcypromine
- Possible side effects
- How to store Tranylcypromine
- Contents of the pack and other information

#### 1. What Tranylcypromine tablets are and what they are used for

Tranylcypromine 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 Tranylcypromine

##### Do not take Tranylcypromine 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 Tranylcypromine" section of this leaflet.

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

#### 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

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

#### Other medicines and Tranylcypromine

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 Tranylcypromine with the following medicines:

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- 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.

#### Tranylcypromine 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 Tranylcypromine if you are taking or might be taking any of these.

#### Tranylcypromine with food, drink and alcohol

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

Tranylcypromine 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 Tranylcypromine, 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.

Tranylcypromine 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 Tranylcypromine. Effects of Tranylcypromine on fertility are unknown.

#### Driving and using machines

Tranylcypromine 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.

#### Tranylcypromine 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.

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

#### 3. How to take Tranylcypromine

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 midday
- 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

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

#### If you take more Tranylcypromine 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 Tranylcypromine

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 Tranylcypromine

Continue to take Tranylcypromine 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, Tranylcypromine 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)
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#### 5. How to store Tranylcypromine

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If your doctor decides to stop treatment, return any leftover tablets to the pharmacist. Only keep them if your doctor tells you to.

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#### 6. Contents of the pack and other information

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Tranylcypromine also contains the following inactive ingredients:

- Tablet core: sucrose, maize starch, calcium sulphate dihydrate, erythrosine (E127), magnesium stearate and gelatin.
- Tablet coating: opadry red 06H250000 (PI 106298) and carnauba wax.

**What Tranylcypromine looks like and contents of the pack**

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

Tranylcypromine is packed in PVC-PVDC/Aluminium blisters in a carton containing 28 (7 tablets/blister x 4) tablets or in white containers of 28 tablets.

**Manufacturer**

Manufactured by:

Cenexi – Fontenay Sous Bois, 52, Rue Marcel et Jacques Gaucher, Fontenay-sous-Bois, 94120, France.

Procured from within the EU and repackaged by:

BModesto B.V., Minervaweg 2, 8239 DL, Lelystad, Netherlands.

Product Licence holder: Doncaster Pharma Limited, Crompton Road, Doncaster, DN2 4PW, UK.

PL No: 56830/0042

POM

Leaflet revision and issue date: 21.02.2024

Blind or partially sighted?  
Is this leaflet hard to see or read?

Call +44 (0) 1302 365000  
(Regulatory)

Please be ready to give the following information:

Product name:

TRANLYCYPROMINE 10MG

FILM COATED TABLETS

Reference No: 56830/0042