

Package leaflet: Information for the patient

Tranlycypromine 10 mg Film-coated Tablets

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. See section 4.

What is in this leaflet

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1. What Tranlycypromine tablets are and what they are used for

Tranlycypromine tablets contains the active substance tranlycypromine sulfate 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. Tranlycypromine should bring these substances back to normal levels.

This medicine is used to treat **major depressive episodes** in adult patients when treatment with other types of antidepressant medication has failed.

2. What you need to know before you take Tranlycypromine tablets

Do not take Tranlycypromine tablets if:

- you are **allergic** to the active substance or any of the 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 other liver diseases 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 tablets’ section of this leaflet

Please tell your doctor if any of the above apply to you, and **do not take** Tranylcypromine 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.
- have severe kidney diseases

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 tablets are not recommended for children and adolescents under 18 years old.

Other medicines and Tranylcypromine 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 Tranylcypromine 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**
- metrizamide, used as a nonionic radiopaque contrast agent.

Tranlycypromine 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, methyldopa)
- medicines to treat **diabetes** (e.g. insulin, metformin)
- antihistamines used to treat **allergies**, e.g. cetirizine.

Consult your doctor before you take Tranlycypromine tablets if you are taking or might be taking any of these.

Tranlycypromine tablets with food, drink and alcohol

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

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

These 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 gradually reduce or stop treatment with Tranlycypromine tablets.

The effects of this medicine on fertility are unknown.

Driving and using machines:

Tranlycypromine 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.

Tranlycypromine tablets contain lactose

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

This medicine also contains allura red AC (E129) which may cause allergic reactions.

3. How to take Tranlycypromine 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. This dose may be increased by your doctor with regular blood pressure monitoring.

When you start to feel better, your doctor may change your dose to one tablet a day.

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

If you take more Tranylcypromine 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 Tranylcypromine tablets

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 tablets

Stopping the tablets suddenly may cause nausea (feeling sick), vomiting (being sick), sweating and difficulty in sleeping.

You should continue to take the 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.

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 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**:

- Symptoms of hypertensive crisis such as 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 side effects (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.

Not known: frequency cannot be estimated from the available data

- difficulty in sleeping, mild headache, sleepiness, weakness, dizziness, fast heart beat (palpitation), restlessness, dry mouth, blurred vision, feeling sick, 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, 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 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 Tranylcypromine tablets

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

Do not use Tranylcypromine tablets after the expiry date which is stated on the label. The expiry date refers to the last day of the month.

This medicinal product does not require any special temperature storage conditions.

For Blister Pack: Store the blister in the original aluminium pouch with desiccant to protect from moisture. Use within 30 days after first opening of pouch.

For Container Pack: Store in the original bottle to protect from moisture and keep the bottle tightly closed.

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

Each film-coated tablet contains 10 mg of tranylcypromine.

It also contains lactose monohydrate, cellulose microcrystalline, croscarmellose sodium, silica colloidal anhydrous, magnesium stearate and coating material (polyvinyl alcohol, macrogol, titanium dioxide (E171), talc (E553b), allura red AC aluminium lake (E129)).

What Tranylcypromine Tablets look like and contents of the pack

Tranlycypromine 10 mg tablets are Pink to light pink, round (diameter 7 mm) biconvex coated tablets debossed with 'Y3' on one side and score line on other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

They are available as:

Blister pack: White opaque PVC/PVDC-Aluminium blister packs in aluminium pouch with molecular sieve desiccant further packed in cardboard cartons. The desiccant is not for ingestion. Pack sizes includes 10, 20, 30 tablets.

Container pack: HDPE containers with child resistant closures containing molecular sieve as desiccant. Pack size includes 28 tablets.

The tablets packed in blister pack and in containers include a desiccant protecting the tablets from moisture. The desiccant available is not for ingestion.

Not all pack sizes may be marketed.

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Other sources of information:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only).

Please be ready to give the following information:

Product name	Reference Number
Tranlycypromine 10 mg film-coated tablets	PL 25258/0313

This is a service provided by the Royal National Institute of Blind People.

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