

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

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 Tablets contain 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 **major depressive episodes** in adults 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

- 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** Tranlycypromine tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tranlycypromine 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

Tranlycypromine is not recommended for children and adolescents under 18 years old.

Other medicines and Tranlycypromine

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 Tranlycypromine 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. amylbarbitone
- 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 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 these tablets. 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 gradually reduce or stop therapy with Tranylcypromine.

The effects of this medicine 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 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 medicine.

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 each 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.

Children and adolescents

Tranlycypromine is not recommended for children under 18 years old.

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 Tranlycypromine

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 Tranlycypromine

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

If you eat foods or take medicines which interact with 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
- 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 possible side effects

Rare (may affect up to 1 in 1,000 people)

- 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)
- 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 (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
- 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 the Yellow Card Scheme at: 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

Do not store above 25°C.

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

Do not use this medicine after the expiry date which is stated on the carton/blister pack after “EXP”. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What Tranylcypromine tablets contain

Each film-coated tablet contains 10 mg tranylcypromine as tranylcypromine sulfate.

The other ingredients are:

Tablet core: Lactose monohydrate, corn starch, microcrystalline cellulose, colloidal anhydrous silica

Film coating: Polyvinyl alcohol, Macrogol 3350, titanium dioxide, talc, iron oxide yellow (E172), iron oxide black (E172), indigo carmine aluminium salt (E132)

What Tranlycypromine tablets look like and contents of the pack

The tablets are green, round, film-coated and have a score line. The tablet can be divided into equal doses.

Pack sizes: 28, 30, 56, 60 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Aristo Pharma GmbH

Wallenroder Straße 8 – 10

13435 Berlin

Germany

This leaflet was last revised in 08/2025.