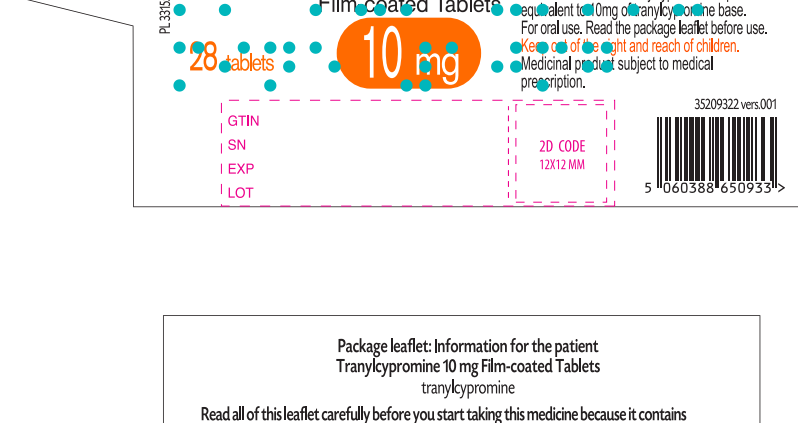


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**Package leaflet: Information for the patient**  
**Tranykypromine 10 mg Film-coated Tablets**  
tranykypromine

**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.

Tranykypromine 10 mg Film-coated Tablets will be referred to as Tranykypromine Tablets throughout this leaflet.

**What is in this leaflet**

- What Tranykypromine Tablets are and what they are used for
- What you need to know before you take Tranykypromine Tablets
- How to take Tranykypromine Tablets
- Possible side effects
- How to store Tranykypromine Tablets

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

- What Tranykypromine Tablets are and what they are used for**

Tranykypromine Tablets contains the active substance tranykypromine 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 depression in adults when other types of antidepressant medicines have not worked.

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**2. What you need to know before you take Tranykypromine Tablets**

**DONOT take Tranykypromine Tablets if:**

- you are allergic to tranykypromine 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 dornopramine 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

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- 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 Tranykypromine Tablets".

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

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**Warnings and precautions**

Talk to your doctor or pharmacist before taking Tranykypromine Tablets 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 dysfunction

Even though some of the above may be obvious, it is important that your doctor is aware if any of them apply to you.

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**Children and adolescents**

This medicine must not be used by children and adolescents under 18 years of age.

**Elderly**

If you are over 65 years of age, your doctor will keep the dosage as low as possible and check your blood pressure regularly. If it is necessary to increase the dosage, this will take place very gradually. If you have palpitations or frequent headaches, have your blood pressure checked.

**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).

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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 of 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

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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.

**Other medicines and Tranykypromine Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription.

**DONOT take Tranykypromine 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)

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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.

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**Tranykypromine 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)

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- antihistamines used to treat allergies, e.g. cetirizine.

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

**Tranykypromine Tablets with food, drink and alcohol**

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

Tranykypromine 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.

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So, whilst you are taking Tranykypromine 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**

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

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Tranykypromine 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 abtactate (gradually reduce) or stop therapy with Tranykypromine Tablets. Effects of Tranykypromine Tablets on fertility are unknown.

**Driving and using machines**

Tranykypromine 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.

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**3. How to take Tranykypromine Tablets**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Do NOT take more than your doctor tells you to.

Swallow the tablets whole with a glass of water.

**Use in adults**

The recommended dose is:

- one tablet in the morning and one tablet in the afternoon, each day

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- 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 the elderly (over 65 years of age)**

In elderly patients, Tranykypromine Tablets should be used with particular caution and normally at a somewhat lower dosage.

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**Use in children and adolescents**

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

**Dosage in impaired kidney function**

If you have kidney dysfunction, your doctor may prescribe a lower dose.

**If you take more Tranykypromine 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.

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**If you forget to take Tranykypromine 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 Tranykypromine Tablets**

Continue to take Tranykypromine 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.

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**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 the active ingredient tranykypromine, 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.

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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:

**Rare: may affect up to 1 in 1000 people**

- Rarely some patients may find the relief of their depression decreases with time and higher doses of the active ingredient, tranykypromine, are needed to get the same effect.
- Seeing or hearing things that are not real (hallucinations).

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- 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 (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.

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**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 Tranykypromine Tablets**

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

This medicinal product does not require any special storage conditions.

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Do not use this medicine after the expiry date which is stated on the bottle label 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 Tranykypromine Tablets contain**

The active substance (the ingredient that makes the tablets work) is tranykypromine.

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Each tablet contains tranykypromine sulphate equivalent to 10mg of tranykypromine base. The other ingredients (excipients) are: microcrystalline cellulose, pregelatinised starch, colloidal anhydrous silica, magnesium stearate (vegetable origin) and Opadry II red 85F250100.

**What Tranykypromine Tablets look like and contents of the pack**

Tranykypromine Tablets are presented as film coated, round, biconvex, red tablets, debossed "10" on one side.

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Tranykypromine 10mg Film-coated Tablets are packaged in White HDPE bottles with a white round plastic child-resistant tamper-evident screw cap and an integrated gel desiccant in packs of 28 tablets.

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**Tranykypromine Film-coated Tablets**

**10 mg**

**ORAL USE** **28 tablets**

Tranykypromine 10mg Film-coated Tablets. Each tablet contains tranykypromine sulphate equivalent to 10mg of tranykypromine base. For oral use. Read the package leaflet before use. Keep out of the sight and reach of children. Medicinal product subject to medical prescription.

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