Pharmacode position may change as per Supplier's m/c requirement & additional small pharma code may appear on the front / back panel





Package leaflet: Information for the user

Tranylcypromine 10mg 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 Tranylcypromine tablets are and what they are used for
2. What you need to know before you take Tranylcypromine tablets
3. How to take Tranylcypromine tablets
4. Possible side effects
5. How to store Tranylcypromine tablets
6. Contents of the pack and other information

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

Tranylcypromine tablets contain 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 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 Tranylcypromine tablets

Do not take Tranylcypromine tablets 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 phaeochromocytoma 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 Tranylcypromine 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 a kidney disease

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

Other medicines and Tranylcypromine Tablets
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.

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

Tranylcypromine Tablets with food, drink and alcohol
You should **NOT** take alcohol (especially red wine) whilst you are taking Tranylcypromine 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 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.

Tranylcypromine 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 stop breast-feeding or stop therapy with Tranylcypromine tablets. Effects of Tranylcypromine tablets on fertility are unknown.

Driving and using machines
Tranylcypromine 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.

3. How to take Tranylcypromine 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 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.

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Use in children and adolescents
Tranylcypromine tablets are not recommended for children and adolescents 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
Continue to take Tranylcypromine 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.

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:
- 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 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 box after 'EXP'. 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.

This medicine does not require any special storage conditions.

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

What Tranylcypromine tablets contains
- The active substance is tranylcypromine. Each film-coated tablet contains 10 mg tranylcypromine (as tranylcypromine sulfate).
- The other ingredients are:
  Tablet core: microcrystalline cellulose, calcium hydrogen phosphate, pregelatinised starch (maize starch), colloidal anhydrous silica, talc and magnesium stearate
  Tablet coating: polyvinyl alcohol, titanium dioxide, macrogol 3350, talc, iron oxide yellow

What Tranylcypromine tablets looks like and contents of the pack
Tranylcypromine 10mg Film-Coated Tablet is a yellow coloured, round, approximately 7.3 mm diameter, biconvex, bevelled-edged, film-coated tablets, debossed with 'T' above and "10" below on one side and plain on other side.

Tranylcypromine tablets are available in an HDPE container with polypropylene child resistant closure and containing silica gel as desiccant.

Pack size: 28 tablets.

Marketing Authorisation Holder
Milpharm Limited
1 Roundwood Avenue
Stockley Park, Uxbridge
UB11 1AF
United Kingdom

Manufacturer
APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far,
Birzebbugia, BBG 3000, Malta

Or

Milpharm Limited
1 Roundwood Avenue
Stockley Park, Uxbridge
UB11 1AF
United Kingdom

Other sources of information
To request a copy of this leaflet in Braille or large print please call, free of charge:
0044(0)2088458811 (UK Only)

Please be ready to give the following information:

Product Name	Reference number
Tranylcypromine 10mg Film-Coated Tablets	PL 16363/0706

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