

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Tranlycypromine 10mg Film-Coated Tablets

(Referred to as Tranlycypromine tablets in the remainder of this leaflet)

Tranlycypromine sulfate

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

1. WHAT TRANLYCYPROMINE TABLETS ARE AND WHAT THEY ARE USED FOR

Tranlycypromine tablets contain 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. Your medicine should help bring these substances back to normal levels.

This medicine is used to treat moderate to severe depression in adults when other types of antidepressant medicines have not worked.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRANLYCYPROMINE TABLETS

Do not take Tranlycypromine tablets if you:

- are allergic to tranlycypromine or any of the other ingredients of this medicine (listed in section 6)
- are taking other MAOIs or have taken other MAOIs within the last two weeks
- are taking, or have recently taken, any of the medicines listed under 'DO NOT take' in the 'Other Medicines and Tranlycypromine tablets' section of this leaflet
- suffer from porphyria (an inherited disease that causes a build-up of certain chemicals in the body and can affect the nervous system and skin)
- have severe heart disease or a condition that affects the flow of blood through your brain
- you have pheochromocytoma (a tumour of the adrenal glands (glands near the kidneys) causing high blood pressure)
- have been diagnosed with an overactive thyroid gland (a gland in the neck)
- have a liver disorder
- have a disorder affecting your blood cells (your doctor will know)

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 this medicine if you:

- are elderly
- have any sort of heart problem which restricts your activity

- suffer from seizures/fits (epilepsy)
- have a history of dependence on drugs or alcohol
- have mild to moderate kidney disease

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Tranylcypromine tablets. Even though some of the above may be obvious, it is important that your doctor knows and that you are monitored during your treatment.

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.

Operations and anaesthetics

If you are going to have an operation or dental work that requires an anaesthetic, tell your doctor or dentist as soon as possible that you are taking Tranylcypromine tablets. This is very important, because it could affect the type of anaesthetic you are given, or you might need to gradually reduce your dose of tranylcypromine and then stop taking your tablets at least 2 weeks before your operation.

Children and adolescents:

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

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. Some medicines can affect the way tranylcypromine works or make it more likely that you will have side effects. Tranylcypromine can also affect the way some other medicines work.

DO NOT take Tranylcypromine tablets if you are taking, or have recently taken, any of the following medicines:

- other MAOIs (e.g. isocarboxazid, procarbazine), including MAOIs taken within the last two weeks
- medicines called selective serotonin reuptake inhibitors (SSRIs), used to treat depression or anxiety disorders, (e.g. fluoxetine, sertraline, citalopram, fluvoxamine). This includes if you have taken fluoxetine within the last 5 weeks, or any other SSRI within the last 2 weeks. Taking Tranylcypromine tablets with, or within a few weeks after, taking SSRIs may cause serious side effects including an abnormally high body temperature, extreme agitation, confusion, muscle stiffness
- tricyclic or tetracyclic medicines, used to treat depression and some types of pain (e.g. amitriptyline, clomipramine, trimipramine, mianserin), including any taken within the last 3 weeks

- carbamazepine, a medicine used to treat epilepsy and nerve pain, including carbamazepine taken within the last 2 weeks
- buspirone, a medicine used to treat anxiety
- tryptophan, used to treat depression or used as a dietary supplement
- medicines called sympathomimetic agents - these include decongestants contained in cough/cold and hayfever remedies (e.g. pseudoephedrine, ephedrine, xylometazoline, phenylpropanolamine, phenylephrine), medicines to control appetite (e.g. amphetamine, fenfluramine), certain medicines used to treat asthma or heart problems (e.g. adrenaline, noradrenaline, dopamine), certain medicines used to reduce blood pressure (e.g. guanethidine, reserpine, methyldopa), levodopa (a medicine for the treatment of Parkinson's disease)
- dextromethorphan (contained in some cough and cough/cold remedies)
- pethidine or nefopam (painkillers)
- bupropion, a medicine to help you stop smoking

CHECK with your doctor or pharmacist before taking Tranylcypromine tablets if you are taking, or have recently taken, any of the following medicines:

- strong painkillers (opioids) (e.g. codeine, tramadol, fentanyl, morphine).
- barbiturates used to treat severe sleeping problems and some types of epilepsy (e.g. amylobarbitone, phenobarbital), or other medicines to help you sleep (e.g. zopiclone, zolpidem, diazepam)
- medicines used to reduce or increase blood pressure
- medicines to treat diabetes (e.g. insulin, metformin)
- antihistamines, usually used to relieve symptoms of allergies, prevent or relieve dizziness and sickness, or help you sleep (e.g. cetirizine, loratadine, chlorphenamine, cinnarizine, diphenhydramine)
- antiepileptic medicines, used to treat epilepsy
- medicines called antimuscarinics, used to relax muscles and relieve gut spasms (e.g. hyoscine, dicycloverine, mebeverine), bladder problems (e.g. oxybutynin, tolterodine, trospium), symptoms of Parkinson's disease (e.g. procyclidine, trihexyphenidyl, orphenadrine)

Tranylcypromine tablets with food, drink and alcohol:

Tranylcypromine 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. Whilst you are taking Tranylcypromine tablets, and for two weeks after stopping the tablets, you should avoid foods that are rich in tyramine or dopa such as:

- alcoholic drinks (especially red wine)
- non-alcoholic beers, lagers and wines
- matured cheeses (e.g. cheddar or processed cheese made from mature cheese)
- meat extract, yeast extract or fermented soy bean extract (e.g. Bovril, Oxo, Marmite, gravy granules, stock cubes, packet soups, soy sauce, miso)
- meat, fish, poultry or game which is not fresh – particularly if it has been smoked, hung, dried, fermented or pickled; processed meat or sausages e.g. salami, chorizo, pâté
- broad bean pods, banana skins.

Pregnancy and breast-feeding

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 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:

Tranlycypromine tablets may make you feel drowsy or dizzy or affect your concentration. If affected you should not drive or use machinery. Do 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 medicine.

3. HOW TO TAKE TRANLYCYPROMINE TABLETS

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

The recommended starting dose for adults is 10 mg each morning and 10 mg each afternoon. After a week your doctor might increase your dose to 10 mg each morning, 10 mg at midday and 10 mg each afternoon. Try to take the afternoon dose before 3 pm.

Do NOT take more than three 10 mg tablets in a day unless your doctor tells you to. Your doctor may reduce your dose when you start to feel better.

Elderly patients (above 65 years of age)

If you are elderly, your doctor will start you on a low dose and regularly check your blood pressure. If the dose needs to be increased, this will be done very gradually.

Patients with kidney problems

If you have kidney problems your doctor will want to monitor you closely while you are taking this medicine.

Use in children and adolescents:

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

Taking this medicine

Swallow the tablets whole with water. Continue taking your Tranlycypromine tablets until your doctor tells you to stop.

If you take more Tranlycypromine 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 Tranlycypromine tablets:

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, do not take the dose you have missed. Just take the next dose at the right time.

If you stop taking Tranlycypromine tablets:

DO NOT STOP taking this medicine without talking with your doctor first, even if you feel better. When the time comes to stop, your doctor will want to gradually reduce your dose before you finally stop taking the tablets. If you suddenly stop taking this medicine you may get withdrawal effects such as nausea (feeling sick), vomiting (being sick), sweating and difficulty 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, Tranlycypromine tablets can cause side effects, although not everybody gets them.

Get emergency medical help immediately if you have:

- a throbbing headache, painful or stiff neck, change in heart rhythm, pain in the middle of your chest, nausea (feeling sick) or vomiting (being sick), sweating, pale skin or flushing (reddening) of your skin, enlarged pupils, sensitivity to light where bright lights hurt your eyes. These could be signs that your blood pressure is dangerously high.
- difficulty breathing or swallowing caused by sudden swelling of the throat, face, lips and mouth; sudden swelling of the hands, feet and ankles; skin rash or itching (especially affecting your whole body). These could be signs of a serious allergic reaction.

Contact your doctor or go to a hospital straight away if you have:

- thoughts of killing or harming yourself (see section 2 ‘Thoughts of suicide and worsening of your depression or anxiety disorder’).

Other possible side effects include:**Rare** (may affect up to 1 in 1,000 people):

- blood disorders - tell your doctor straight away if you get a sore throat or high fever or become very tired and pale or notice any unusual bruising or bleeding
- liver damage - tell your doctor straight away if you feel unusually tired, feel sick, have abdominal pain, yellowing of the skin and whites of the eyes (jaundice), very itchy skin, a high temperature (fever), a general sense of feeling unwell
- seeing or hearing things that are not really there (hallucinations)
- feeling very excited and happy, with rapidly changing thoughts and being very active
- the medicine becoming less effective over time, with higher doses needed to relieve the depression; feeling the need to carry on taking the medicine even when it does not work
- burning, prickling sensations, pain or numbness in the hands and feet - this may be a sign of inflamed nerves.

Frequency not known (cannot be estimated from the available data):

- difficulty sleeping (insomnia), sleep disturbances, sleepiness
- anxiety, agitation, restlessness
- dizziness
- headache
- blurred vision
- awareness of an irregular, pounding, or rapid heartbeat (palpitations)
- feeling lightheaded, dizzy or faint when standing up from a sitting or lying position. This is usually temporary but if it continues your doctor may decide to stop your medicine.
- dry mouth, feeling sick (nausea), being sick (vomiting), diarrhoea
- skin rash
- tiredness which is not relieved by sleep and rest
- swelling in the ankles, feet and legs, caused by a build-up of fluid
- putting on weight

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 MHRA 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 box. The expiry date refers to the last day of that month.

This medicinal product 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 10 mg film-coated tablets contain

The active ingredient is tranylcypromine. Each tablet contains 13.68 mg tranylcypromine sulfate which is equivalent to 10 mg tranylcypromine.

The other ingredients are: lactose, maize starch, microcrystalline cellulose, colloidal silica, Opadry II 85F97012 Beige.

What Tranylcypromine tablets look like and contents of the pack

Tranylcypromine tablets are round, beige coloured, film-coated tablets. They are packed in Aluminium PVC/PVDC (Opaque) blisters placed in a printed carton containing 28 or 56 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Blackrock Pharmaceuticals Limited

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