

## **Package leaflet: Information for the user**

### **Tranlycypromine 10 mg coated tablets** tranlycypromine

**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, pharmacist or nurse.
- 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, pharmacist or nurse. 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 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 help bring these substances back to normal levels.

Tranlycypromine is indicated in adults for the treatment of severe depressive episodes in adult patients who have not adequately responded to at least two other antidepressant treatments.

#### **2. What you need to know before you take Tranlycypromine**

##### **Do not take Tranlycypromine:**

- if you are allergic to tranlycypromine or any of the other ingredients of this medicine (listed in section 6)
- if you are taking other MAOIs or have taken other MAOIs within the last two weeks (see Other medicines and Tranlycypromine)
- if you have phaeochromocytoma, which is a tumour of the adrenal glands (glands near the kidneys) which causes high blood pressure
- if you have a tumour, usually in the region of the gastrointestinal tract, which produces substances that increase blood pressure (carcinoid tumours)
- if you have severe heart (cardiovascular) disease or any disease of the blood vessels in the brain
- if you have high blood pressure which is difficult to control
- if you have vascular disease (aneurysms)
- if you have impaired liver function or liver disease
- if you have severe impaired kidney function or kidney disease
- if you suffer from porphyria (an inherited disease affecting the nervous system and skin)
- if you have diabetes insipidus (a pituitary gland disorder leading to excessive thirst and large amounts of urine)
- if you have delirium, an acute state of confusion

- if you have suffered from a condition called malignant hyperthermia (a rare hereditary disease that can lead to a rise in body temperature during anaesthesia)
- if you have uncontrolled hyperthyroidism (overactive thyroid gland, a gland in the neck)
- if you are taking any of the medicines listed under “Do not take” in the “Other Medicines and Tranylcypromine” section of this leaflet.

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

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Tranylcypromine.

Particular caution when taking Tranylcypromine is required,

- while eating and drinking. You must not consume foods and beverages that are rich in tyramine over a period from 1 day before treatment to 14 days after treatment with Tranylcypromine 10 mg coated tablets, which is also referred to as having a low-tyramine diet (see also under: “Tranylcypromine with food, drink and alcohol”). You also must not drink alcohol during treatment with Tranylcypromine. Alcohol changes and strengthens the effects of Tranylcypromine in an unpredictable way.
- if you have too high or too low blood pressure or if you have an overactive thyroid. You must inform your doctor about this. He will then only use Tranylcypromine with careful monitoring of blood pressure.
- if you notice that you have a pathologically increased drive with elevated mood (manic episode). You must immediately inform your doctor or carer about this. In this case, Tranylcypromine must be discontinued. This also applies when depressive disorders are treated in the course of another mental disorder and delusions, hallucinations and abnormal thoughts occur.
- if you have previously abused drugs or alcohol. You must inform your doctor about this.
- if you are having or have had seizures or epilepsy. You must inform your doctor about this. It cannot be excluded that Tranylcypromine will lead to seizures.
- if you have diabetes. You must inform your doctor about this. Your blood glucose levels may decrease during treatment with Tranylcypromine. The dose of insulin and oral medicines must then be adjusted. Your blood glucose values need to be checked more frequently.
- if you have impaired kidney function. You must inform your doctor about this. There is insufficient experience of the treatment of patients with impaired kidney function. Therefore, patients with severely impaired kidney function must not be treated with Tranylcypromine. Patients with impaired kidney function must be carefully monitored (see under 3: “How to take Tranylcypromine”)
- are due to have surgery within the next few weeks
- are taking any of the medicines listed under: “Other Medicines and Tranylcypromine” section of this leaflet.

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

**If you have thoughts about harming yourself or suicide before or while taking Tranylcypromine** talk to your doctor or a pharmacist immediately. It may be helpful to tell a friend or family member that you have a depression. Ask them to read this leaflet. Ask them to tell you if they feel that your depression is getting worse or if they are worried about changes in your behaviour.

### ***Suicidal thoughts 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 have shown an increased risk of **suicidal behaviour** in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

#### *Serotonin syndrome*

Serotonin syndrome is a serious condition, with symptoms such as high blood pressure, irritability and rising body temperature, which may occur at concomitant use of tranylcypromine with certain other medicines. See “Other medicines and Tranylcypromine” in this leaflet for examples of these medicines.

#### **Elderly people**

If you are over 65 years of age, your doctor will increase the total daily dose slowly, keeping the dosage as low as possible and checking your blood pressure regularly (see section 3. "Dosage in elderly patients").

#### **Children and adolescents**

Tranylcypromine must not be used in children under 18 years of age (see section 3 ‘Use in children and adolescents’).

#### **Other medicines and Tranylcypromine**

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 with the following medicines**

- other antidepressants which are serotonin reuptake inhibitors such as all selective serotonin reuptake inhibitors (SSRIs) including citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline. Taking your medicine with these products may cause the following serious side effects: high blood pressure, sweating, extreme agitation, confusion, muscle stiffness (known as serotonin syndrome)
- selective serotonin-norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine and duloxetine
- tricyclic antidepressants (such as clomipramine, imipramine, amitriptyline, desipramine, nortriptyline and protriptyline)
- tetracyclic antidepressants (such as mirtazapine)
- other MAO inhibitors (such as fenelzine)
- sumatriptan, zolmitriptan, naratriptan, rizatriptan, eletriptan and other so-called “triptans”, medicines for the treatment of migraine. There is a risk of serotonin syndrome (see first item)
- pethidine, nefopam, tramadol (medicines to treat severe pain) dextromethorphan (present in cough suppressants)
- 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)
- amphetamines
- L-Tryptophan. Behavioural and neurological symptoms have been reported
- buspirone, used to treat anxiety
- bupropion, a medicine to help you stop smoking
- levodopa, a medicine to treat Parkinson’s disease
- general anaesthetics such as propofol, which are used in surgery.

#### **Tranylcypromine must be taken with caution if you are taking the following medicines**

- strong pain killers e.g. codeine
- medicines to treat seizures/fits, e.g. carbamazepine
- medicines for high blood pressure (e.g. guanethidine, reserpine, methyl dopa)
- medicines to treat diabetes (e.g. insulin, metformin)

- medicines that have a calming/sedative effect on the brain may be strengthened if they are taken at the same time as Tranylcypramine e.g. neuroleptics, antidepressants, benzodiazepines and analgesic
- buprenorphine. The triggering of a potentially life-threatening serotonin syndrome has been reported in rare cases for certain agents for the treatment of depression and simultaneous treatment with buprenorphine (agent for severe pain). It cannot be ruled out that a serotonin syndrome may also occur with simultaneous treatment of buprenorphine and Tranylcypramine
- dopamine, a medicine used to treat certain heart conditions
- antihistamines used to treat allergies, e.g. cetirizine.

### **Interactions during surgery and dental procedures**

If you are scheduled for surgery in which **anaesthetics** and certain **analgesics** will be used, your doctor needs to discontinue Tranylcypramine s for 14 days beforehand. Interactions have been reported between medicines that are similar to Tranylcypramine and anaesthetics, which in some cases were serious (e.g. unstable circulation, coma).

Please tell your anaesthetist before the operation that you are taking Tranylcypramine. You must not under any circumstances be administered **pethidine**, a strong analgesic used, for example, for postoperative pain, if you are being treated with Tranylcypramine.

**Local anaesthetics:** The usually low concentrations of epinephrine or norepinephrine in agents for local numbing (local anaesthetics), e.g. in dentistry procedures or in eye drops, do not constitute a particular risk for patients treated with Tranylcypramine.

Please be aware that this information may also apply when the medicines are used only for short periods.

### **Tranylcypramine with food, drink and alcohol**

Intake of certain food and drinks should be avoided whilst you are taking Tranylcypramine. You must strictly follow the dietary advice from your doctor and dietician.

Starting 1 day before treatment with tranylcypramine, during treatment and for up to 14 days after the last dose, you must avoid certain foods and beverages with a relatively high content of biogenic amines (e.g. air-cured, fermented or aged meat, sausages, salami, fish or poultry, mature cheese, broad beans, fish sauces, all fermented soy products, yeast extracts, fermented beverages like beer or wine). This low-tyramine diet applies to every dose of tranylcypramine.

Tranylcypramine stops the body's breakdown of a substance called tyramine which is found in large amounts in certain foods. If this substance is not broken down, it can cause very high blood pressure (hypertensive crisis). See section 4 - Possible side effects of this leaflet.

### **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.

Tranylcypramine tablets should NOT be used during pregnancy or breastfeeding unless your doctor thinks it is essential. This medicine may pass into breast milk.

Your doctor will decide whether you should ab lactate (gradually reduce) or stop therapy with Tranylcypramine. Effects of Tranylcypramine on fertility are unknown.

### **Driving and using machines**

Do not drive or use machines when you first start to take this medicine as it may make you feel drowsy or dizzy or affect your concentration. Wait 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.

### **Tranylcypramine 10 mg coated tablets contains Sucrose**

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 contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

### **3. How to take Tranylcypromine**

Always take this medicine exactly as your doctor or pharmacist has told you. Do **NOT** take more than your doctor tells you to. Check with your doctor or pharmacist if you are unsure. Swallow the tablets whole with a glass of water.

#### Recommended dose for adults

- treatment should be started with 10 to 20 mg per day (10 mg in the morning **or** 10 mg in the morning and 10 mg in the afternoon)
- try to take the last dose before 3 p.m. in the afternoon to avoid sleep disturbances
- the number of tablets you take each day may be adjusted by your doctor. This depends on how you respond to the medicine. The maximum total daily dose is 60 mg tranylcypromine.

After the depressive disorder has improved, your doctor may reduce the total daily dose.

#### Dosage in the elderly:

- 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.

#### **Use in children and adolescents:**

Tranylcypromine must not be used in children under 18 years of age.

#### **If you take more Tranylcypromine 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 Tranylcypromine**

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 Tranylcypromine**

Continue to take Tranylcypromine 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 usually decrease your dose gradually as stopping the tablets suddenly may cause ill-effects such as nausea (feeling sick), vomiting (being sick), feeling unwell vivid nightmares, fits, loss of contact with reality, usually including false beliefs about what is taking place or who one is (delusions) and seeing or hearing things that aren't there (hallucinations). Symptoms will usually start 24 to up 72 hours after you stop taking this medicine abruptly.

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 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:

**Rare: may affect up to 1 in 1,000 people**

- soreness in the hands and feet, which may be a sign of inflamed nerves
- a need to take increasingly higher doses to obtain the same effect (tolerance)
- seeing or hearing things that are not real (hallucinations)
- elated moods and excitability (hypomania)
- drug dependence (addiction).

**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.

**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 HPR

Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Tranylecypromine**

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, after EXP. The expiry date refers to the last day of that month.

Store below 30°C. Store in the original package.

Bottle: discard 28 days after opening.

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 Tranylecypromine 10 mg coated tablets contains**

- the active substance is tranylcypromine (as tranylcypromine sulfate). Each sugar-coated tablet contains 10mg of the active substance.
- the other ingredients are: Calcium sulfate dihydrate, Sucrose, Maize starch, Croscarmellose, Magnesium stearate, Gelatin, Talc, Calcium carbonate, Titanium dioxide and Carnauba wax.

#### **What Tranylcypromine looks like and contents of the pack**

Tranylcypromine are off-white, round, biconvex, sugar-coated tablet.

They are packed in:

- PVC or PVC-PVDC/ Aluminium blisters, or
- HDPE bottle with HDPE moisture-proof child resistant closure

The pack sizes are 1, 8, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 100 or 112 tablets.

Not all pack-sizes may be marketed.

#### **Marketing Authorisation Holder**

Activase Pharmaceuticals Limited  
11 Boumpoulinas Street  
Nicosia 1060 Cyprus.

#### **Manufacturer**

Elara Pharmaservices Europe Limited  
Regus Block 1, Blanchardstown Corporate Park,  
Ballycoolin Road, Blanchardstown, Dublin 15,  
D15 AKK1, Ireland.

#### **This medicine is authorised in the Member States of the European Economic Area under the following names:**

Ireland: Tranylcypromine 10 mg coated tablets

Netherland: Tranylcypromine Activase 10 mg omhulde tabletten

Germany: Tranylcypromin Activase 10 mg überzogene Tabletten

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