

Tranlycypromine 10mg Tablets

(tranlycypromine sulphate)

Patient Information Leaflet

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.

What is in this leaflet:

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

1 What Tranlycypromine 10mg Tablets are and what they are used for

Tranlycypromine Tablets contains 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 moderate to severe depression in adults. It can also help you if you are having feelings of fear (phobia) which sometimes occurs in depression. This medicine is often used when other types of antidepressant medicines have not worked.

2 What you need to know before you take Tranlycypromine 10mg 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)
- 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 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 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.

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

Tranlycypromine Tablets is not recommended for children under 18 years old (see section 3 'Use in children and adolescents').

Other medicines and Tranlycypromine 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 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. 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, methyl dopa)
- medicines to treat diabetes (e.g. insulin, metformin)
- antihistamines used to treat allergies, e.g. cetirizine.

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

Tranlycypromine Tablets with food, drink and alcohol

You should **NOT** take alcohol (especially red wine) whilst you are taking Tranlycypromine Tablets. This includes non-alcoholic beer or lager. Tranlycypromine Tablets 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 Tranlycypromine 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 planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Tranlycypromine 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 ab lactate (gradually reduce) or stop therapy with Tranlycypromine Tablets. Effects of Tranlycypromine Tablets on fertility are unknown.

Driving and using machines

Tranlycypromine 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.

Tranlycypromine Tablets contains:

- Ponceau 4R (E124): which may cause allergic reactions.
- sucrose: 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 10mg 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 mid-day
- 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.

Tranlycypromine 10mg Tablets

(tranlycypromine sulphate)

Patient Information Leaflet (continued)

Use in children and adolescents

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

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

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 Tranlycypromine Tablets

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 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, Tranlycypromine Tablets can cause side effects, although not everybody gets them.

If you eat foods or take medicines which interact with the active ingredient 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 (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, diarrhea, 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, tranlycypromine, 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 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 Tranlycypromine 10mg Tablets

Keep out of the sight and reach of children.

Do not store above 25°C.

Store in the original container to protect from light.

Keep the container tightly closed to protect from moisture.

Do not take this medicine after the expiry date shown on the container or carton label. The expiry date refers to the last day of the month. If your doctor tells you to stop taking the medicine, take any remaining medicine back to the pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.

If your medicine becomes discoloured or show any other signs of deterioration, ask your pharmacist who will advise you what to do.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

6 Contents of the pack and other information

Each tablet contains 10mg of the active substance, tranlycypromine as tranlycypromine sulphate.

Tranlycypromine 10mg Tablets also contains sucrose, maize starch, calcium sulphate dihydrate (E516), carmellose sodium, magnesium stearate (E470b). The coating contains gelatine, sucrose, docusate sodium, purified talc (E553b), light kaolin (E559), calcium carbonate (E170), ethylcellulose, acacia (E414), ponceau 4R (E124), maize starch, titanium dioxide (E171) and carnauba wax (E903).

What Tranlycypromine 10mg Tablets look like and contents of the pack

Tranlycypromine 10mg Tablets are geranium red coloured, bi-convex, sugar-coated tablets.

They are packed in plastic containers with 28 tablets.

Manufacturer and Licence Holder

This medicine is manufactured by Dales Pharmaceuticals Ltd., Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, UK and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

POM PL 15184/1390 Tranlycypromine 10mg Tablets

Revision date: 20/01/21

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone Lexon UK Limited,

Tel: 01527 505414 to obtain the leaflet

in a format suitable for you.

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- medicines that treat Parkinson's disease, e.g. levodopa
- dopamine, a medicine used to treat certain heart conditions
- the pain killers pethidine and nefopam
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- 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. 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, methyl dopa)
- medicines to treat diabetes (e.g. insulin, metformin)
- antihistamines used to treat allergies, e.g. cetirizine.

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

Tranlycypromine Tablets with food, drink and alcohol

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Pregnancy, breast feeding and fertility

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Driving and using machines

Tranlycypromine 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.

Tranlycypromine Tablets contains:

- Ponceau 4R (E124): which may cause allergic reactions.
- sucrose: 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 10mg 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:

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- this dose may be increased by your doctor to three tablets a day. Take the extra tablet at mid-day
- 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.

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Tranlycypromine 10mg Tablets

(tranlycypromine sulphate)

Patient Information Leaflet (continued)

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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, Tranlycypromine Tablets can cause side effects, although not everybody gets them.

If you eat foods or take medicines which interact with the active ingredient 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.
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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, diarrhea, 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

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They are packed in plastic containers with 28 tablets.

Manufacturer and Licence Holder

This medicine is manufactured by Millmount Healthcare Limited, Block-7, City North Business Campus, Stamullen, Co. Meath, K32 YD60, Ireland and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

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