

Package Leaflet: Information for the patient

Tranlycypromine Eignapharma 20 mg film-coated tablets
Tranlycypromine Eignapharma 40 mg film-coated tablets

For use in adults
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 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 Eignapharma is and what it is used for
2. What you need to know before you take Tranlycypromine Eignapharma
3. How to take Tranlycypromine Eignapharma
4. Possible side effects
5. How to store Tranlycypromine Eignapharma
6. Contents of the pack and other information

1. What Tranlycypromine Eignapharma is and what it is used for

Tranlycypromine Eignapharma is a medicine to treat **depression** (antidepressant) and belongs to the group of MAO (monoamine oxidase) inhibitors.

Tranlycypromine Eignapharma is used for the treatment of depressive disorders (episode of so-called major depression) in adults.

Tranlycypromine Eignapharma should be used when other antidepressants have not brought about a satisfactory improvement or cannot be used, i.e. as a reserve antidepressant.

2. What you need to know before you take Tranlycypromine Eignapharma

Do not take Tranlycypromine Eignapharma

- if you are **allergic** to tranlycypromine or any of the other ingredients of this medicine listed in section 6;
- if you have hormone-producing **tumours** of the **adrenal medulla** (phaeochromocytoma);
- if you have a **tumour**, usually in the region of **gastrointestinal tract**, which produces substances that increase blood pressure (carcinoid);
- if you suffer from disorders of the blood vessels of the brain (e.g. after a **stroke**);
- if you have blood vessel malformations such as widening of arterial blood vessels (aneurysms);
- if you suffer from severe forms of **high blood pressure** or **cardiovascular diseases**;
- if you suffer from liver dysfunction or **liver diseases**;
- if you suffer from **severe kidney dysfunction** or **kidney diseases**
- if you suffer from metabolic disorders in the **blood-producing system** (porphyria);
- if you suffer from an illness characterised by **increased urine output** and **increased thirst** with increased consumption of liquids (Diabetes insipidus);
- if you are in an **acute state of confusion** (delirium);

- if you suffer from **acute intoxication with central nervous system depressants** (e.g. sleeping pills, analgesics and psychotropic drugs such as neuroleptics, antidepressants, lithium) or alcohol;
- if you have a condition known as **malignant hyperthermia** (a rare condition that can occur with anaesthesia), even when this condition has occurred in the past.
- if you are a child or adolescent.

Do not take Tranylcypromine Eignapharma if you are taking/using any of the following medicines:

- **citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline** and other drugs known as selective serotonin reuptake inhibitors (a group of antidepressants). There is a risk of triggering what is known as serotonin syndrome, with symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control eye movement, agitation, increase in blood pressure, hallucinations, coma, excessive sweating, trembling, exaggerated reflexes, increased muscle tension, irritability, and a rise in body temperature above 38 °C.
- **vortioxetine**, a drug used to treat depression. There is a risk of serotonin syndrome (see above).
- **venlafaxine, duloxetine and milnacipran**, drugs used to treat depression. There is a risk of serotonin syndrome (see above).
- **sibutramine**, a drug used for weight loss (now out of use). There is a risk of serotonin syndrome (see above).
- **clomipramine**, a drug used to treat depression. There is a risk of serotonin syndrome (see above).
- **sumatriptan, zolmitriptan, naratriptan, rizatriptan, eletriptan** and other agents known as “triptans”, used to treat migraine. There is a risk of serotonin syndrome (see above).
- **L-tryptophan**
- **buspirone**, a drug used to treat anxiety and restlessness. A severe rise in blood pressure has been reported.
- **imipramine**, a drug used to treat depression. Serious adverse effects such as irritability, coma, rise in body temperature, seizures and severe fluctuations in blood pressure, especially a rise in blood pressure, can occur.
- certain **drugs to increase the blood pressure**, which can also be contained in medicines for nasal congestion, coughs or flu and in appetite suppressants (known as indirect sympathomimetics e.g. ephedrine, amezinium methylsulfate, phenyl propanolamine, cathine, amfepramone, metamfepramone and amphetamines - also known as ‘**wake-up amines**’). There is a risk of severe hypertensive crisis, characterised by sudden increase in blood pressure.
- **pethidine** (medicine for severe pain), **tramadol** (medicine for moderate pain) and **dextrometorphan** (contained in cough medicines). Life-threatening side effects on the central nervous system or a life-threatening influence on respiratory and circulatory functions are possible.
- **disulfiram**, a medicine used to treat chronic alcoholism. Delirium may occur.
- **levodopa** (medicine for the treatment of Parkinson’s disease), if this is not combined with drugs such as **benserazide** or **carbidopa**. There is the risk of uncontrolled rise of blood pressure.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tranylcypromine Eignapharma.

When taking Tranylcypromine Eignapharma, you need to be especially careful

- about eating and drinking. You must not consume **foods or drinks** with increased levels of tyramine from 1 day before treatment to 14 days after the treatment with Tranylcypromine Eignapharma. This is also known as a low-tyramine diet (see Section 2 under “Taking Tranylcypromine Eignapharma with food, drink and alcohol”). You must also **not drink any alcohol** during treatment with Tranylcypromine Eignapharma. Alcohol changes and enhances the effect of Tranylcypromine Eignapharma in an unpredictable way.
- if you suffer from high or low blood pressure or if you have an overactive **thyroid**. You should inform your doctor of this. Then your doctor will administer Tranylcypromine

- Eignapharma only with careful monitoring of your blood pressure.
- if you notice an unusually increased drive with elated mood (**manic episode**). You should then inform your doctor or carer immediately. In this case Tranylcypramine Eignapharma must be discontinued. This also applies if you are being treated for depressive disorders in the course of other mental illnesses and **delusions, hallucinations and thought disturbances** occur.
 - If you have misused **drugs** or **alcohol** in the past. You should inform your doctor of this.
 - if you suffer from or have suffered from seizures or epilepsy. You should inform your doctor of this. The possibility cannot be ruled out that Tranylcypramine Eignapharma leads to seizures.
 - if you are taking **buprenorphine** (medicine for severe pain) (see also section 2 under (“Taking Tranylcypramine Eignapharma with other medicines”).
 - if you suffer from **diabetes**. You should inform your doctor of this. Your blood sugar levels may fall during treatment with Tranylcypramine Eignapharma. The dosage of insulin and oral medication must then be adjusted. Your blood sugar levels should be checked more often.
 - if you suffer from **kidney dysfunction**. You should inform your doctor of this. There are insufficient clinical data on the treatment of patients with impaired kidney function. Therefore, patients with severe renal impairment should not be treated with Tranylcypramine Eignapharma. Patients with impaired kidney function should be monitored carefully (see section 3. “How to take Tranylcypramine Eignapharma”).

Thoughts of suicide and worsening of your depression:

If you are depressed you may sometimes have thoughts of harming or killing yourself (suicide). These may be increased when you first take antidepressants, as all these medicines take time to work, usually around two weeks but sometimes even longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Results from clinical trials have shown an increased risk of attempted suicide in young adults up to 25 years of age with a psychiatric condition who were treated with an antidepressant.

See your doctor or go to hospital immediately if at any time you have thoughts of harming yourself or taking your own life.

You may find it helpful to tell a friend or relative that you are depressed. Ask that person to read this leaflet. Ask them to tell you if they think that your depression is getting worse or if they are worried about changes in your behaviour.

Elderly patients

If you are over 65 years old, your doctor will slowly increase the total daily dose, keep the dose as low as possible and check your blood pressure regularly (see section 3. “Dosage in elderly patients”).

Children and adolescents

Tranylcypramine Eignapharma must not be administered to children and adolescents.

Other medicines and Tranylcypramine Eignapharma

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Tranylcypramine Eignapharma must not be taken at the same time as certain medicines. Read about this list in section 2 “What do you need to know before taking Tranylcypramine Eignapharma” carefully read the section “Do not take Tranylcypramine Eignapharma if you are taking any of the following medicines” and talk to your doctor. Please additionally note that for

certain **drugs** which are **incompatible with** Tranylcypromine Eignapharma a break in treatment must be observed.

If you **switch** to Tranylcypromine Eignapharma from any other drug the **treatment break** after the previously administered medicine is the time it takes for the active substance to be eliminated from the body. If you have recently completed treatment with Tranylcypromine Eignapharma, you must wait at least 14 days before you can start taking any other medicine.

Enhancement of the risk of side effects from Tranylcypromine Eignapharma

Avoid taking Tranylcypromine Eignapharma at the same time as certain so-called direct sympathomimetics (e.g. contained in medicines to treat poor circulation to relax the bronchial muscles or in) nasal drops.

If you suffer from long-lasting depression that has been treated with antidepressants (tricyclic antidepressants, e.g. amitriptyline) without satisfactory improvement so far, in individual cases your doctor may administer an additional dose of Tranylcypromine Eignapharma with a slow dose increase. However, this does not apply to clomipramine and antidepressants given by infusion.

Tranylcypromine Eignapharma increases the effects of other drugs and increase of the risk of side effects

The antihypertensive effect of medicines used to treat high blood pressure (**e.g. guanethidine, methyldopa**) can be enhanced by Tranylcypromine Eignapharma. In individual cases, however, an increase in blood pressure with states of agitation can also be triggered.

The effect of **insulin** and oral medicines for diabetes may be increased (see Section 2 under “Warnings and precautions for Use”).

Side effects of **bupropion or amfebutamone** (a medicine for smoking cessation) such as seizures and states of agitation, can be increased by treatment with Tranylcypromine Eignapharma at the same time. Therefore, this combination should be avoided.

The effect of **neuroleptics, antidepressants, benzodiazepines** and **pain killers** (medicines that have a calming effect on the brain) can be increased if Tranylcypromine Eignapharma is taken at the same time.

Certain antidepressants, which are known to cause a potentially life-threatening serotonin syndrome, and concomitant treatment with buprenorphine (a medicine for severe pain) have been reported in rare cases to cause serotonin syndrome. The possibility cannot be ruled out that serotonin syndrome may also occur with simultaneous treatment with buprenorphine and Tranylcypromine Eignapharma. Symptoms of serotonin syndrome are described in section 2 under “Do not take Tranylcypromine Eignapharma if you are taking any of the following medicines”. Tell your doctor if you get symptoms of serotonin syndrome.

Interaction during surgery and dental treatment

If you are due to have surgery in which you will receive anaesthetics and certain pain killers, your doctor should tell you to stop taking Tranylcypromine Eignapharma 14 days before the planned date of surgery. Interactions of medicines similar to Tranylcypromine Eignapharma have been reported with anaesthetics, some of which have been serious (e.g. unstable circulation, coma).

Please tell the anaesthetist before the surgery that you are taking Tranylcypromine Eignapharma. Pethidine, a strong pain killer used, for example, to treat postoperative pain, must not be given to you if you are being treated with Tranylcypromine Eignapharma.

Inhalation anaesthetics (vaporisable agents used to induce anaesthesia) pose no greater risk to patients treated with Tranylcypromine Eignapharma than to any other patients undergoing anaesthesia. Ether is the only exception and therefore cannot be used.

Local anaesthetics: The usually low concentrations of adrenaline or noradrenaline in local anaesthetics, e.g. for dental procedures or in eye drops, do not present any particular risk to patients treated with Tranylcypromine Eignapharma.

Please note that this information may also apply to recently administered medicines.

Tranylcypromine Eignapharma with food, drink and alcohol

When taking Tranylcypromine Eignapharma, you must bear in mind the particular **problem of biogenic amines** (especially tyramine). Biogenic amines are natural ingredients of many food. Their content in unprocessed vegetable and animal-based food is usually very low. The content of biogenic amines can be significantly increased by certain processing methods in which microbiological conversions take place (e.g. fermentation in cheese production) but also as a result of excessively warm storage or spoilage.

In low concentrations, the biogenic amines are harmless to humans since the human body has enzymes (mono-oxidases and diamine oxidases) that break down amines. However, the intake of higher concentrations of biogenic amines can lead to a toxic (poisonous) effect, especially if medicines such as Tranylcypromine Eignapharma with a blocking effect on amine oxidases are being taken at the same time. The toxic effect of the biogenic amines can manifest itself as nausea, vomiting, throbbing headache in the back of the head and disorders of the nervous system, and particularly as changes in blood pressure up to a very severe increase in blood pressure (hypertensive crisis).

During treatment with Tranylcypromine Eignapharma you must avoid certain foods and drinks with a relatively high content of biogenic amines for 1 day before the treatment, during treatment and for up to 14 days after the last dose. This low tyramine diet applies to every dose of Tranylcypromine Eignapharma.

Please use **all food** in as **fresh a state** as possible. Eat uncooked or undercooked food on the day it is prepared. Consume opened semi-preserved and thawed frozen food products immediately. You can keep opened whole preserves or fully cooked food in the refrigerator for a maximum of 48 hours before consumption.

Set your refrigerator to a low temperature of $< 4^{\circ}\text{C}$ if possible.

You will find a list of **permitted foods, prohibited foods and foods permitted in small quantities** (according to their biogenic amines content) at the end of the leaflet. Please note: Per meal, only one permitted foodstuff in small quantity is recommended.

You must also **not drink any alcohol** during treatment with Tranylcypromine Eignapharma. Alcohol changes and enhances the effect of Tranylcypromine Eignapharma in an unpredictable way.

Pregnancy and breast-feeding

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.

Pregnancy

There are insufficient data for the administration of tranylcypromine in pregnant women.

Tranylcypromine can have negative effects on the unborn child. Existing high blood pressure in the mother can be increased and reduced blood flow to the placenta is also possible.

Your doctor will therefore not prescribe Tranylcypromine Eignapharma during pregnancy, especially in the first trimester, unless it is absolutely necessary. Please tell your doctor immediately if you are planning to become pregnant or if you think that you might be pregnant. Your doctor may then switch to another medicine if necessary.

Breast-feeding

You should not take Tranylcypromine Eignapharma while breast-feeding. If your doctor considers it absolutely necessary to use while you are breast-feeding, you should stop breast-feeding.

Driving and using machines

Tranlycypromine has small or moderate influence on your ability to drive and use machines. Therefore Tranlycypromine Eignapharma may impair ability to drive and use machines, even when used as directed, especially during the first few days of treatment,

This applies to a greater extent in combination with substances that affect the central nervous system.

Remember that you must not drink alcohol during treatment with Tranlycypromine Eignapharma

During the first days of treatment, you should **not drive a car or other vehicle**, operate machinery or electrical equipment, or do any work that requires a high level of attention, e.g. working without a firm foothold.

The decision is made on a case-by-case basis by the treating doctor, taking into consideration the individual's response and the relevant dose.

Tranlycypromine Eignapharma contains 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 Eignapharma

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

Unless otherwise prescribed by your doctor, the recommended dose is as follows:

At the beginning of treatment, take 10 mg tranlycypromine once a day in the morning. Your doctor may increase this dose by 10 mg tranlycypromine per week up to a total daily dose that is suitable for you.

The recommended total daily dose is 20 mg to 40 mg tranlycypromine.

Typically, you can expect the mood-boosting and anti-depressant effect after 1 to 3 weeks. Your doctor will check the dosage during therapy and adjust if necessary.

If you do not respond adequately to the recommended daily dose of 20 mg to 40 mg tranlycypromine, your doctor may further increase the dose in increments of 10 mg tranlycypromine per day under inpatient conditions every 1 to 3 weeks. The maximum total daily dose is 60 mg tranlycypromine.

After your depressive symptoms have improved, your doctor may reduce the daily dose to a maintenance dose of 10 mg to 20 mg tranlycypromine.

Dosage in elderly patients

In elderly patients, your doctor will increase the dose slowly with regular blood pressure monitoring. (see section 2 under "Elderly people")

renal impairment

Patients with severe renal impairment should not be treated with Tranlycypromine Eignapharma as there is a lack of therapeutic experience. If you suffer from impaired kidney function, your doctor will carefully monitor the course of your treatment (see Section 2 under "Warnings and Precautions for use").

hepatic impairment

Tranlycypromine Eignapharma must not be used in to treat patients with impaired liver function (see Section 2 under "Do not take Tranlycypromine Eignapharma").

Use in children and adolescents

Tranlycypromine Eignapharma must not be used in children and adolescents (see Section 2 under "Do not take Tranlycypromine Eignapharma").

Method of administration

The film-coated tablets are for oral use.

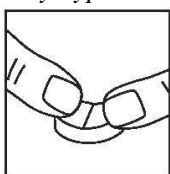
Swallow the film-coated tablets whole with sufficient liquid (preferably a glass of drinking water).

The film-coated tablet can be divided into equal doses (halves).

The total daily dose can be divided into 1 to 3 doses. To avoid sleep disturbances, do not take the last Tranylcypromine Eignapharma later than 3pm

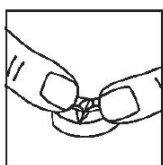
Instructions for easier divisibility

Tranylcypromine Eignapharma 20 mg film-coated tablets



Place the tablet on a firm, flat surface (score line facing up). Press the top of the tablet with both thumbs or forefingers to the left and right of a score line to break the tablet.

Tranylcypromine Eignapharma 40 mg film-coated tablets



Place the tablet on a firm, flat surface (score line facing up). Press the top of the tablet with both thumbs or forefingers to the left and right of a score line to break the tablet. When dividing into 4 equal parts, the centre of the tablet must be pressed with the thumb.

Duration of treatment

The duration of a period of treatment with Tranylcypromine Eignapharma until improvement of a depressive illness is generally at least 4 to 6 weeks. The doctor treating you may want to continue treatment with Tranylcypromine Eignapharma at a reduced dose for 4 to 6 months.

If you are switching to Tranylcypromine Eignapharma from another treatment for depression, your doctor will generally prescribe a break from treatment of at least 7 days and only prescribe 10 mg tranylcypromine for at least the first week after starting treatment.

It is important not to stop the treatment or change the dose without your doctor's advice.

Talk to your doctor or pharmacist if you think that the effect of Tranylcypromine Eignapharma is too strong or too weak.

If you take more Tranylcypromine Eignapharma than you should

Inform your doctor immediately; he/she will decide what **action** to take.

Symptoms of overdose are confusion, agitation, brain seizures, clouding of consciousness unconsciousness accompanied by fever and impairment of respiratory function (including respiratory arrest), the cardiovascular system (severe fluctuations of blood pressure, irregular heart rate) and the muscles (severe muscle cramps).

Under certain circumstances, the signs of an overdose may not appear for several hours after taking the tablet.

If you forget to take Tranylcypromine Eignapharma

Do not take a double dose to make up for the forgotten dose. Take the next dose when due.

If you stop taking Tranylcypromine Eignapharma,

Withdrawal symptoms such as anxiety, restlessness, trouble sleeping, drowsiness or delirium may occur. Avoid suddenly stopping long-term, high-dose treatment with Tranylcypromine Eignapharma. Always stop the treatment under medical supervision by slowly reducing the dose. Please tell your doctor if you experience these withdrawal symptoms after reducing the dose or stopping Tranylcypromine Eignapharma. You may need to go back to the last dose you took and then decrease it in smaller steps.

If you have any further questions on the taking 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.

Significant side effects or signs to look out for and what to do if you are affected

If you experience any of the side effects listed below, stop taking Tranylcypromine Eignapharma and contact your doctor as soon as possible.

If an abnormally elevated or irritable mood (manic mood) occurs, Tranylcypromine Eignapharma should be discontinued immediately.

Other side effects

The following undesirable effects are very common, especially at the start of treatment: Trouble sleeping, low blood pressure, drop in blood pressure when you stand up.

Very common (may affect more than 1 in 10 people)

- Insomnia, sleep disorders
- Drop in blood pressure when standing up, low blood pressure

Common (may affect up to 1 in 10 people)

- Anxiety, restlessness, agitation
- Dizziness, dry mouth, tiredness
- Palpitations
- High blood pressure (hypertension)
- Weight gain, weight loss, weakness

Uncommon (may affect up to 1 in 100 people)

- Severe increase in blood pressure (hypertensive crisis) which may be accompanied by a rapid heartbeat or racing heart, facial flushing, headache (especially at the back of the head), stiff neck, nausea, vomiting and extreme sensitivity of light.
In individual cases, particularly when dietary restrictions are not observed and when the medicinal product interacts with other medicines, they can lead to bleeding in the brain (intracranial bleeding) (see section 2 under “Tranylcypromine Eignapharma with food, drinks and alcohol” or “Other medicines and Tranylcypromine Eignapharma”).

Rare (may affect up to 1 in 1,000 people)

- Anaemia, reduced number of certain blood cells
- Psychological dependency

- Seizures
- Swelling due to accumulation of tissue fluid (oedema)
- Constipation, diarrhoea
- Sweating
- Muscle cramps, muscular pain
- Orgasm disorders, erectile dysfunction, disorders of the ability to ejaculation
- Delusions (hallucinations), confusion (rare/very rare)
- Nerve pain (polyneuropathy) (rare/very rare)
- Blurred vision (rare/very rare)
- Liver function disorders, increase in activity of liver enzymes (rare/very rare)
- Allergic skin rash (rare/very rare)
- Joint pain (rare/very rare)
- Increase in body temperature (rare/very rare)

Very rare (may affect up to 1 in 10,000 people)

- Hair loss
- Increased release of the hormone ADH, which regulates the bodies fluid balance and results in reduced urine production

Not known (frequency cannot be estimated from the available data)

- Suicidal thoughts, suicidal behaviour*
 - * Cases of suicidal ideation and suicidal behaviour have been reported during treatment with medicinal products containing the same active substance as Tranlycypromine Eignapharma, or a short time after stopping treatment (see section 2 under “Warnings and precautions for Use”).
- There are reports that tranlycypromine has led to trembling, drowsiness and light-headedness in patients.
- There are reports that tranlycypromine has led to tinnitus (ringing in the ears) in patients.
- There are reports that tranlycypromine has led to nausea with and without vomiting as well as non-specific gastrointestinal symptoms in patients.
- There are reports that tranlycypromine has led to muscle twitching in patients.
- There are reports that tranlycypromine has led to urination problems in patients.
- There are reports that tranlycypromine has led to breast pain, sensations of cold and states of exhaustion in patients.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the [HPRA 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 Tranlycypromine Eignapharma

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 blister and the carton after EXP. The expiry date refers to the last day of the month.

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 throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tranlycypromine Eignapharma contains

The active substance is tranlycypromine.

Tranlycypromine Eignapharma 20 mg film-coated tablets

Each film-coated tablet contains 27.36 mg tranlycypromine sulphate, corresponding to 20 mg tranlycypromine.

Tranlycypromine Eignapharma 40 mg film-coated tablets

Each film-coated tablet contains 54.72 mg tranlycypromine sulphate, corresponding to 40 mg tranlycypromine.

The other ingredients are:

Tablet core:

cellulose, microcrystalline; lactose anhydrous; maize starch; silica colloidal, anhydrous.

Film-coating:

polyvinyl alcohol; titanium dioxide (E171); macrogol 4000; talc.

What Tranlycypromine Eignapharma looks like and contents of the pack

Film-coated tablet

Tranlycypromine Eignapharma 20 mg film-coated tablets

White to off-white, round-shaped film-coated tablets with a score line on one side and score line on the other

The film-coated tablet can be divided into equal doses.

Tranlycypromine Eignapharma 40 mg film-coated tablets

White to off-white, round-shaped film-coated tablets with a cross-shaped score line on one side and cross-shaped score line on the other

The film-coated tablet can be divided into equal doses.

They are available in blister packs containing 28 tablets.

Marketing Authorisation Holder

Neuraxpharm Ireland Limited

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Manufacturer

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This leaflet was last revised in 10/2022.

Annex

Please note the following: At any meal, do not eat more than one food that is permitted in small amounts.

	Prohibited	Permitted in small amounts	Permitted
Milk and dairy products	<ul style="list-style-type: none"> • Brine hard cheese (e.g. Emmental, Bergkäse, Parmesan and similar cheeses for slicing and grating made from raw milk • Cheese containing edible moulds e.g. Roquefort, Camembert and similar varieties • Smear-ripened cheese, e.g. Limburger, Butterkäse ‘butter cheese’, red smear cheese, Harzer cheese Handkäse(sour milk-cheese) 	<ul style="list-style-type: none"> • Semi-hard cheese for slicing (stored cold and for a short time, little odour) made from pasteurised milk (e.g. Gouda, Cheshire, Edam): 1 x 20 g slice • Mozzarella or Feta-type cheese each made from pasteurised milk with cow’s milk content up to 20 g • Yoghurt, kefir and drinks/dishes containing them, approx. 250 ml • Vanilla and fruit-flavoured ice-cream: 1 scoop 	<ul style="list-style-type: none"> • Fresh raw milk (4 °C, to be consumed within 48 h from farm) • Milk, pasteurised (4 °C, can be kept for 48 hours from the dairy, corresponds to the expiry date) • Homogenised milk, UHT milk and mixed milk products made from them (milk flavoured with fruit, vanilla, chocolate, etc.) • Butter, cream, sour cream, buttermilk, coffee cream, quark, cream cheese and preparations with herbs, vegetables, etc. • Processed cheese
Meat and meat products	<ul style="list-style-type: none"> • Beef and poultry liver • Kidneys of all farmed animals and game • Stock and bouillon cubes • Game meat and other meat products with strong ageing and a strong odour Matured hard salami and similar raw sausages, especially with edible mould casing 	<ul style="list-style-type: none"> • pork liver: maximum 100 g • Fresh knackwurst (similar to Frankfuters): maximum 100 g • Air-dried and cured ham, up to 20 g • Teewurst (similar to Bologna sausage), mettwurst (pork and beef paté) fine Braunschweiger (finely minced pork and beef sausage): up to 50 g • Commercial sauces up to 100ml 	<ul style="list-style-type: none"> • Fresh meat of all slaughterable domestic mammals and game, including tongues and hearts • Fresh poultry meat and frozen goods • Canned meat, luncheon meats, corned beef, canned meats & sauce • Meat pies and cold meats • Broth, stock granules • All types of boiled sausage, e.g. B. vienna sausages, bockwurst, ham sausage, Mortadella, Jagdwurst, etc. • Cooked sausage, e.g. jellied sausages, liver sausage, black puddings • Kassler, salted meat, salted tongue, ham (not air-dried and matured), e.g. cooked and smoked ham, bacon

Fish and fish products	<ul style="list-style-type: none"> • Salted herring, soused herring, salted sardines, anchovies, caviar and similar salt-cured raw products • Cold smoked fish (e.g., cold smoked kipper, cold smoked mackerel, etc.) • Dried fish, stockfish, dried salted fish • Cod liver • Squid • Fish sauces, Asian sauces 	<ul style="list-style-type: none"> • Pickled herring, rollmops: up to 100 g • Herring pieces in mayonnaise or jelly: up to 100 g • Tinned tuna: up to 50 g 	<ul style="list-style-type: none"> • Fresh fish (stored in ice!) • Frozen fish • Fish fingers or fillets, frozen • Hot smoked fish (kippers, smoked mackerel, sprats, halibut, redfish, cod, etc.) • Fresh crayfish, oysters and crabs • Canned sardine and herring products (e.g. sardines in oil, herring in tomato, oil or cream sauces, etc.)
Eggs and egg products	<ul style="list-style-type: none"> • Pickled eggs 		<ul style="list-style-type: none"> • Fresh eggs, egg powder
Yeast and yeast products	<ul style="list-style-type: none"> • Marmite and other concentrated yeast extracts, 	<ul style="list-style-type: none"> • Commercial ready-made sauces and sauces etc from industrial kitchens, up to 100 ml sauce • Commercially available powders for the preparation of sauces up to 100ml of sauce • Commercial available ready meals with up to 100ml of sauce 	<ul style="list-style-type: none"> • Baker's yeast, baked goods made with yeast • Commercial instant soups
Cereals and cereal products	<ul style="list-style-type: none"> • Sprouted barley seedlings (malt) 		<ul style="list-style-type: none"> • sprouted wheat • Grains, flakes, flours, semolina and pearl barley of wheat, rye, oats, barley, corn, rice, buckwheat, millet • Pasta • Bread, rolls, cake

Pulses	<ul style="list-style-type: none"> • Ripe brown beans (e.g. kidney beans), broad beans (also known as fava beans or field beans) haricot beans • Bean sprouts • Asian soy sauces, matured tofu products, etc. 		<ul style="list-style-type: none"> • Peas, lentils • Green, unripe beans in the pod • Soya beans, soya bean sprouts • Soya milk
Cocoa and cocoa products	<ul style="list-style-type: none"> • Dark chocolate in solid bars or in figures • Cognac chocolate liqueurs, liqueur chocolates, cocoa liqueur • Chocolate and nougat ice-cream 	<ul style="list-style-type: none"> • Chocolates with cream, fruit or marzipan fillings: up to 20 g • Hazelnut nougat: up to 20 g • Marzipan: up to 20 g • Milk chocolate: up to 20 g; chocolate bars with milk, cream or marzipan filling: up to 50 g (including White chocolate) • Muesli bars with chocolate coating: up to 20 g • Chocolate with whole hazelnuts, cashew nuts or almonds: up to 20 g 	<ul style="list-style-type: none"> • Drinking cocoa, drinking chocolate, cappuccino • Couverture on baked goods
Fruit	<ul style="list-style-type: none"> • Very ripe bananas, pears and avocados, red plums, figs • Fruit preserved in rum 	<ul style="list-style-type: none"> • Blackcurrants: up to 50 g, red grapes: up to 250 g, ½ a not too ripe banana, pear or avocado, • Dried fruit: up to 20 g 	<ul style="list-style-type: none"> • Apples, pineapple, cherries, yellow and blue plums, strawberries, currants and gooseberries, blueberries or bilberries, cranberries, rhubarb, lemons, mangoes, grapefruit, oranges, tangerines, peaches, apricots, white grapes
Vegetables and vegetable products	<ul style="list-style-type: none"> • Raw sauerkraut • Raw gherkins, barrel gherkins • Mixed pickles, pickled mushrooms 	<ul style="list-style-type: none"> • Pasteurised wine sauerkraut: up to 100 g • Pasteurised pickled gherkins: up to 100 g • carrots (i.e. young carrots, usually shorter and with green tops): up to 20 g 	<ul style="list-style-type: none"> • Potatoes, carrots, red, white and savoy cabbage, Brussels sprouts, broccoli, cauliflower, salsify, celery, onions, leeks, cucumber, tomatoes, peppers, garlic, edible mushrooms, fennel, asparagus, courgettes, beetroot (fresh or vacuum-packed), salads, fresh herbs

Package Leaflet: Tranylcypramine Eignapharma 20 40 mg film-coated tablets

Revision:

Nuts and nut products	<ul style="list-style-type: none">• Walnuts• Walnut nougat or nougat undeclared ingredients	<ul style="list-style-type: none">• Hazelnut nougat: up to 20 g	<ul style="list-style-type: none">• Coconut, hazelnuts, peanuts, cashew nuts, Brazil nuts, sweet almonds• Hazelnut butter and hazelnut paste• Hazelnut marzipan
Drinks	<ul style="list-style-type: none">• Juices with a high pear, banana or plum content• Commercial grapefruit juices• juices from citrus fruit concentrates• Alcoholic drinks, e.g. beer, wine, sparkling wine, cognac, liqueurs, brandies, whiskey, rum, etc. (including alcohol-free beer and wine)	<ul style="list-style-type: none">• Commercial orange juice: up to 100 ml	<ul style="list-style-type: none">• Commercial non-alcoholic juices with little or no citrus, pear, banana or plum content (e.g. musts, lemonade, multivitamin juice)• Freshly squeezed citrus juices• Seltzers, coffee, cola, herbal teas, black tea, fruit tea, malt coffee
Other foodstuffs			<ul style="list-style-type: none">• Honey• Sugar beet syrup• Vinegar, mustard
