

Package leaflet: information for the patient

Tracydal 20 mg film-coated tablets

Tranlycypromine

Please read this entire leaflet before you take this drug, as it contains important information for you.

- Please retain this leaflet. You may need it again later. Do you have questions? Contact your doctor or pharmacist.
- Do not share this drug with others, because it has only been prescribed for you. It can be harmful for others, even if they have the same symptoms as you.
- Are you experiencing any of the side effects listed in Section 4? Or do you experience a side effect which is not listed in this leaflet? Contact your doctor or pharmacist.

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1. What is Tracydal 20 mg film-coated tablets and what is it used for?

Tracydal is an anti-depressant and is part of the group of monoamine oxidase inhibitors (MAO inhibitors). The drug is used for the treatment of severe depression, on which treatment with other antidepressants, supplemented with e.g. lithium, has had sufficient effect.

Have your symptoms not alleviated after 3 weeks, or have they become even worse? Contact your doctor.

2. When should you not use this drug, or when should you be extra vigilant?

When should you not use this drug?

- If you are allergic to any of the substances in this drug. These substances can be found in Section 6.
- If you have a specific type of cancer of the adrenal glands or the gastro-intestinal tract (your doctor will determine whether you may still use this drug).
- If you have cardio-vascular problems, for instance, you recently had a stroke (CVA), you have an aneurysm (dilation of the arteries), or you have high blood pressure.
- If you have liver problems.
- If you have severe kidney problems.
- If you suffer from porphyria, a haematologic disorder.
- If you have diabetes insipidus, a disease where you drink a lot because you are often thirsty and have to urinate a lot.
- If you have a delirium, an acute state of confusion.
- If you have acute drug poisoning because of taking too many sleeping pills, painkillers or anti-psychotics, and because you might also have consumed too much alcohol.
- If you suffer from malignant hyperthermia (a rare hereditary disease which can cause a life-threatening increase in the body temperature under anaesthesia).

When should you be extra vigilant with this drug?

Tracydal tablets should be taken with the utmost caution in the following cases:

- If you are simultaneously taking other drugs which can increase the chance of serotonin syndrome (see the Section "Are you taking other drugs?").
- If you suffer attacks of persistent and abnormal agitation or irritability (manic episode). In that case, contact your doctor or nurse **immediately**. Treatment with Tracydal has to be stopped.

Also notify your doctor or nurse if you are being treated for any depressive disorders that are related to another psychological disorder which can be associated with delusions, hallucinations and mental disorders.

- If you used to consume a lot of alcohol or use a lot of drugs in the past, or have been addicted to alcohol or drugs. Please notify your doctor.

- If you have suffered from or are suffering from epileptic seizures. Please notify your doctor. It cannot be excluded that Tracydal may cause epileptic seizures.
- If you have diabetes. Please notify your doctor. The treatment with Tracydal can lower your blood sugar levels. The dose of insulin and other drugs you take have to be adjusted, and your blood levels should be checked regularly.
- If you suffer from reduced renal function. Notify your doctor for a thorough examination.

Children under the age of 18 years

This drug cannot be used by children under the age of 18.

Elderly patients

If you are older than 65, your doctor may want to keep the dosage as low as possible and will regularly check your blood pressure. If the dosage needs to be increased, this will be done very gradually.

Are you taking other drugs?

Do you take other drugs in addition to Tracydal, have you taken other drugs recently, or is there a possibility that you will have to take other drugs in the near future? Notify your doctor or pharmacist. If Tracydal is used simultaneously with other drugs, it is possible that the effect of either Tracydal or of the other drug is strongly affected. Tracydal can therefore not be used in combination with certain other drugs that are listed below. You will find warnings about the use of this drug in combination with other drugs.

Serotonin syndrome

A potentially life-threatening condition or neuroleptic malignant syndrome (NMS)-like reactions (see the Section "Possible side effects") may occur during treatment with tranlycypromine, mainly when taken simultaneously with other drugs. Examples of these drugs are:

- Triptans (used for migraine);
- Other antidepressants, such as SNRIs, SSRIs, tricyclic antidepressants or drugs containing lithium;
- Drugs which contain linezolid, an antibiotic (used to treat infections);
- Drugs which contain moclobemide, an MAOI (used to treat depression);
- Drugs which contain sibutramine (used for weight loss);
- Drugs which contain tramadol, fentanyl, tapentadol, pethidine or pentazocine (used to treat severe pain);
- Drug which contain dextromethorphan (used to treat coughs);
- Drugs which contain methadone (used to treat opioid drug addiction or severe pain);
- Drugs which contain methylene blue (used to treat high concentrations of methaemoglobin in the blood);
- Products which contain St John's Wort (also called "Hypericum perforatum", a natural or herbal remedy to treat mild depression);
- Products which contain tryptophan (used for sleeping problems and depression);
- Antipsychotics (which are used to treat a disease with symptoms such as hearing, seeing or feeling things which are not there, delusions, unusual suspicions, unclear reasoning and withdrawal from society).

Signs and symptoms of serotonin syndrome can include a combination of the following:

Restlessness, hallucinations, loss of coordination, elevated heart rate, elevated body temperature, rapid changes in blood pressure, hyperactive reflexes, diarrhoea, coma, nausea, vomiting.

In its most serious form, serotonin syndrome can look like neuroleptic malignant syndrome (NMS). Signs and symptoms of NMS can include a combination of fever, elevated heart rate, sweating, severe muscle stiffness, confusion, elevated muscle enzymes (this is determined by a blood test).

Notify your doctor immediately or go to the emergency department of the nearest hospital if you think that you are about to suffer from serotonin syndrome.

Do not take Tracydal in combination with the following drugs:

- Antidepressants such as citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine and sertraline, venlafaxine, duloxetine, clomipramine, imipramine, amitriptyline, desipramine, nortriptyline, protriptyline (and other tricyclic antidepressants), phenelzine (and other MAO inhibitors) and buspirone (against anxiety and restlessness);
- Triptans (drugs to treat migraine);

- Sympathomimetics (drugs to elevate the blood pressure which can also be present in drugs against the common cold, cough and flu, and in appetite-suppressant drugs);
- Pethidine (a drug against severe pain), tramadol (a drug against mild pain) and cough medicine which contains dextromethorphan.

If you are using or have recently used one of the drugs above, your doctor will tell you how long you have to wait before you can start taking Tracydal. If the treatment with Tracydal is stopped, you have to wait at least 14 days before you can start using another drug.

Increased risk of side effects of Tracydal

- If Tracydal is used simultaneously with certain drugs to treat circulatory disorders, drugs to relieve the muscles in the airways, or with nasal drops (sympathomimetics), you have an increased risk of side effects of Tracydal.
- There is a greater risk of side effects of Tracydal when the dosage is increased by the doctor.

Increased risk of side effects of other drugs used simultaneously with Tracydal

- The effect of antihypertensive drugs, such as guanethidine or methyldopa, can be stronger. In the event of agitation, however, the blood pressure can increase.
- The effect of insulin and drugs against diabetes can be stronger.
- Side effects of bupropion and amfebutamone (drugs to help you stop smoking), such as epileptic seizures and agitation, can become worse.
- The effect of antipsychotics, antidepressants, benzodiazepines and analgesics (drugs with a soothing effect on the brain) can be stronger.

Possible side effects of drugs used during surgery and dental treatment

- If you have to undergo a surgical procedure where anaesthetics or pain relief will be used, your doctor should stop your treatment with Tracydal 14 days in advance. There is a risk of serious side effects, because Tracydal affects the effect of anaesthetics. Tell the anaesthesiologist before the surgery that you are using Tracydal.
- Inhalation anaesthetics (anaesthetics you breathe in) do not constitute a greater risk to patients who are treated with Tracydal than to other patients. However, ether should not be used.
- Local anaesthetics: The generally low concentrations of adrenaline or noradrenaline in drugs for local anaesthesia, e.g. during dental surgery or in eye drops, constitute no specific risk for patients who are treated with Tracydal.
- Pethidine, a strong painkiller, which can, for instance, be used to treat pain after surgery, should never be used if you are being treated with Tracydal. Please note: This information can also apply to drugs you have recently used.

What does taking Tracydal mean for what you can eat and drink, and for your alcohol intake?

Users of Tracydal should strictly follow the dietary advice from their doctor, because the effect of Tracydal can be strongly influenced by the consumption of certain foodstuffs and beverages.

Foodstuffs and beverages that contain tyramine, can cause a dangerous increase in your blood pressure, which can result in serious headaches, nausea, blurred vision, chest pain and palpitations. For that reason, there are certain foodstuffs and beverages that you should absolutely not consume at all. Alcohol can have a stronger effect when you are simultaneously using Tracydal.

Suicidal thoughts and aggravation of your depression

If you are feeling depressed, you sometimes get thoughts about hurting yourself or about suicide. The chance that you get this kind of thoughts is greater at the beginning of the treatment with antidepressants, because the drugs need some time before they start to work. This can take up to two weeks, but sometimes longer.

It is more probably that these thoughts arise:

- If you have had these thoughts in the past;
- If you are a young adult. Results of clinical studies have shown that there is an increased risk of suicidal behaviour in young adults under 25 years who suffered from psychiatric disorders and who were treated with antidepressants.

Notify your doctor immediately or go to a hospital if you get thoughts about hurting yourself or committing suicide. It may be helpful to tell a friend or family member that you are suffering from depression. Ask these people to read this leaflet. Ask them to tell you when they have the impression that your depression is getting worse or if they are worried about changes in your behaviour.

Pregnancy and lactation

Are you pregnant, do you think you are pregnant, would you like to become pregnant or are you breastfeeding? Contact your doctor or pharmacist before you start using this drug.

Pregnancy

The use of Tracydal is not recommended during pregnancy and for women of child-bearing age who do not use contraception.

Lactation

Tracydal should not be used when you are breastfeeding. If your doctor feels the use of this drug is necessary, you have to stop breastfeeding.

Effects on the ability to drive and operate machinery

Tracydal has a minor to moderate effect on the ability to drive and operate machinery. Tracydal can, even during regular use but certainly on the first day of the treatment, have a negative effect on the ability to actively participate in traffic and to operate machinery. This effect can be even stronger when you use other drugs which affect the central nervous system at the same time.

During the first day of the treatment, you should not drive a car or other vehicles, operate machinery or electrical equipment, or carry out activities which require attention and caution.

The decision as to whether you are allowed to drive or operate machinery may be taken by your doctor, taking into account the dosage used and the way in which you respond to Tracydal.

Tracydal contains Ponceau 4R cochineal red colourant (E124)

This substance may cause allergic reactions.

3. How do you take this drug?

Always take this drug exactly as told by your doctor. Are you not sure about the correct use?

Contact your doctor or pharmacist.

Swallow the tablets with a glass of water. Do not chew.

The total daily dose can be divided over 1 to 2 intakes per day. To prevent problems sleeping, the second dose of the day should not be taken after 15.00 hours.

Recommended dosage

At the start of the treatment, you will take half a Tracydal tablet once a day, in the morning. Your doctor may increase this dose with half a tablet a week, until the dose is reached which is suitable for you. The recommended daily dose is 1 to 2 Tracydal tablets.

To split the tablet: Put the tablet on a hard level surface, with the scored side up. With your thumb, press on the middle of the top of the tablet, to split it into two halves.

If the effect is not sufficient with the recommended daily dose, your doctor may increase the dosage with half a tablet every 1 to 3 weeks. The maximum daily dose is 3 Tracydal tablets (i.e. a total of max. 60 mg).

When your depression has improved, your doctor may lower the total daily dose to a maintenance dose of half or a whole Tracydal tablet per day.

Duration of treatment

Normally, you will notice an improvement in your mood and an alleviation of your depression within 1 to 3 weeks. Your doctor will assess your condition and adjust the dose if necessary. The treatment with Tracydal usually lasts 4 to 6 weeks, but your doctor may continue the treatment for 4 to 6 months with a lower dose.

If you switch from a different drug to Tracydal for the treatment of your depression, your doctor will first schedule a treatment-free period of at least 7 days, and then start with half a tablet a day for at least the first week.

Contact your doctor or pharmacist if you have the impression that the effect of Tracydal is too strong or too weak.

Did you take too many pills?

Contact **your doctor immediately**. He/she can decide what measures should be taken.

Symptoms of overdosing are confusion, irritability to epileptic seizures, clouding of consciousness to unconsciousness, with fever, breathing difficulties (up to respiratory arrest) and cardio-vascular problems (severe blood pressure fluctuations, irregular heart rate) and also muscle problems (severe muscle cramps). Sometimes, the symptoms of overdosing only occur after 6-12 hours, and in rare cases only after 24-32 hours after taking the tablets.

Did you forget to take the drug?

Do not take a double dose in case you forgot a dose, but continue with the prescribed treatment when it is time for the next dose.

If you stop taking this drug

It is important to never stop the treatment or change the dose on your own initiative, without consulting your doctor.

Withdrawal symptoms such as anxiety, restlessness, insomnia, drowsiness or confusion may occur. When the treatment can be stopped, your doctor will gradually lower the dose. Contact your doctor if you notice withdrawal symptoms after the dose has been lowered or after you have stopped taking Tracydal. It may be necessary to go back to the previous dose and lower the dose in smaller steps.

Do you have other questions about the use of this drug? Contact your doctor or pharmacist.

4. Possible side effects

As with any drug, this drug may also have side effects, although not everyone will be affected.

Significant side effects

If you suffer abnormal agitation or irritability (manic episode/depression), you should **immediately** stop the treatment with Tracydal. Contact your doctor immediately.

Other side effects

Very common side effects (more than 1 in 10 users)

- Low blood pressure, also when getting up in the morning
- Insomnia, sleep disorders

Common side effects (more than 1 in 100 users)

- Anxiety, excitement, restlessness
- Dry mouth
- Dizziness
- Weight gain, weight loss
- Palpitations
- High blood pressure
- Fatigue
- Weakness

Less common side effects (more than 1 in 1000 users)

- Strong increase in blood pressure (hypertensive crisis), that can be associated with a fast heart rate (tachycardia), blushing, headache (especially to the back of the head), stiff neck, nausea, vomiting and aversion to light (photophobia)

Rare side effects (more than 1 in 10,000 users)

- Anaemia
- Epileptic seizures
- Orgasm, erection and ejaculation disorders
- Psychological dependency
- Muscle cramps, myalgia (muscle pain)

- Olyguria (decreased urine output)
- Constipation, diarrhoea
- Swelling as a result of fluid retention (oedema)
- Excessive perspiration

Very rare side effects (fewer than 1 in 10,000 users)

- Abnormal liver function, increased activity of liver enzymes
- Allergic skin reaction
- Arthralgia (joint pain)
- Hair loss
- Hallucinations
- Fever
- Confusion
- Blurred vision
- Polyneuropathy (nerve pain)

Side effects of which it is not known how often they occur

- Cold intolerance
- Nausea, vomiting, gastro-intestinal problems
- Tinnitus
- Chest pain
- Drowsiness
- Muscle spasms
- Urinary tract problems
- Tremors
- Signs and symptoms of serotonin syndrome may include restlessness, hallucinations, loss of coordination, elevated heart rate, elevated body temperature, rapid fluctuations in blood pressure, hyperactive reflexes, diarrhoea, coma, nausea, vomiting. In its most serious form, serotonin syndrome can look like neuroleptic malignant syndrome (NMS). Signs and symptoms of NMS may include a combination of fever, elevated heart rate, sweating, severe muscle stiffness, confusion, elevated muscle enzymes (this is determined by a blood test)
- Exhaustion
- Suicidal thoughts, suicidal behaviour
- In some cases, especially if the dietary advice is not strictly observed or if there is an interaction with other drugs, brain haemorrhages may occur.

Reporting side effects

Contact your doctor or pharmacist if you suffer from side effects. This also applies to any side effects not listed in this leaflet. You can also directly report side effects to the **Netherlands Pharmacovigilance Center Lareb www.lareb.nl**. By reporting side effects, you can help us obtain more information about the safety of this drug.

5. How do you store this drug?

Keep out of sight and reach of children.

There are no special storage conditions for this drug.

Do not use this drug after the expiry date. This date can be found on the box and the blister packaging (blister strip) after EXP. A month and year is given. The last day of that month is the expiry date.

Do not flush drugs down the sink or toilet, and do not put them in the bin. Ask your pharmacist what you should do with drugs that you no longer use. They will then be disposed of in a responsible manner and cannot pollute the environment.

6. Contents of packaging and other information

What substances does the drug contain?

- The active substance in this drug is tranlycypromine. One film-coated tablet contains 20 mg tranlycypromine in the form of tranlycypromine sulphate.
- The other substances in this drug are microcrystalline cellulose (E460), anhydrous calcium hydrogen phosphate (E341), pre-gelatinised starch, silicon dioxide (E551), talc (E553B). Film coating: Partially

hydrolysed polyvinyl alcohol (E1203), macrogol, Ponceau 4R cochineal red colourant (E124), talc (E553B), titanium dioxide (E171), indigo carmine colourant (E132).

What do Tracydal 20 mg film-coated tablets look like and how many are there in a packaging?

Tracydal 20 mg film-coated tablets are red, round tablets with a V-shaped score line. The tablet can be divided into equal doses.

A box contains 6 blister strips. Each blister strip contains 15 tablets.

Marketing authorisation holder

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