

Package leaflet: Information for the patient

Abbonate 20 mg film-coated tablet tranylcypromine

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 Abbonate is and what it is used for
2. What you need to know before you take Abbonate
3. How to take Abbonate
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1. What Abbonate is and what it is used for

Abbonate contains the active substance tranylcypromine which belongs to a group of antidepressants known as monoamin oxidase inhibitors (MAOIs).

This medicinal product is used to treat severe depressive episodes in adults with major depressive disorder where appropriate standard treatment with two antidepressants (including tricyclic antidepressants) supplemented with for example lithium, did not have a sufficient effect.

2. What you need to know before you take Abbonate

Do not take Abbonate

- if you are allergic to tranylcypromine or any of the other ingredients of this medicine (listed in section 6)
- if you have cancer in the adrenal glands (pheochromocytoma) or in the gastrointestinal tract (carcinoid tumours)
- if you are suspected to have or have recently had problems with heart or blood vessels, such as a recent stroke
- if you have severe high blood pressure which is difficult to control
- if you have a vascular disease (aneurysms)
- if you have impaired liver function or liver disease
- if you have severe impaired kidney function or kidney disease
- if you have porphyria (a hereditary disease which affects the nervous system and the skin)
- if you have diabetes insipidus (a pituitary disorder which leads to intense thirst and large amounts of urine)
- if you have delirium, an acute state of confusion
- if you have acute poisoning because you have used too many sleeping pills, painkillers or medicines for mental illness or because you may have used too much alcohol
- if you have malignant hyperthermia (a rare hereditary disease that can lead to a rise in body temperature during anaesthesia)

- if you take any of the medicinal products which are stated in the “Do not take” in section “Other medicines and Abbonate” in this package leaflet.

Abbonate should not be used by children and adolescents younger than 18 years.

Warnings and precautions

If you have thoughts about harming yourself or suicide before or while taking Abbonate 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 behavior.

Suicidal thoughts and worsening of your depression

If you are depressed, you can sometimes get thoughts about harming yourself. You are more likely to have this kind of thoughts at the beginning of antidepressant treatment, as these medicines will take some time before they start working. This can take two weeks, but sometimes longer.

It is more likely that these thoughts occur if you:

- previously have had thoughts about killing or harming yourself
- are a young adult. Results from clinical trials have shown an increased risk of suicidal behavior in young adults aged less than 25 years with psychiatric illnesses 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 Abbonate” in this leaflet for examples of these medicines.

Abbonate tablets should be taken with the extreme caution if you:

- have increased or low blood pressure
- have periods of abnormally agitated or excited mood (manic episode). Contact your doctor or nurse immediately if this occurs since treatment with Abbonate may need to be stopped.
- have other depressive conditions in the context of another mental illness.
- are or have been addicted to alcohol or drugs.
- have or have had epileptic seizures since Abbonate may lower the threshold for seizures.
- have diabetes since treatment with Abbonate may affect the amount of sugar in your blood. The dose of insulin and other medicines may need to be adjusted, and your blood sugar should be checked regularly.
- are elderly since you are more sensitive for drop in blood pressure.

Other medicines and Abbonate

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

If you use another medicine or have recently used it, your doctor will tell you how long you should wait before you can start taking Abbonate. In certain cases, you will have to wait 14 days after treatment with Abbonate is stopped before you can start taking another medicine. The doctor will tell you which setup is applicable for you.

If Abbonate is used simultaneously with other medicines, it is possible that this will greatly affect the action of Abbonate or the other medicines. Abbonate should therefore not be used in combination with certain other medicines.

Do not take Abbonate with the following medicines

- other antidepressants which are serotonin reuptake inhibitors such as all selective reuptake inhibitors (SSRIs such as citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine and

sertraline) and selective serotonin- and noradrenalin reuptake inhibitors (SNRIs such as venlafaxine and duloxetine).

- tricyclic antidepressants (such as clomipramine, imipramine, amitriptyline, desipramine, nortriptyline, protriptyline)
- other MAO inhibitors (such as phenelzine)
- serotonin agonists such as triptans for the treatment of migraine
- buspirone, medicine for anxiety
- sympathomimetics (such as ephedrine, pseudoephedrine, adrenalin, and noradrenalin (may be present in medicines used to treat heart problems and asthma and also in certain decongestants and cough/cold medicines and medicines for ADHD)
- pethidine, tramadol (medicines for pain)
- dextromethorphan (cough medicine)

Abbonate must be used with caution if you take any of the following medicines:

- medicines containing lithium
- sibutramine used for weight reduction
- fentanyl, tapentadol, pethidine, pentazocine, buprenorphine or naloxone which are all used for treating severe pain
- methadone used to treat opioid drug addiction or severe pain
- St. John's Wort, a natural or herbal remedy for the treatment of mild depression
- tryptophans used for sleeping disturbances and depression
- antipsychotics
- benzodiazepines
- medicines for circulatory issues, medicines for muscle relax in respiratory organs or nasal drops (sympathomimetics)
- medicines used to lower the blood pressure, such as guanetidine or methyl dopa
- insulin and other medicines for diabetes since the effect of them may increase
- bupropion (medicine to help you stop smoking)

If you need to undergo surgery using anesthetic or painkillers, your doctor should stop your Abbonate treatment 14 days in advance.

Abbonate with food, drink and alcohol

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

You should not drink alcohol (especially red wine) while treated with Abbonate. The effects of alcohol may be enhanced at concurrent use with Abbonate. You should also avoid alcohol free beer and lager.

Abbonate stops the body's breakdown of the substance tyramine, which is found in large amounts in certain food. If you during treatment with Abbonate eat food containing the substance tyramine it may cause the blood pressure to rise dangerously which may be life-threatening. You should contact your doctor and check your blood pressure if you get symptoms such as headache, nausea, blurred vision, chest pain or palpitations.

You should avoid the following food while you are taking Abbonate and 14 days after the treatment:

- matured and ripened cheeses such as blue cheese and cheddar cheese
- meat, fish or poultry which is not fresh
- protein-rich foods used in hydrolysis, fermentation, brining or drying; pickling or hanging or ripened meat; fish and poultry; airdried sausage, fermented or smoked fish
- broad beans
- soy products
- sauerkraut
- concentrated yeast extracts
- banana peel
- alcoholic beverage

- non-alcoholic beer or lager

You should be given dietary advice before you start taking Abbonate. A dietician who has knowledge of psychiatric diseases and medicines should give you advice. You must strictly follow the dietary advice from your doctor and dietician.

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.

Women of childbearing potential

Should not be used by women of childbearing potential who are not using contraception.

Pregnancy

Do not use Abbonate during pregnancy.

Breast-feeding

Abbonate should not be used during breastfeeding. If your doctor considers the use of this medicine necessary, you should stop breast-feeding.

Driving and using machines

Abbonate may make you feel sleepy or dizzy or may affect your vision. You should not drive, use machines and perform tasks which require high attention until you are sure that you do not experience side effects from Abbonate which may impact your attention. Talk to your doctor if you are unsure before you drive and operate machines.

Abbonate contains Ponceau 4R (E124)

Ponceau 4R may cause allergic reactions.

3. How to take Abbonate

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure.

Do NOT take more than your doctor tells you to.

Swallow the tablets with a glass of water. The tablets have a score line to make it possible to divide the tablet.

To divide the tablet: Place the tablet on a hard and flat surface with the score line up. Press your thumb on the center of the top to divide the tablet into two equal doses.

Recommended dose

- The startdose is half a tablet (10 mg) once a day in the morning.
- The dose will be adjusted individually to suit your needs. Recommended dose is 1 to 2 tablets daily.
- The daily dose may be taken in 2 to 3 divided doses per day. The first dose should be taken in the morning and the last dose at lunch time. Do not take the medicine after 3 pm to avoid sleep disturbances.
- If the effect is not sufficient at the recommended daily dose, your doctor may increase the dose further. The maximum daily dose is 3 Abbonate tablets (a maximum of 60 mg daily).

Duration of treatment

Normally, within 3 to 6 weeks of treatment you will notice that your mood starts to improve, and your depression becomes less severe. Abbonate treatment usually lasts for 4 to 6 months.

Switch of medicine

If you switch from another medicine to Abbonate to treat your depression, your doctor will prescribe a treatment-free period of at least 7 days. Your doctor will tell you when to take your medicine.

Contact your doctor or pharmacist if you feel that Abbonate's effect is too strong or too weak.

Children and adolescents

This medicine should not be taken by children and adolescents younger than 18 years.

If you take more Abbonate than you should

Contact your doctor or hospital in case you have taken more medicine than you should. Bring any remaining tablets and this leaflet so that health care professionals know exactly what you have taken.

Overdose symptoms include confusion, overstimulation to epileptic seizures, transfer from consciousness to unconsciousness, fever, difficulty breathing (including respiratory arrest) and problems with the heart and blood vessels (severe blood pressure fluctuations, irregular heartbeat) and problems with muscles (severe muscle cramps).

Careful monitoring of the blood pressure is important. You must be monitored at least for a week after intake of a too large dose, since the symptoms of overdose may be delayed or long lasting.

If you forget to take Abbonate

If you miss a dose, wait until your next dose. Do not take a double dose to make up for a forgotten dose, but continue with the prescribed treatment when it is time for the next dose.

Do not take more than one dose at a time.

If you stop taking Abbonate

It is important not to stop the treatment or to change the dose without consulting your doctor.

Withdrawal symptoms such as anxiety, restlessness, insomnia, drowsiness, or confusion may occur when you stop treatment. Your doctor will discontinue the treatment by gradually reducing the dose.

Contact your doctor if you notice withdrawal symptoms after a dose reduction or after stopping using Abbonate. It may then be necessary to go back to the previous dose and reduce the dose in smaller steps.

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.

Serious side effects (may affect up to 1 in 10 patients)

Contact your doctor or emergency care **immediately** if an abnormally agitated or excited mood (manic episode/depression) occurs.

Contact your doctor immediately if aggression, hallucinations, coma, rapid heartbeat, change in blood pressure, feeling of heat, nausea, vomiting or diarrhea occurs since this could be signs of serotonin syndrome.

Other side effects

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

- Insomnia, sleep disorders
- Low blood pressure, low blood pressure when standing up

Common (may affect up to 1 in 10 patients)

- Anxiety, excitement, restlessness

- Dizziness, dry mouth, fatigue
- Palpitations
- Weight gain, weight loss, weakness

Uncommon (may affect up to 1 in 100 patients)

- Sharp rise in blood pressure (hypertensive crisis) which can be accompanied by a rapid heartbeat (tachycardia), flushing, headache (especially in the back of the head), stiff neck, nausea, vomiting and sensitivity to light (photophobia).
- Bleeding in the brain. This may occur especially if the dietary requirements are not strictly observed (see Abbonate with food, drink and alcohol) or in the case of concurrent use with other medicines (see Other medicines and Abbonate)

Rare (may affect up to 1 in 1000 patients)

- Anemia, decreased level of blood cells
- Psychological dependence
- Seizures
- Swelling due to retention of tissue fluid (edema)
- Constipation, diarrhea
- Sweating
- Muscle cramps, muscle pain
- Orgasm-, erection- and ejaculation disorders

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

- Hallucinations, confusion
- Nerve pain (polyneuropathy)
- Blurred vision
- Abnormal liver function, increased activity of liver enzymes
- Hair loss
- Allergic skin reactions
- Joint pain
- Decreased formation of urine
- High body temperature

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

- Suicidal thoughts, suicidal behavior
- Sleepiness, tremors
- Tinnitus
- Nausea, vomiting, gastrointestinal symptoms
- Difficulty urinating
- Chest pain
- Feeling cold
- Exhaustion

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 national reporting system listed in Appendix V**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Abbonate

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

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.

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 Abbonate contains

- The active substance is tranylcypromine. Each film-coated tablet contains tranylcypromine sulfate equivalent to 20 mg tranylcypromine.
- The other excipients are:
Tablet core: microcrystalline cellulose, calcium hydrogen phosphate (water-free), Pregelatinised starch, water-free colloidal silica, talc.
- The shell contains: partially hydrolysed polyvinyl alcohol, macrogol, Ponceau 4 R (E 124), talc, titanium dioxide (E 171), indigo carmine aluminium lake (E 132).

What Abbonate looks like and contents of the pack

Abbonate tablets are red, round (diameter approx. 9 mm), convex tablets with a V-shaped score line in one side. The tablet can be divided in two equal doses.

Abbonate is available in Alu-PVC/PVdC blister with 30, 60, 90 and 105 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

To be completed nationally

Manufacturer

To be completed nationally

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