

Mirtazapine (Noumed)

Mirtazapine Ph. Eur.

Mirtazapine (Noumed), film-coated tablets, 30 mg & 45 mg

What is in this leaflet

Please read this leaflet carefully before you start using Mirtazapine (Noumed).

This leaflet answers some common questions about Mirtazapine (Noumed). It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Mirtazapine (Noumed) against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Mirtazapine (Noumed) is used for

Mirtazapine (Noumed) is used in the treatment of depression including relapse prevention.

Depression is longer lasting or more severe than "low moods" everyone has from time to time due to the stress of everyday life. It affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing.

This medicine may help relieve the symptoms of depression.

Ask your prescriber if you have any questions about why mirtazapine has been prescribed for you.

Your prescriber may have prescribed it for another reason. This medicine is available only with a prescriber's prescription. This medicine is not addictive.

Before you use Mirtazapine (Noumed)

When you must not use it

Do not take mirtazapine if you are allergic to:

- Mirtazapine
- other medicines containing mirtazapine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or trouble breathing.

Do not take Mirtazapine (Noumed) if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking an MAOI within the last 14 days. If you stop taking Mirtazapine, do not take MAOI during the next two weeks either.

Taking Mirtazapine (Noumed) with an MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

Examples of this type of medicine include phenelzine, tranylcypromine and selegiline.

Ask your prescriber or pharmacist if you are not sure if you are or if you have been taking a MAOI medicine.

Do not take this medicine if the expiry date (EXP) printed on the packaging has passed or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your prescriber.

Do not give Mirtazapine (Noumed) to a child or adolescent.

The safety of Mirtazapine (Noumed) in patients under 18 years has not been established.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your prescriber if you have any other health problems, including:

- thoughts of suicide or self-harm
- epilepsy (fits or convulsions)
- liver disease such as jaundice
- kidney disease
- heart disease
- low blood pressure
- certain kinds of heart conditions that may change your heart rhythm, a recent

heart attack, heart failure, or take certain medicines that may affect the heart's rhythm.

- any mental illness (e.g., schizophrenia, manic depression)
- diabetes
- glaucoma (increased pressure in the eye)
- problems in urinating due to an enlarged prostate
- unexplainable high fever, sore throat, and mouth ulcers
- galactose intolerance
- glucose-galactose malabsorption

Tell your prescriber if you are pregnant or plan to become pregnant.

Like most medicines of this kind, Mirtazapine (Noumed) is not recommended to be used during pregnancy. Your prescriber will discuss the risks and benefits of taking Mirtazapine (Noumed) when pregnant.

Tell your prescriber if you are breast-feeding or wish to breastfeed

It is not known whether Mirtazapine (Noumed) passes into breast milk.

Tell your prescriber if you react badly to lactose or milk before you start taking Mirtazapine (Noumed).

Mirtazapine (Noumed) tablets contain lactose.

If you have not told your prescriber about any of the above, tell them before you start taking mirtazapine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking Mirtazapine (Noumed).

Some medicines may interfere with mirtazapine or increase the risk of side effects. These include:

- other medicines (e.g., SSRIs, venlafaxine, L-tryptophan, nefazodone) for depression, anxiety, obsessive compulsive disorders or pre-menstrual dysphoric disorder
- Monoamine Oxidase Inhibitors (such as tranylcypromine, phenelzine, and selegiline)
- medicines containing St. John's Wort (*hypericum perforatum*)
- phenytoin or carbamazepine, medicines used to treat epilepsy
- benzodiazepines, medicines used to treat anxiety and sleeping problems
- lithium, a medicine used to treat some psychiatric conditions
- methylene blue (used to treat high levels of methaemoglobin in the blood)
- tramadol, a pain killer
- morphine, a medicine for severe pain
- cetirizine, a medicine for allergies

- warfarin, a medicine used to prevent blood clotting
- linezolid or erythromycin, both antibiotics
- rifampicin, a medicine used to treat tuberculosis
- medicines used to treat fungal infections such as ketoconazole
- HIV/AIDS medications
- cimetidine, a medicine used to treat reflux and stomach ulcers
- triptans such as sumatriptan, naratriptan and zolmitriptan, medicines used to treat migraine
- medicines that may affect the heart's rhythm such as certain antibiotics and some anti-psychotics.

Your prescriber will tell you what to do if you are taking any of these medicines.

These medicines may be affected by mirtazapine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your prescriber or pharmacist has more information on medicines to be careful with or to avoid while taking mirtazapine.

How to use Mirtazapine (Noumed)

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the carton, ask your prescriber or pharmacist for help.

How much to take

Your prescriber will tell you how much Mirtazapine (Noumed) to take each day. Take exactly the amount your prescriber tells you.

The usual starting dose is 15 mg per day. Your prescriber may slowly increase this dose depending on how you respond to Mirtazapine (Noumed). The effective dose for most people is usually between 30 mg and 45 mg per day.

Your prescriber may have prescribed a different dose.

If you do not understand the instructions on the box, ask your prescriber or pharmacist for help.

How to take it

Swallow the tablet(s), without chewing, together with some water or other fluid.

When to take it

Take this medicine at the same time each day.

The tablet(s) should be taken at the same time each day, preferably as a single night-time dose before going to bed; or as recommended by your prescriber.

Mirtazapine (Noumed) 30 mg tablets may be taken in sub-doses equally divided over the day (once in the morning and once at night-time before going to bed).

How long to take it

Keep taking Mirtazapine (Noumed) until your prescriber tells you to stop.

For depression, the length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to work, so do not be discouraged if you don't feel better right away. Some of your symptoms may improve in 1 to 2 weeks but it can take up to 2 - 4 weeks to feel the full benefit of the medicine.

Even when you feel well, you will usually have to take Mirtazapine (Noumed) for 4 to 6 months or even longer to make sure the benefits will last.

If you have questions about how long to take Mirtazapine (Noumed), talk to your prescriber or your pharmacist.

If you forget to take it

ONCE DAILY DOSING

If you forget to take the tablet before you go to bed, do not take the missed dose next morning. It may cause drowsiness or sleepiness during the day. Continue treatment in the evening with your normal dose.

TWICE DAILY DOSING

- Morning dose forgotten - simply take it together with your evening dose.
- Evening dose forgotten - do not take it with the next morning dose. Continue treatment with your normal morning and evening doses.
- Both doses forgotten - do not try to make up for the missed tablets. Continue with your usual morning and evening dose the next day.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are using Mirtazapine (Noumed)

Things you must do

Tell your prescriber immediately if you develop fever, chills, sore throat or mouth ulcers or other signs of frequent infections. Stop taking Mirtazapine (Noumed) and consult with your prescriber for a blood test.

In rare cases mirtazapine can cause disturbances in the production of blood cells (bone marrow depression). Some people become less resistant to infection because Mirtazapine (Noumed) can cause a temporary shortage of white blood cells (granulocytopenia).

In rare cases Mirtazapine (Noumed) can also cause a shortage of red and white blood cells, as well as blood platelets (aplastic anaemia), a shortage of blood platelets (thrombocytopenia) or an increase in the number of white blood cells (eosinophilia). While rare, these symptoms most commonly appear after 4-6 weeks of treatment.

Tell your prescriber immediately or go to the nearest hospital for treatment if you have any suicidal thoughts or other mental/mood changes.

Occasionally, the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. Until the full antidepressant effect of your medicine becomes apparent, it is possible these symptoms may increase in the first few weeks of treatment.

Information from clinical trials have shown an increased risk of suicidal behaviour in young adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you or someone you know is showing warning signs of suicide-related behaviour while taking Mirtazapine (Noumed), contact your prescriber or a mental health professional right away or go to the nearest hospital for treatment. These signs include:

- thoughts or talk about death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation.

All mentions of suicide or violence must be taken seriously.

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

If you become pregnant while taking Mirtazapine (Noumed), tell your prescriber immediately.

Do not stop taking your tablets until you have spoken to your prescriber.

If you use Mirtazapine (Noumed) until, or shortly before birth, your baby should

be supervised for possible adverse effects.

Ask your prescriber whether you can breast-feed, while taking Mirtazapine (Noumed).

If you are about to be started on any new medicine, tell your prescriber and pharmacist that you are taking Mirtazapine (Noumed).

Take Mirtazapine (Noumed) exactly as your prescriber has prescribed.

If you do not follow your prescriber's instructions, your condition may not improve, or you may have unwanted side effects.

If, for any reason, you have not taken your medicine exactly as prescribed, tell your prescriber. Otherwise, your prescriber may think that it was not effective and change your treatment unnecessarily.

If you feel the medicine is not helping, tell your prescriber.

This will help your prescriber to determine the best treatment for you.

Be sure to keep all of your prescriber's appointments so that your progress can be checked.

Your prescriber may want to take some blood tests from time to time. This helps to prevent unwanted side effects.

Things you must not do

Do not give Mirtazapine (Noumed) to anyone else, even if they have the same condition as you.

Do not suddenly stop taking Mirtazapine (Noumed), or lower the dose, without first checking with your prescriber.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not stop taking Mirtazapine (Noumed), even if you feel better, unless advised by your prescriber.

Suddenly stopping Mirtazapine (Noumed) may cause nausea, headache, dizziness, anxiety, agitation.

Your prescriber may want to gradually reduce the amount of Mirtazapine (Noumed) you are taking before stopping completely.

Do not use Mirtazapine (Noumed) to treat any other medical complaints unless your prescriber tells you to.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Mirtazapine (Noumed) may cause drowsiness, dizziness or sleepiness in some people and affect alertness and concentration. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

You are advised not to drink any alcohol while taking Mirtazapine (Noumed).

Combining Mirtazapine (Noumed) and alcohol can make you sleepier and less alert. Your prescriber may suggest you avoid alcohol while being treated with this medicine.

In case of overdose

Immediately telephone your prescriber or Poisons Information Centre (telephone in New Zealand - 0800 POISONS or 0800 764 766) for advice if you think that you or anyone else may have taken too much mirtazapine.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too many Mirtazapine (Noumed) tablets, you may feel drowsy, dizzy, confused, and agitated.

You may also have changes to your heart rhythm (fast, irregular heartbeat) and/or fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Mirtazapine (Noumed).

Tell your prescriber as soon as possible if you do not feel well while you are taking mirtazapine or if you have any questions or concerns.

Mirtazapine (Noumed) helps most people with depression, but it may have unwanted side effects in a few people.

Like other medicines, mirtazapine can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your prescriber or pharmacist to answer any questions you may have.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Tell your prescriber or pharmacist if you notice any of the following and they worry you:

- lethargy, drowsiness or sleepiness
- headache
- tiredness
- increase in appetite and weight gain
- dry mouth
- nausea, vomiting
- diarrhoea
- constipation
- dizziness
- dizziness or faintness when getting up quickly from a lying or sitting position (low blood pressure)
- abnormal sensations in the mouth sensations of numbness in the mouth or swelling in the mouth
- aggression
- swollen ankles or feet as a result of fluid accumulation (oedema)
- rash or skin eruptions
- nightmares/vivid dreams
- tingling fingers or toes
- painful joints
- back pain
- muscle aches and pains
- restless legs
- abnormal sensation in the skin for example burning, stinging, tickling or tingling
- urge to move
- speech disorders
- difficulty in passing urine (urinary retention)
- anxiety, insomnia.

These may be symptoms of depression.

Tell your prescriber immediately, or go to the Accident and Emergency at your nearest hospital if you notice any of the following:

- suicidal ideation or behaviour
- epileptic attack (seizures)
- shaking or tremors
- sudden muscle contractions (myoclonus)
- attack of excessive excitability (mania)
- agitation
- confusion
- hallucinations
- changes to your heart rhythm
- fainting
- yellow colouring of eyes or skin; this may suggest disturbance in liver function
- abdominal pain and nausea; this may suggest inflammation of the pancreas
- generalised fluid retention with weight gain
- skin rash, itching or hives; swelling of the face, lips or tongue which may cause

- difficulty breathing
- signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers
 - a combination of symptoms such as fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes unconsciousness and increased salivation (serotonin syndrome)
 - muscle pain, stiffness and/or weakness, darkening or discolouration of the urine (rhabdomyolysis)

Other adverse effects not listed above may also occur in some patients. Tell your prescriber if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Ask your prescriber or pharmacist if you don't understand anything in this list.

After using Mirtazapine (Noumed)

Storage

Keep your medicine in its original packaging until it is time to take it. If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window-sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your prescriber tells you to stop taking this medicine, or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

Mirtazapine (Noumed), film-coated tablets, 30 mg are:

Reddish brown, biconvex capsule shaped film-coated tablets with score line on one side and 30 debossed on the other side. **This tablet can be halved to give a 15 mg dose.**

Mirtazapine (Noumed), film-coated tablets, 45 mg are:

White, biconvex, capsule shaped film-coated tablets. Plain on one side and 45 debossed on other side. **This tablet cannot be halved.**

The product is available in blister packs of 30 tablets.

Ingredients

Active ingredient:

Each film-coated tablet contains either 30 mg or 45 mg of Mirtazapine.

Mirtazapine (Noumed) tablets also contain the following inactive ingredients:

Core tablets
Lactose monohydrate
Hydroxypropylcellulose
Maize starch
Colloidal anhydrous silica
Low-Substituted hydroxypropyl cellulose
Magnesium stearate
Coating ingredients
Hypromellose
Hydroxypropyl cellulose
Titanium dioxide
For 30 mg tablets only
Iron oxide yellow, Iron oxide red and Iron oxide black

This medicine contains lactose.

Sponsor Details

Mirtazapine (Noumed), film-coated tablets 30 mg & 45 mg are supplied in New Zealand by:

Noumed Pharmaceuticals Limited
Auckland, NZ
Freephone 0800 527 545

Date of Preparation

This leaflet was prepared on 30/10/2023.