

NOUMED MIRTAZAPINE

mirtazapine tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NOUMED MIRTAZAPINE.

It does not contain all of 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 taking this medicine against the benefits it is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What NOUMED MIRTAZAPINE is used for

NOUMED MIRTAZAPINE tablets contain the active ingredient mirtazapine.

Mirtazapine helps relieve symptoms of major depression by correcting imbalances in brain chemicals that are involved in controlling moods.

Depression is longer lasting or more severe than the "low moods" that everyone has from time to time due to the stress of everyday life.

Chemical imbalances in parts of the brain can affect the whole body and cause emotional and physical symptoms including being low in spirit, lacking interest in activities, inability to enjoy life, poor appetite or overeating, disturbed sleep or

waking up too early, loss of sex drive, lack of energy and feelings of guilt.

This medicine is available only with a doctor's prescription.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

NOUMED MIRTAZAPINE is not addictive.

Do not give this medicine to a child or adolescent.

Its safety and use in patients under 18 years of age have not been established.

Before you take it

When you must not take it

Do not take this medicine if you have an allergy to mirtazapine or to any of the other ingredients listed at the end of this leaflet under Product Description.

Some of the symptoms of an allergic reaction may include shortness of breath; wheezing or difficulty in breathing; swelling of the face, lips tongue or other parts of the body; rash, itching or hives on the skin.

Do not take NOUMED MIRTAZAPINE if you are also taking, or have been taking, a monoamine oxidase inhibitor (MAOI) within the last 14 days.

Allow at least 14 days to elapse before starting on mirtazapine after your last dose of the MAOI, or vice versa.

Phenelzine, tranylcypromine and selegiline are examples of MAOIs, which are also medicines used to treat depression.

Taking mirtazapine with MAOIs may cause a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

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

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you take it after the expiry date has passed, it may not work as well.

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

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

Before you start to take it

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

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

Medicines of this kind are not recommended during pregnancy, but your doctor can discuss with you the potential risks and benefits if it is necessary for you to take this medicine.

Tell your doctor if you are breastfeeding or wish to breastfeed.

It is not known if mirtazapine passes into breast milk.

Tell your doctor if you have or have ever had any medical conditions, especially:

- thoughts of suicide or self-harm
- epilepsy (fits or convulsions)
- liver disease such as jaundice
- kidney disease
- heart disease
- low blood pressure (hypotension)
- certain kinds of heart conditions that may change your heart rhythm, a recent heart attack, heart failure, or you take certain medicines that may affect the heart's rhythm
- any mental illness (e.g. schizophrenia, manic depression)
- diabetes
- glaucoma (increased pressure in your eyes)
- problems in urinating due to an enlarged prostate
- unexplainable high fever, sore throat or mouth ulcers
- galactose intolerance
- glucose-galactose malabsorption.

If you have not told your doctor about any of the above, tell him/her before you start taking this medicine.

Taking other medicines

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

Some medicines and NOUMED MIRTAZAPINE may interfere with each other, including:

- other medicines for depression, anxiety, obsessive compulsive disorders or pre-menstrual dysphoric disorder (e.g. SSRIs, venlafaxine, L-tryptophan, nefazodone)
- monoamine oxidase inhibitors (MAOIs), e.g. tranylcypromine, phenelzine and selegiline

- medicines containing St John's Wort (*Hypericum perforatum*)
- phenytoin or carbamazepine (for epilepsy)
- benzodiazepines (for anxiety and sleeping problems)
- lithium (for psychiatric conditions)
- methylene blue (for high levels of methemoglobin in the blood)
- tramadol (a pain killer)
- morphine (for severe pain)
- cetirizine (for allergies)
- warfarin (to prevent blood clots)
- linezolid or erythromycin (antibiotics)
- rifampicin (for tuberculosis)
- medicines for fungal infections, such as ketoconazole
- medicines used to treat HIV/AIDS
- cimetidine (for reflux and stomach ulcers)
- triptans such as sumatriptan, naratriptan and zolmitriptan, medicines (for migraines)
- medicines that may affect the heart's rhythm such as certain antibiotics and anti-psychotics.

These medicines may be affected by NOUMED MIRTAZAPINE, or may affect how well it works. Your doctor will tell you what to do if you are taking any of these medicines. You may need to take different amounts of your medicine or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking NOUMED MIRTAZAPINE.

How to take NOUMED MIRTAZAPINE

How much to take

Your doctor will determine the dose that is suitable for you. The usual starting dose is 15 mg per day, but

your doctor may slowly increase it depending on how you respond. The effective dose for most people is between 30 mg to 45 mg per day.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you or do not understand the instructions.

They will tell you exactly how much to take.

Follow all directions they give you carefully.

If you take the wrong dose, NOUMED MIRTAZAPINE may not work as well and your condition may not improve.

How to take it

Swallow the tablet(s) with plenty of water or other fluid. Do not chew.

If you need to break the 30 mg tablet in half, hold it with both hands and snap along the break line.

When to take it

Take your medicine at about the same time each day, preferably as a single dose in the evening before going to bed.

Taking it at the same time each day will have the best effect and will also help you remember when to take it.

Your doctor may recommend taking your medicine in smaller doses twice a day, for example 15 mg each in the morning and night-time instead of a single 30 mg dose.

You can take the tablets with or without food.

How long to take it

You should continue taking NOUMED MIRTAZAPINE as long as your doctor tells you, even if you begin to feel better.

Most antidepressant medicines take time to work so do not be discouraged if you do not feel better right away. Some symptoms may improve in 1 to 2 weeks, but it can

take 2 to 4 weeks to feel the full benefit of the medicine.

Since individuals respond differently to treatment, your doctor will check your progress at regular intervals. Treatment usually lasts for about 4 to 6 months. If you stop treatment too soon, your symptoms may return.

If you forget to take it

Once a day dose

Since this medicine may cause drowsiness or sleepiness, your doctor may have told you to take only a single dose in the evening.

If you have forgotten to take your dose before going to bed, do not take the missed dose the next morning. Skip that dose and take your next dose in the evening when you are meant to.

Twice a day dose

Your doctor may have recommended taking your medicine in smaller doses twice a day: once in the morning and another in the evening.

If you forgot to take your morning dose, take it together with your evening dose.

If you forgot your evening dose, skip that dose. Take your usual dose in the morning, as you would normally.

If you forgot both doses, do not take double doses to make up for the doses that you missed.

This may increase the chance of you getting an unwanted side effect.

Continue treatment with your usual morning and evening doses the next day.

If you are not sure what to do, ask your doctor pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (13 11 26) for advice, or go

to Accident and Emergency at the nearest hospital, if you think that you or anyone else has taken too much NOUMED

MIRTAZAPINE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep this telephone number handy.

If you take too much mirtazapine, you may feel drowsy, dizzy, confused, agitated, have increased heart rate or lose consciousness.

While you are taking it

Things you must do

Always follow your doctor's instructions carefully.

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are taking NOUMED MIRTAZAPINE.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Tell your doctor immediately if you become pregnant while taking NOUMED MIRTAZAPINE.

Tell your doctor immediately if you develop fever, chills, sore throat, mouth ulcers or other signs of frequent infections.

These may be symptoms of rare effects where mirtazapine disturbs the production of blood cells in the bone marrow. People with low white blood cell counts (granulocytopenia) become less resistant to infection. Low levels of red and white blood cells and platelets (aplastic anaemia), low platelets (thrombocytopenia) or higher white blood cell counts (eosinophilia) can also occur rarely after 4-6 weeks of treatment.

Your doctor may advise you to stop taking NOUMED MIRTAZAPINE, and arrange a blood test.

Tell your doctor immediately or go to the nearest hospital if you have thoughts about harming or killing yourself, or if you know someone using NOUMED MIRTAZAPINE who talks about or shows signs of suicide-related behaviour.

All mentions of self-harm, suicide or violence must be taken seriously.

Occasionally, symptoms of depression or other psychiatric conditions may include thoughts of suicide or self-harm. These symptoms may emerge or worsen until the full effects of the medicine become apparent. This is more likely to occur in young adults, i.e. 18 to 24 years old who have not used antidepressant medicines before.

Patients and care givers should be aware of any of the following warning signs of suicide-related behaviour while taking NOUMED MIRTAZAPINE. Tell your doctor or mental health professional immediately, or go to the nearest hospital for treatment.

- thoughts or talk of 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.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may arrange some blood tests from time to time. This helps prevent unwanted side effects.

Tell your doctor if you feel the tablets are not helping your condition.

Tell your doctor if you have not taken your medicine exactly as prescribed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not take NOUMED MIRTAZAPINE to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop taking NOUMED MIRTAZAPINE, or lower the dose, without checking with your doctor.

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

Suddenly stopping this medicine may cause nausea, headache, dizziness, anxiety, agitation.

Your doctor may want you to gradually reduce the amount you are taking before stopping completely. This may help reduce the possibility of withdrawal symptoms such as nausea, headache, dizziness, anxiety and agitation.

Things to be careful of

Make sure you know how NOUMED MIRTAZAPINE affects you before you drive or operate machinery.

It may cause drowsiness, dizziness or sleepiness in some people, and affect alertness and concentration. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Avoid alcohol while you are taking this medicine.

It is not advisable to drink alcohol while you are being treated for depression.

Combining this medicine with alcohol can make you more sleepy and less alert.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are taking NOUMED MIRTAZAPINE.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. Ask your doctor or pharmacist if you do not understand anything in these lists.

You may not experience any of them.

Tell your doctor 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 or faintness, especially when getting up quickly from a lying or sitting position (low blood pressure)
- numbness, swelling or unusual feeling in the mouth
- aggression
- swollen ankles or feet due to fluid accumulation (oedema)
- rash or skin eruptions
- unusual feeling on the skin such as burning, stinging, tickling or tingling sensations
- nightmares/vivid dreams
- tingling fingers or toes
- painful joints
- back pain, muscle aches and pains
- restless legs
- unusual urges to move
- speech disorder
- difficulty in passing urine (urinary retention)
- anxiety or insomnia (*these may be symptoms of depression*)

- symptoms of increased prolactin hormone levels in the blood (hyperprolactinaemia), including enlarged breasts, milky nipple discharge
- sleepwalking
- prolonged painful erection of the penis
- memory problems.

Tell your doctor immediately, or go to 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; which may suggest disturbance in liver function
- abdominal pain and nausea, which 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
- severe skin reactions
- signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers
- a combination of fever, sweating, higher heart rate, uncontrollable diarrhoea, muscle contractions, shivering, overactive reflexes, restlessness, mood changes, unconsciousness and drooling of saliva (symptoms of serotonin syndrome)
- a combination of muscle pain, stiffness and/or weakness, dark

or discoloured urine (symptoms of rhabdomyolysis)

These are very serious side effects that may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking it

Storage

Keep your medicine in the original container until it is time to take them.

If you take the tablets out of its container, they may not keep well.

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

Do not store it, or any other medicine, in the bathroom or near a sink. Do not leave it on a windowsill 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 doctor tells you to stop taking this medicine or its expiry date has passed, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

NOUMED MIRTAZAPINE is available in 2 strengths that are supplied in blister packs of 30 tablets each.

30 mg: beige, round, biconvex, film-coated tablet with a one-sided breakline.

45 mg: white, round, biconvex, film-coated tablet.

Ingredients

Active ingredient

NOUMED MIRTAZAPINE tablets contain either 30 mg or 45 mg of mirtazapine.

Inactive ingredients

- lactose monohydrate
- maize starch
- hypromellose
- colloidal anhydrous silica
- magnesium stearate
- hypromellose
- macrogol 8000
- titanium dioxide

The 30 mg tablets also contain the colourants: iron oxide black, iron oxide red and iron oxide yellow.

NOUMED MIRTAZAPINE does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Avallon Pharmaceuticals Pty Ltd
Level 5, 7 Eden Park Drive
Macquarie Park NSW 2113
Telephone 1800 930 999

Australian registration numbers

30 mg: AUST R 308469

45 mg: AUST R 308471

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