

Noumed Risperidone

risperidone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Noumed Risperidone.

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 taking this medicine against the benefits they expect it will 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 Risperidone is used for

Noumed Risperidone contains the active ingredient risperidone.

Risperidone belongs to a group of medicines called antipsychotic agents, which improve the symptoms of certain types of mental illness.

It is used for:

- Treatment of sudden (acute) and long-term (chronic) schizophrenia and other types of related psychoses. These are disorders related to thought, feeling and/or action.
- Short term treatment of acute mania associated with bipolar I disorder. Symptoms of this condition include elevated,

expansive or irritable mood, inflated self esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility or poor judgement including disruptive or aggressive behaviours.

- Treatment of behavioural problems in patients with a decline in mental ability (dementia). These problems include: aggression through words or action, morbid suspiciousness, agitation or wandering.
- Treatment of conduct and other disruptive behaviours such as aggression, impulsiveness and self-injury in children (> 5 years), adolescents and adults who are intellectually disabled.
- Treatment of behavioural symptoms of autism in children and adolescents.

This medicine helps to correct a chemical imbalance in the brain associated with the conditions mentioned above.

Ask your doctor if you have any questions about why Noumed Risperidone was prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that Noumed Risperidone is addictive.

Before you take Noumed Risperidone

When you must not take it

Do not take this medicine if you have an allergy to:

- risperidone, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines, especially if they are in the same drug class as risperidone.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

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 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 doctor.

Before you start to take it

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

1. Tell your doctor if you have or have ever had any medical conditions, especially the following:

- heart or blood vessel problems, including high or low blood pressure.

Low blood pressure can result from using Noumed Risperidone together with medications to treat high blood pressure. So, if you need to use both Noumed Risperidone and medications to reduce blood pressure, consult your doctor. Noumed Risperidone should be used with caution, and only after consultation with your doctor, if you have heart problems, particularly irregular heart rhythm, abnormalities in electrical activity of the heart, or if using medications that can change the heart's electrical activity.

- diseases of the blood vessels of the brain, including stroke
- unusual, excessive sweating or diarrhoea, dehydration or problems with your body
- kidney or liver problems
- you are prone to dizziness when standing up from a lying or sitting position
- Parkinson's disease (a disease of the brain affecting movement)
- dementia or Lewy body dementia
Older people suffering dementia may be at increased risk of death with Noumed Risperidone
- unusual thirst, tiredness, blurred vision, upset stomach or need to urinate - common signs of high blood sugars
- epilepsy, seizures or fits
- continuous and/or painful erections (called 'priapism')
- unusual restlessness or difficulty sitting still
- intraoperative iris syndrome (a complication that may occur during cataract extraction)
- suicidal thoughts or past suicide attempts
- low blood potassium levels (hypokalaemia)
- low blood sugar
- breast cancer
- cancer of the pituitary gland

- sugar diabetes
- Tardive dyskinesia (a reaction to some medicines with uncontrollable twitching or jerking movements of the tongue, face, mouth, jaw, arms and legs)
- Neuroleptic Malignant Syndrome (a serious reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions).

- blood clots

Tell your doctor if you or someone else in your family has a history of blood clots.

Blood clots in the lungs and legs can occur with Noumed Risperidone. Blood clots in the lungs can result in death.

- low white blood cell count

If you have low numbers of some white blood cells, your risk of contracting an infection or developing a fever is increased with Noumed Risperidone.

2. Tell your doctor if:

- **you have any eye surgery planned.**

Your doctor will need to assess whether you are at increased risk of a surgical complication (called 'Intraoperative Floppy Iris Syndrome'). You may be recommended to stop your Noumed Risperidone temporarily prior to your eye surgery

- **you are pregnant or intend to become pregnant.**

Your doctor will advise you whether you should take Noumed Risperidone. Newborn babies of mothers taking this medicine in their last trimester may be at risk of having difficulty feeding or breathing, shaking, muscle stiffness and/or weakness, sleepiness or agitation.

- **you are breast-feeding.**

Your doctor will advise you whether or not you should use Noumed Risperidone.

Taking other medicines

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

Ask your doctor or pharmacist before taking any other medicines. Noumed Risperidone can increase the effects of medicines which slow your reactions.

These include herbal treatments.

Some medicines and Noumed Risperidone may interfere with each other. These include:

- sleeping tablets, tranquillisers, strong pain-killers, certain allergy medicines called antihistamines, certain antidepressants and alcohol
- medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).
- medicines used to treat bacterial infections such as rifampicin
- medicines to treat fungal infections such as itraconazole and ketoconazole
- medicines to treat HIV/AIDS, such as ritonavir and tipranavir
- other medicines to treat mental illness or psychotic conditions
- medicines to treat depression, panic disorder, anxiety or obsessive-compulsive disorder, such as fluoxetine, paroxetine, sertraline and fluvoxamine
- medicines for your heart or blood pressure
- verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm
- diuretics (e.g. frusemide), a medicine used to treat high blood pressure and fluid build-up. There is an increased risk of side effects or death in older people if frusemide is also taken with Noumed Risperidone.

- medicines to treat epilepsy
- carbamazepine, a drug mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face)
- medicines to treat Parkinson's disease or a tremor

These medicines may be affected by Noumed Risperidone or may affect how well it works. You may need different amounts of your medicines, 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 this medicine.

How to take Noumed Risperidone

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, ask your doctor or pharmacist for help.

How much to take

Your doctor will decide the dose suitable for you.

Do not change or stop the required dosage without consulting your doctor first.

Important note:

Never take more tablets than your doctor tells you to take.

The maximum daily dose is 5 milligrams taken twice a day. Check with your doctor if more than this has been prescribed. The effects of high doses are not yet known.

This medicine cannot be recommended for use in children with schizophrenia under 15 years at the present time as there is little experience with the product in this group.

For schizophrenia and related psychoses

The usual starting dose of Noumed Risperidone is 1mg twice a day. This will be gradually increased by your doctor to suit your needs.

From then on, the dose can be taken once a day or twice a day according to your doctor's instructions. For long-term treatment, 4 to 6 milligrams per day is usually sufficient but your doctor will determine the dose most suitable for you.

For elderly patients with schizophrenia or related psychoses

For older patients a starting dose of 0.5mg twice a day (in the morning and in the evening) is usual. The dose may be increased by 0.5mg twice daily to 1mg to 2mg twice a day (in the morning and in the evening).

For patients with impaired kidney and liver function

If you have kidney or liver disease a starting dose of 0.5mg twice a day (in the morning and in the evening) is usual. The dose may be increased by 0.5mg twice daily to 1 to 2mg twice a day (in the morning and in the evening).

For acute mania

The recommended starting dose is 2mg once a day. This dose can be adjusted by dose increases of 1mg every 24 hours, when needed. Most people feel better with doses between 2mg and 6mg a day. Your doctor may decide that you should take another drug called a mood stabiliser as well as Noumed Risperidone.

For behavioural problems in people with dementia

The usual starting dose is 0.25mg (a half of a 0.5mg tablet) twice daily. This may be gradually increased by your doctor to suit your needs.

From then on the dose can be taken once a day or twice a day according to your doctor's instructions. For long-term treatment, 1mg daily is the usual dose but your doctor will

determine the dose most suitable for you.

For disruptive behaviour disorders in adults and children

For people who weigh 50kg or more, the usual starting dose is 0.5mg once a day. The dose may be increased by 0.5mg once every two days, to the usual dose of 0.5mg to 1.5mg once a day.

For people who weigh less than 50kg, the usual starting dose is 0.25mg once a day (a half of a 0.5mg tablet). The dose may be increased by 0.25mg once every two days, to the usual dose of 0.25mg to 0.75mg once a day.

Your doctor will advise you on how much Noumed Risperidone you need. Noumed Risperidone cannot be recommended for use in children with disruptive behaviour disorders under 5 years at the present time as there is little experience with the product in this group.

For behavioural disorders associated with autism in children and adolescents

For people weighing less than 20kg, the usual starting dose is 0.25mg (a half of a 0.5mg tablet). On day 4 this dose can be increased to 0.5mg.

For people weighing 20kg or more, the usual starting dose is 0.5mg. On day 4 this dose can be increased to 1mg.

Response should be assessed at day 14; only in patients not achieving sufficient clinical response should additional dose increases be considered. Your doctor will advise you on how much Noumed Risperidone you need. When trialled, the maximum dose in patients with autism did not exceed 1.5mg/day in patients less than 20kg, 2.5mg in patients 20kg or more, or 3.5mg in patients more than 45kg.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

It is very important that you take the correct amount of tablets, but this will vary from person to person. Your doctor will adjust the number and strength of the tablets until the desired effect is obtained.

How to take it

Swallow the tablets with water or other liquid.

If you need to break Noumed Risperidone, hold tablet with both hands and snap along break line.



When to take Noumed Risperidone

This medicine may be taken as a single dose, once a day or it may be taken in divided doses twice a day (in the morning and in the evening). You may take it either with or between meals.

How long to take Noumed Risperidone

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. Therefore you must take this medicine every day.

Do not stop taking it unless your doctor tells you to, even if you feel better.

If you forget to take your dose

If you forget to take Noumed Risperidone, take the missed dose as soon as you remember instead of your next dose. Then go back to taking it as you would normally.

Do not take a double dose to make up for the dose you missed.

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

If you forget to take Noumed Risperidone for 5 days or more, tell

your doctor before starting your medicine again.

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

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

If you take too much (overdose)

The reference to Accident and Emergency and urgent medical attention could be left out, depending on the type of product.

Include the relevant New Zealand telephone number if appropriate.

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much [Medicine name]. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include: drowsiness, sleepiness, excessive trembling, excessive muscle stiffness, increased heart rate, very low blood pressure causing fainting or unconsciousness.

While you are using Noumed Risperidone

Things you must do

Always follow your doctor's instructions carefully and seek your doctor's advice before changing or stopping treatment.

Try to eat a moderate diet: risperidone can cause weight gain.

If you become pregnant while taking this medicine, tell your doctor immediately.

Pre-menopausal women should tell their doctor if they do not have a

period for more than six weeks while taking Noumed Risperidone.

Tell your doctor immediately if you notice any worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs.

These are symptoms of a condition called tardive dyskinesia, which may develop in people taking antipsychotic medicines, including Noumed Risperidone. This condition is more likely to occur during long term treatment with Noumed Risperidone, especially in elderly women. In very rare cases, this may be permanent. However, if detected early, these symptoms are usually reversible.

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

If you are about to be started on any new medicine, including herbal treatments and drugs bought in a pharmacy or supermarket, remind your doctor and pharmacist that you are taking Noumed Risperidone.

Try to drink plenty of water, especially if you are elderly and taking frusemide (a diuretic).

This will help decrease your risk of certain side effects.

Things you must not do

Do not take Noumed Risperidone to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or change the dosage without checking with your doctor.

Do not drink alcohol.

Noumed Risperidone can increase the effects of alcohol.

Things to be careful of

Be careful driving or operating machinery until you know how Noured Risperidone affects you.

This medicine may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to this medicine before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

Avoid excessive eating as there is a possibility of weight gain when taking this medicine.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Noured Risperidone.

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

Do not be alarmed by this lists of side effects. You may not experience any of them.

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

Taking it for the first time:

At the start of treatment you may have a fall in blood pressure making you feel dizzy on standing up, or your heart may beat faster. These should go away after a few days. Tell your doctor if they continue or worry you.

Tell your doctor if you notice any of the following and they worry you:

- Difficulty thinking or working because of:
 - sleeplessness
 - headache
 - trembling

- drowsiness, tiredness, difficulty in concentrating.
- Behavioural changes such as:
 - agitation
 - anxiety.
- Joint or movement changes such as:
 - muscle stiffness
 - restlessness in the legs.
- Other changes such as:

weight gain

- indigestion, nausea, abdominal pain, constipation
- excessive thirst
- frequent urination
- blockage in the bowel
- unusual secretion of breast milk
- breast swelling
- missed or irregular menstrual periods
- involuntary movements of the tongue, face, mouth, jaws, arms, legs or trunk.

These are mild side effects of Noured Risperidone but may require medical attention.

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

- Heart or blood pressure problems such as:
 - fall in blood pressure, particularly on standing. This will be apparent to you as light-headedness or dizziness that passes after a few seconds or after sitting down again.
 - faster heart rate, slowed heart rate, heart beat irregularities.
- Body temperature changes such as:
 - fever
 - abnormally high body temperature.

These may be serious side effects of Noured Risperidone. You may need

urgent medical attention. Serious side effects are uncommon.

If any of the following happen, stop taking Noured Risperidone and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body. If you have them, you may have had a serious allergic reaction to Noured Risperidone.
- sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech (these are called mini-strokes)
- in elderly patients with dementia, occurrence of following even for a short period time: sudden weakness or numbness of the face, arms or legs, especially on one side, instances of slurred speech and stroke.

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

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

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

After using Noured Risperidone

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

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

Do not store Noured Risperidone 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 it 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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Noumed Risperidone comes in five types of tablets:

Noumed Risperidone 0.5mg — red, oval, scored film-coated tablets.

Noumed Risperidone 1mg — white, oval, scored film-coated tablets, coded “1” on one side.

Noumed Risperidone 2mg — apricot, oval, scored film-coated tablets, coded “2” on one side.

Noumed Risperidone 3mg — yellow, oval, scored film-coated tablets, coded “3” on one side.

Noumed Risperidone 4mg — green, oval, scored film-coated tablets, coded “4” on one side.

The 0.5 mg tablets are packaged in either PVC/PCTFE (aclar) /Aluminium foil blisters or PVDC/PE/PVC-Aluminium foil blisters.

The 1 mg, 2 mg, 3 mg & 4 mg tablets are packaged in either PVC/COC/PVdC/Al (Topas) or PVC/PE/PVDC/Aluminium foil blisters.

Available in packs of 60 tablets.

Ingredients

Noumed Risperidone contains 0.5 mg, 1 mg, 2 mg, 3 mg or 4 mg of risperidone as the active ingredient.

Inactive ingredients:

- microcrystalline cellulose
- lactose monohydrate
- magnesium stearate
- colloidal anhydrous silica
- hypromellose
- pregelatinised maize starch (1mg, 2mg, 3mg and 4mg tablets only)
- macrogol 4000 (1mg, 2mg, 3mg and 4mg tablets only)
- croscarmellose sodium (0.5mg tablets only)
- stearic acid (0.5mg tablets only)
- titanium dioxide
- iron oxide red (0.5mg and 2mg tablets only)
- iron oxide yellow (2mg tablets only)
- quinoline yellow (3mg and 4mg tablets only)
- indigo carmine aluminium lake (4mg tablets only).

This medicine 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

Australian Register Number(s)

Noumed Risperidone 0.5mg film-coated tablets: AUST R 284369 (blister pack)

Noumed Risperidone 1mg film-coated tablets: AUST R 284370 (blister pack)

Noumed Risperidone 2mg film-coated tablets: AUST R 284371 (blister pack)

Noumed Risperidone 3mg film-coated tablets: AUST R 284372 (blister pack)

Noumed Risperidone 4mg film-coated tablets: AUST R 284373 (blister pack)

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