

Noumed Fluoxetine

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Noumed Fluoxetine?

Noumed Fluoxetine contains the active ingredient fluoxetine hydrochloride. Noumed Fluoxetine is used to treat depression and obsessive compulsive disorder (OCD). For more information, see Section [1. Why am I using Noumed Fluoxetine?](#) in the full CMI.

2. What should I know before I use Noumed Fluoxetine?

Do not use if you have ever had an allergic reaction to fluoxetine hydrochloride or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Noumed Fluoxetine?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Noumed Fluoxetine and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Noumed Fluoxetine?

Your doctor will tell you how much Noumed Fluoxetine you need to take each day. The usual dose is one capsule taken once a day, swallowed whole. Your doctor may increase or decrease your dose depending on your condition.

More instructions can be found in Section [4. How do I use Noumed Fluoxetine?](#) in the full CMI.

5. What should I know while using Noumed Fluoxetine?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking Noumed Fluoxetine.• Tell your doctor if you become pregnant while taking Noumed Fluoxetine• Keep all of your doctor's appointments so that your progress can be checked.• If you or someone you know is demonstrating any of the following warning signs, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment:<ul style="list-style-type: none">• worsening of your depression• thoughts or talk of death or suicide• thoughts or talk of self-harm or harm to others• any recent attempts at self-harm• increase in aggressive behaviour, irritability or any other unusual changes in behaviour or mood.• All mentions of suicide or violence must be taken seriously.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.• Do not take Noumed Fluoxetine to treat any other complaints unless your doctor tells you to.• Do not give your medicine to anyone else, even if their symptoms seem similar to yours.• Do not take the herbal remedy St John's Wort while you are being treated with Noumed Fluoxetine.• Do not let yourself run out of Noumed Fluoxetine over the weekend or on holidays.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery until you know how Noumed Fluoxetine affects you.• Noumed Fluoxetine may cause drowsiness in some people. If you experience drowsiness, do not drive, operate machinery or do anything else that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.• Although drinking alcohol is unlikely to affect your response to Noumed Fluoxetine, your doctor may suggest avoiding alcohol while you are being treated for depression.
Looking after your medicine	<ul style="list-style-type: none">• Store your medicine in a cool dry place where the temperature stays below 25°C.• Keep it where children cannot reach it.

For more information, see Section [5. What should I know while using Noumed Fluoxetine?](#) in the full CMI.

6. Are there any side effects?

Common side effects include: nausea, vomiting, upset stomach, diarrhoea, loss of appetite, weight loss, changes in taste, dry mouth, trouble sleeping, unusual dreams, nervousness, anxiety, drowsiness, weakness, dizziness, excessive sweating, flushing, chills, lesions of skin and mucous membrane, fever and joint aches, sexual problems, more frequent urination and changes in vision. **Serious side effects include:** itching, skin rash or hives, shortness of breath, wheezing or trouble breathing, swelling of the face, lips, tongue or other parts of the body, muscle spasms, tremors, twitches, convulsions or fits, fast, irregular heart beat, abnormal bleeding or bruising, sudden switches of mood to one of overactivity and uninhibited behaviour, sudden fever, hallucinations, loss of coordination, confusion and overactive reflexes. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Noumed Fluoxetine

Active ingredient(s): [*fluoxetine (as hydrochloride)*]

Consumer Medicine Information (CMI)

This leaflet provides important information about using Noumed Fluoxetine. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Noumed Fluoxetine.**

Where to find information in this leaflet:

- [1. Why am I using Noumed Fluoxetine?](#)
- [2. What should I know before I use Noumed Fluoxetine?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Noumed Fluoxetine?](#)
- [5. What should I know while using Noumed Fluoxetine?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Noumed Fluoxetine?

Noumed Fluoxetine contains the active ingredient fluoxetine hydrochloride. Noumed Fluoxetine is a selective serotonin reuptake inhibitor (SSRI). It works by inhibiting the neuronal uptake of serotonin in the central nervous system. Serotonin is one of several brain chemicals called amines which are involved in controlling mood.

Noumed Fluoxetine is used to treat depression and obsessive compulsive disorder (OCD).

2. What should I know before I use Noumed Fluoxetine?

Warnings

Do not use Noumed Fluoxetine if:

- you are allergic to fluoxetine hydrochloride, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are allergic to any other similar medicines.
- you are taking another medicine for depression called monoamine oxidase inhibitor (MAOI), or have been taking a MAOI within the last 14 days. Examples of MAOIs are phenelzine and tranylcypromine. There may be others so please check with your doctor. If you do take Noumed Fluoxetine while you are taking a MAOI, you may experience shaking (tremor), shivering, muscle stiffness, fever, rapid pulse, rapid breathing or confusion.
- you are taking pimozone, a medicine used to treat disturbances in thinking, feelings and behaviour.

Taking pimozone together with Noumed Fluoxetine may alter the rhythm of your heart.

- you are taking metoprolol, a medicine used to treat cardiac failure.

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.

Check with your doctor if you:

- have any other medical conditions such as:
 - kidney problems
 - liver problems
 - diabetes
 - fits
 - a bleeding disorder or a tendency to bleed more than usual.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of taking this medicine during pregnancy. If Noumed Fluoxetine is taken during pregnancy, you should be careful, particularly at the end of pregnancy. Transitory withdrawal symptoms have been reported rarely in the newborn after maternal use in the last 3 months of pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some combinations of medicines may increase the risk of serious side effects and are potentially life threatening.

Some medicines may interfere with Noumed Fluoxetine and affect how it works. These include:

- monoamine oxidase inhibitors (MAOIs), medicines used to treat some types of depression.

You should stop taking MAOIs at least two weeks before starting Noumed Fluoxetine

- lithium, a medicine used to treat mood swings and some types of depression
- SNRIs, SSRIs and other medicines for depression, obsessive compulsive disorder or premenstrual dysphoric disorder (PMDD)
- metoprolol, used to treat cardiac failure
- mequitazine, used to treat allergies and rhinitis
- sleeping tablets or sedatives
- medicines used to relieve anxiety
- medicines used to treat certain mental and emotional conditions, also called antipsychotics
- medicines used to treat disturbances in thinking, feelings and behaviour, such as pimozide
- medicines used to control fits
- medicines used to prevent blood clots, such as warfarin
- flecainide, a medicine used to treat some heart conditions
- tryptophan
- St John's Wort
- medicines used to relieve pain, such as tramadol
- sumatriptan, a medicine used to treat migraine
- tamoxifen, a medicine used to treat or prevent breast cancer.

Do not start taking other medicines for depression without checking with your doctor. Do this even if you have already stopped taking Noumed Fluoxetine.

Monoamine oxidase inhibitors (MAOIs), which are other medicines used for depression, may interfere with Noumed Fluoxetine. You should not start a MAOI for at least 5 weeks after stopping Noumed Fluoxetine

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Noumed Fluoxetine.

4. How do I use Noumed Fluoxetine?

How much to take / use

Your doctor will tell you how much Noumed Fluoxetine you need to take each day. The usual dose is one capsule taken once a day. Your doctor may increase or decrease your dose depending on your condition.

Swallow the capsules whole with a glass of water.

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. If you take the wrong dose, Noumed Fluoxetine may not work as well and your problem may not improve.

When to take / use Noumed Fluoxetine

Noumed Fluoxetine is usually taken as a single morning dose. If your doctor tells you to take it twice a day, take a dose in the morning and at noon.

Take your medicine at about the same time each day.

Taking it at the same time each day will help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take Noumed Fluoxetine

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

The length of treatment will depend on how quickly your symptoms improve.

Most medicines of this type take time to work so don't be discouraged if you do not feel better right away. While some symptoms will be relieved sooner than others, Noumed Fluoxetine commonly takes two to four weeks before improvement is really apparent.

If you do not start to feel better in about four weeks, check with your doctor.

If you forget to use Noumed Fluoxetine

Noumed Fluoxetine should be used regularly at the same time each day. If you miss your dose at the usual time, take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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 are not sure what to do or missed several doses, ask your doctor or pharmacist.

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

If you use too much Noumed Fluoxetine

If you have taken too much Noumed Fluoxetine, you may feel sick in the stomach, vomit, feel restless, agitated or excited.

If you think that you have used too much Noumed Fluoxetine, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Noumed Fluoxetine?

Things you should do

Tell all doctors, dentists, and pharmacists who are treating you that you are taking this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using Noumed Fluoxetine.

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

The symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or suicide. These symptoms may continue or get worse during the first one or two months of treatment until the full anti-depressant effect of your medicine becomes apparent. This is more likely to occur in young adults under 25 years of age.

If you or someone you know is demonstrating any of the following warning signs, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment:

- worsening of depression
- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts at self-harm
- increase in aggressive behaviour, irritability or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

Things you should not do

- Do not stop using this medicine suddenly or lower the dosage without checking with your doctor. Suddenly stopping Noumed Fluoxetine may cause symptoms such as dizziness, anxiety, headache, feeling sick, or tingling or numbness of the hands or feet. Your doctor may want you to gradually reduce the amount of Noumed Fluoxetine you are taking before stopping completely.
- Do not take Noumed Fluoxetine to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if their symptoms seem similar to yours.
- Do not take the herbal remedy St John's Wort while you are being treated with Noumed Fluoxetine. If you are already taking the herbal remedy, stop taking St John's Wort and mention it to your doctor at your next visit.
- Do not let yourself run out of Noumed Fluoxetine over the weekend or on holidays.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Noumed Fluoxetine affects you.

Noumed Fluoxetine may cause drowsiness in some people. If you experience drowsiness, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Although drinking alcohol is unlikely to affect your response to Noumed Fluoxetine, your doctor may suggest avoiding alcohol while you are being treated for depression.

Looking after your medicine

- Keep your medicine in the original container
- If you take it out of its original container, it may not keep well
- Store your medicine in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Adults <ul style="list-style-type: none">• nausea, vomiting• upset stomach, diarrhoea• loss of appetite, weight loss, changes in taste, dry mouth• trouble sleeping, unusual dreams• nervousness, anxiety• drowsiness, weakness• dizziness• excessive sweating, flushing, chills• lesions of skin and mucous membrane• fever and joint aches• sexual problems• more frequent urination• changes in vision. Children & Adolescents <ul style="list-style-type: none">• Headaches• Weight loss• Decreased height gain	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">itching, skin rash or hivesshortness of breath, wheezing or trouble breathingswelling of the face, lips, tongue or other parts of the bodymuscle spasmstremorstwitchesconvulsions or fitsfast, irregular heart beatabnormal bleeding or bruisingsudden switches of mood to one of overactivity and uninhibited behavioursudden feverhallucinationsloss of coordinationconfusionoveractive reflexes.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Noumed Fluoxetine contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">Fluoxetine hydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">pregelatinised maize starchdimeticone 350gelatintitanium dioxideiron oxide yellow CI 77492patent blue V CI42051

Do not take this medicine if you are allergic to any of these ingredients.

What Noumed Fluoxetine looks like

Noumed Fluoxetine is a green, size 3, hard-shell gelatin capsule filled with a homogeneous white powder. (Aust R 308455).

It is available in PVC/PVDC/Al blister packs of 28 capsules.

Who distributes Noumed Fluoxetine

Sponsor

Avallon Pharmaceuticals Pty Ltd
Level 5, 7 Eden Park Drive
Macquarie Park NSW 2113
Tel: 1800 930 999
www.avallon-pharma.com.au

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