

Noumed Pregabalin

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.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before taking this medicine.

1. Why am I taking Noumed Pregabalin?

Noumed Pregabalin contains the active ingredient, pregabalin. Noumed Pregabalin is taken to treat neuropathic pain, which is pain caused by an abnormality of, or damage to, the nerves.

For more information, see Section [1. Why am I using Noumed Pregabalin?](#) in the full CMI.

2. What should I know before I take Noumed Pregabalin?

Do not use if you have ever had an allergic reaction to pregabalin 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 (including benzodiazepines and opioids), or are pregnant or plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with Noumed Pregabalin 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 take Noumed Pregabalin?

- Noumed Pregabalin should be administered once daily after an evening meal. It should be swallowed whole and should not be split, crushed or chewed.

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

5. What should I know while taking Noumed Pregabalin?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking Noumed Pregabalin.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine.• It is recommended to withdraw it gradually over a minimum of one week
Driving or using machines	<ul style="list-style-type: none">• Noumed Pregabalin may cause dizziness and drowsiness in some people.• If you experience any of these symptoms, do not drive, operate machinery or do not do anything else that could be dangerous
Drinking alcohol	<ul style="list-style-type: none">• If you drink alcohol, symptoms such as dizziness and drowsiness may be worsen
Looking after your medicine	<ul style="list-style-type: none">• Keep your capsules in a cool dry place where the temperature stays below 25°C.

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

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

Some common, less serious side effects include dizziness, feeling tired or drowsy, headache, unsteadiness when walking, reduced coordination, shaking or tremors, constipation, diarrhoea, nausea, dry mouth, blurred or double vision, abdominal pain, and increase in weight.

Serious side effects include unusual changes in mood or behaviour, increased irritability, anxiety or depression, thoughts of suicide, swelling of the face, lips, tongue, hands, ankles or feet, unexplained muscle pain, tenderness and weakness, irritated red eyes that are sensitive to light, and shortness of breath, wheezing or difficulty breathing.

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.

WARNING:

Noumed Pregabalin as an add-on therapy for adults with partial onset seizures has not been established. Noumed Pregabalin should be gradually decreased over a minimum period of 1 week to avoid seizures.

Before taking Noumed Pregabalin, tell your doctor if you have a history of drug abuse. Pregabalin poses risks of misuse, abuse and dependence. Using Noumed Pregabalin with other medicines that can make you feel drowsy such as sleeping tablets and other pain relievers (e.g. benzodiazepines and opioids), antihistamines, antidepressants, antipsychotics, cannabis, and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. If you have any concern about taking this medicine, speak to your doctor.

Noumed Pregabalin

Pregabalin

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking Noumed Pregabalin?

Noumed Pregabalin contains the active ingredient pregabalin.

Noumed Pregabalin belongs to a group of medicines called anticonvulsants and has pain relieving effects.

Noumed Pregabalin is used to treat neuropathic pain, which is pain caused by an abnormality of, or damage to, the nerves.

2. What should I know before I take Noumed Pregabalin?

Warnings

Do not take Noumed Pregabalin if:

- you are allergic to pregabalin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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.
 - reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes.

Check with your doctor if you:

- have any other medical conditions such as:
 - congestive heart failure,
 - kidney problems,
 - diabetes,
 - depression.
- take any medicines for any other condition.
- have a history of drug abuse.

Pregabalin poses risks of misuse, abuse and dependence. Your body may become used to you taking Noumed Pregabalin and this may result in physical dependence. It means that you may experience withdrawal symptoms if you stop taking Noumed Pregabalin suddenly. So it is important to strictly follow the directions given by your doctor.

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.

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

Noumed Pregabalin is not recommended for use during pregnancy.

Pregabalin use during the first 3 months of pregnancy may cause birth defects in the unborn child that require medical treatment. In a study reviewing data from women in Nordic countries who took pregabalin in the first 3 months of pregnancy, 6 babies in every 100 had such birth defects. This compares to 4 babies in every 100 born to women not treated with pregabalin in the study.

Abnormalities of the face (orofacial clefts), the eyes, the nervous system (including the brain), kidneys and genitals have been reported.

Effective contraception must be used by women of childbearing potential.

The active ingredient in Noumed Pregabalin passes into breast milk and its safety in infants is unknown. It is recommended that you do not breast-feed while taking Noumed Pregabalin.

Use in Children.

- There is not enough information to recommend the use of this medicine in children under the age of 18 years.

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 herbal supplements that you buy without a prescription from your pharmacy, supermarket, naturopath or health food shop.

Noumed Pregabalin and certain other medicines may influence each other (interaction).

Using Noumed Pregabalin with other medicines that can make you feel drowsy, such as sleeping tablets and other pain relievers (e.g. benzodiazepines and opioids), antihistamines, antidepressants, antipsychotics, cannabis, and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimize the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation.

You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

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 Pregabalin.

4. How do I take Noumed Pregabalin?

How much to take

- Take Noumed Pregabalin exactly as prescribed. Your doctor will tell you how much Noumed Pregabalin to take.

- Your doctor may recommend that you start with a low dose of Noumed Pregabalin and slowly increase the dose to the lowest amount needed to control your epilepsy/convulsions or neuropathic pain.
- Follow the instructions provided and take Noumed Pregabalin until your doctor tells you to stop.
- Take Noumed Pregabalin once a day, after an evening meal. Your medicine may not be as effective if taken on an empty stomach.

When to take Noumed Pregabalin

- Noumed Pregabalin must be taken once daily after an evening meal. The capsule should be swallowed whole and should not be split, crushed or chewed. Always take your medicine as directed by your doctor.

If you forget to take Noumed Pregabalin

Noumed Pregabalin must be taken once daily after an evening meal.

If you miss your dose at the usual time, take it prior to bedtime following a snack.

If you miss the dose prior to bedtime, then take it following your morning meal.

If you do not take the dose the following morning, then take the next dose at your regular time after your evening meal.

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

If you take too much Noumed Pregabalin

If you think that you have taken too much Noumed Pregabalin, you may need urgent medical attention.

Symptoms of an overdose with Noumed Pregabalin may include mood changes, feeling tired, confusion, depression, agitation, restlessness or seizures.

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 taking Noumed Pregabalin?

Things you should do

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

If you have nervous system or respiratory disorders, kidney problems, or you are older than 65, your doctor may adjust your dose.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine it may affect other medicines taken during the procedure.

Call your doctor straight away if you:

- experience any hypersensitivity reactions (such as skin redness, hives, rash, reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes): Discontinue Noumed Pregabalin and immediately seek medical care.
- experience any changes in your vision: Noumed Pregabalin may cause blurring or other changes in eyesight.
- have any thoughts of suicide or self-harm, any unusual changes in mood or behaviour, or show signs of depression
- experience trouble breathing or shallow breaths.
- become pregnant while taking Noumed Pregabalin
- feel that Noumed Pregabalin is not helping your condition

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

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine, even if you feel well.

Things you should not do

- Do not stop using this medicine suddenly or lower the dosage without checking with your doctor
- Do not let yourself run out of medicine over the weekend or on holidays.

Stopping Noumed Pregabalin suddenly may worsen your condition or increase your chance of experiencing withdrawal symptoms, such as sleeplessness, headache, nausea (feeling sick), anxiety, excessive sweating or diarrhoea (runny stools). If appropriate, your doctor will slowly reduce your dose before you can stop taking it completely.

If appropriate, your doctor will slowly reduce your dose before you can stop taking it completely.

- Do not take Noumed Pregabalin 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 or they have the same condition as you.

Driving or using machines

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

Noumed Pregabalin may cause dizziness in some people, with other anticonvulsant medicines. If you have any of these symptoms, do not drive, operate machinery or do not do anything else that could be dangerous

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may interfere with Noumed Pregabalin and increase side effects such as sleepiness and dizziness.

Looking after your medicine

- Keep your capsules 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
Nervous system related <ul style="list-style-type: none">• dizziness• feeling tired or drowsy• headache• unsteadiness when walking, reduced co-ordination, shaking or tremors	Speak to your doctor if you have any of these less serious side effects and they worry you.
Gastrointestinal related <ul style="list-style-type: none">• constipation	

<ul style="list-style-type: none"> • diarrhoea • nausea • abdominal pain • dry mouth <p>Eye related</p> <ul style="list-style-type: none"> • blurred or double vision <p>Body related</p> <ul style="list-style-type: none"> • increase in weight 	
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Serious side effects

Serious side effects	What to do
<p>Nervous system related</p> <ul style="list-style-type: none"> • unusual changes in mood or behaviour • extreme increase in activity and talking (mania) • acting aggressive, being angry, or violent • panic attacks • signs of irritability, agitation, or restlessness • signs of new or worse anxiety • signs of new or worse depression • thoughts about suicide or dying • attempts to commit suicide • acting on dangerous impulses • trouble sleeping (insomnia) • confusion <p>General effect</p> <ul style="list-style-type: none"> • swelling of the face, lips, tongue, hands, ankles or feet • enlargement of breasts • passing little to no urine. <p>Musculoskeletal related</p> <ul style="list-style-type: none"> • unexplained muscle pain, tenderness and weakness • swelling of the feet and legs • weight increase due to fluid build-up <p>Eye related</p> <ul style="list-style-type: none"> • irritated red eyes that are sensitive to light <p>Respiratory related</p> <ul style="list-style-type: none"> • shortness of breath, wheezing or difficulty breathing 	<p>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.</p>

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 Pregabalin contains

Active ingredient (main ingredient)	Pregabalin
Other ingredients (inactive ingredients)	<p>Starch, Talc</p> <p>The capsule shells (cap and body) contain: <i><u>25 mg, 75 mg, 150 mg and 300 mg capsule</u></i></p> <p>Gelatin,</p> <p>Sodium lauryl sulphate,</p> <p>Titanium dioxide. <i><u>75 mg and 300 mg capsule</u></i></p> <p>FD&C Blue 1, FD&C Red 40, FD&C Yellow 6.</p> <p><u>Printing ink contains:</u></p> <p>Black iron oxide, Butyl alcohol, Dehydrated alcohol, Isopropyl alcohol, Potassium hydroxide, Propylene glycol, Shellac, Strong ammonia solution.</p>

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

What Noumed Pregabalin looks like

25 mg - white to off white powder filled in size '4' hard gelatin white opaque and white opaque capsule linear printed in black ink with 'Cipla 25 mg' on the cap and '677' on the body.

75 mg - white to off white powder filled in size '4' hard gelatin orange opaque and white opaque capsule linear printed in black ink with 'Cipla 75 mg' on the cap and '679' on the body.

150 mg - white to off white powder filled in size '2' hard gelatin white opaque and white opaque capsule linear printed in black ink with 'Cipla 150 mg' on the cap and '682' on the body.

300 mg - white to off white powder filled in size '0' hard gelatin orange opaque and white opaque capsule linear printed in black ink with 'Cipla 300 mg' on the cap and '685' on the body.

Each carton contains 56 capsules.

Blister pack-

AUST R 378955,

AUST R 378956,

AUST R 378957,

AUST R 378958

Who distributes Noumed Pregabalin

Avallon Pharmaceuticals
Level 5, 7 Eden Park Drive,
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Australia
Phone: 1800 930 999

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