

Nupentin

gabapentin

Consumer Medicine Information

WARNING: Before taking Nupentin, tell your doctor if you have a history of drug abuse and/or psychiatric disorders. Nupentin poses risks of abuse and dependence. Using Nupentin 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.

What is in this leaflet

This leaflet answers some common questions about Nupentin.

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 Nupentin 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 Nupentin is used for

What Nupentin does

Nupentin is used to control epilepsy. Epilepsy is a condition where you have repeated seizures (fits). There are many different types of seizures, ranging from mild to severe.

Nupentin is also used to treat neuropathic pain, a type of pain caused by damage to the nerves.

This medicine belongs to a group of medicines called anticonvulsants.

How Nupentin works

This medicine is thought to work by controlling brain chemicals which send signals to nerves to help control seizures or neuropathic pain.

Nupentin also has pain relieving effects.

Your doctor may have prescribed Nupentin in addition to other medicines that you may be taking. This may be necessary if your current treatment is no longer working as well.

Your doctor may have prescribed Nupentin for another reason.

Nupentin may lead to dependence on this medicine.

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

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

Use in children

There is not enough information to recommend the use of this medicine in children:

- under the age of 3 years to control epilepsy, or
- under the age of 18 years to treat neuropathic pain.

Before you take Nupentin

When you must not take it

Do not take Nupentin if you have an allergy to:

- any medicine containing gabapentin, the active ingredient in Nupentin
- any of the ingredients listed at the end of this leaflet.

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 Nupentin 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 Nupentin, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines, especially barbiturates or any other anticonvulsant medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- mixed seizure disorders that include absence seizures.

Tell your doctor if you have a history of drug abuse and/or psychiatric disorders. Nupentin poses risks of abuse and dependence. Your body may become used to you taking Nupentin and this may result in physical dependence. It means that you may experience withdrawal symptoms if you stop taking Nupentin suddenly. So it is important to strictly follow the directions given by your doctor.

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

Nupentin may affect your developing baby if you take it during pregnancy. However, it is very important to control your fits while you are pregnant. If it is necessary for you to take Nupentin, your doctor can help you decide whether or not to take it during pregnancy.

Tell your doctor if you are breastfeeding or plan to breast-feed.

Nupentin passes into breast milk. The effect on your breast-fed baby is unknown.

If you do breast-feed, watch your baby carefully.

If your baby develops a skin rash, becomes sleepy or has unusual symptoms, don't breast-feed again until you speak to your doctor.

Your doctor can discuss the risks and benefits of breast-feeding with you.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Nupentin.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by Nupentin 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 or pharmacist will advise you accordingly.

Nupentin and certain other medicines may influence each other.

Using Nupentin 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 minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation.

Tell your doctor or pharmacist if you are taking any of the following:

- cimetidine, a medicine used to treat stomach or duodenal ulcers
- antacids, medicines used to treat heartburn or reflux
- opioids, medicines used to treat severe pain e.g. morphine.

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

How to take Nupentin

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 pack, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many capsules you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.

Your doctor may recommend that you start with a low dose of Nupentin and slowly increase the dose to the lowest amount needed to control your epilepsy/convulsions or neuropathic pain.

How to take it

Swallow Nupentin whole with a full glass of water.

When to take it

Take Nupentin at about the same time each day.

Taking Nupentin at the same time each day will have the best effect. It will also help you remember when to take the capsules.

If you are taking Nupentin three times a day, do not allow more than 12 hours between doses.

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

How long to take it

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

Nupentin helps control your condition, but does not cure it. Therefore you must take your medicine every day, even if you feel well.

Do not stop taking Nupentin, or lower the dose, without checking with your doctor. Do not let yourself run out of medicine over the weekend or holidays.

Stopping Nupentin 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 you forget to take it

If it is almost time for your next dose (within 4 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking Nupentin as you would normally.

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

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

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

If you have trouble remembering to take Nupentin, ask your pharmacist for help.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) 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 Nupentin.

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

You may need urgent medical attention.

Symptoms of an overdose may include you falling unconscious, feeling drowsy, weak, unsteady when walking, having double vision, slurred speech or diarrhoea.

While you are taking Nupentin

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Nupentin.

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

If you are going to have surgery or emergency treatment, tell the surgeon or anaesthetist that you are taking Nupentin.

Tell your doctor immediately if you have any thoughts of suicide or self-harm, any unusual changes in mood or behaviour, or show signs of depression.

Some people being treated with antiepileptics, such as Nupentin, have had thoughts of harming or killing themselves.

Patients and caregivers should be alert and monitor for signs and symptoms of suicide, these include:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- new or an increase in aggressive behaviour, irritability or agitation
- new onset of or worsening of depression.

Mention of suicide or violence must be taken seriously.

If you or someone you know is demonstrating these warning signs and symptoms of suicide while taking Nupentin, contact your doctor or a mental health professional right away.

Tell your doctor if you feel Nupentin is not helping your condition.

Your doctor may need to change your medicine.

Tell your doctor if, for any reason, you have not taken Nupentin exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily.

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

If you need to have any medical tests while you are taking Nupentin, tell your doctor.

It may interfere with the results of some tests.

If you are going to have any surgery or procedure, including dental surgery, tell your surgeon, doctor or dentist that you are taking this medicine.

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

Your doctor will check your progress and may want to take some tests from time to time. This helps to prevent unwanted side effects.

Things you must not do

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

Do not give Nupentin to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.

Do not stop taking Nupentin or lower the dose without checking with your doctor.

Stopping Nupentin suddenly, if you have epilepsy, may cause unwanted side effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

Things to be careful of

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

As with other anticonvulsant medicines, Nupentin may cause drowsiness, dizziness, lightheadedness or sleepiness in some people. Make sure you know how you react to Nupentin before you drive a car, operate machinery,

or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or sleepy.

Be careful when drinking alcohol while you are taking Nupentin.

Combining Nupentin and alcohol can make you more sleepy, dizzy or light-headed. Your doctor may suggest you avoid alcohol while you are being treated with Nupentin.

Side effects

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

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

It can be difficult to tell whether side effects are the result of taking Nupentin; of your condition; or side effects of other medicines you may be taking, for this reason it is important to tell your doctor of any change in your condition.

If you are over 65 years of age you may have an increased chance of getting side effects.

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

If you get any side effects, do not stop taking Nupentin without first talking to your doctor or pharmacist.

Tell your doctor if...

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

- dizziness* or light-headedness
- feeling tired or drowsy*
- unfriendliness*

- unusually overactive*
- forgetfulness, loss of concentration or confusion
- difficulty speaking
- changes in your weight*
- constipation, diarrhoea
- nausea and/or vomiting*, indigestion
- dry mouth, red swollen gums
- muscle pain or cramps, back pain
- swelling of the hands or feet
- runny or blocked nose
- fever*
- bronchitis*, lung infection*
- sore throat and discomfort when swallowing, coughing.

The above list includes the more common side effects of Nupentin. They are usually mild and short-lived.

Tell your doctor as soon as possible if...

Tell your doctor as soon as possible if you notice any of the following:

- weakness, unsteadiness when walking including falling, reduced co-ordination or slowed reactions
- unusual changes in mood* or behaviour such as restlessness, nervousness, or excitement
- signs of new onset of, or increased irritability or agitation
- signs of depression
- seeing or hearing things that are not there, irrational thinking
- blurred or double vision, uncontrollable jerky eye movements, difficulty seeing
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- trouble breathing or shallow breaths (respiratory depression)
- loss of consciousness

The side effects in the above lists marked * have been specifically reported in children taking Nupentin.

Go to hospital if...

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

- more frequent or more severe seizures (fits)
- chest pain, a very fast heart rate
- sudden signs of allergy such as rash, itching or hives, fever, swollen lymph glands, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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.

Some of these side effects (for example, changes in thyroid function, structures of bones, high cholesterol, levels of sugar in your blood or blood pressure) can only be found when your doctor does blood tests from time to time to check your progress.

Do not be alarmed by the list of possible side effects.

You may not experience any of them.

After taking Nupentin

Storage

Keep Nupentin 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.

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they may not keep well.

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

Do not store Nupentin or any other medicine in the bathroom or near a sink.

Do not leave Nupentin in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor or pharmacist tells you to stop taking Nupentin, or your capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Nupentin

Nupentin capsules are available in 3 strengths:

- Nupentin 100 - white capsule, with "GP100" printed on one half and "G" on the other half
- Nupentin 300 - yellow capsule, with "GP300" printed on one half and "G" on the other half
- Nupentin 400 - orange capsule, with "GP400" printed on one half and "G" on the other half.

Nupentin capsules are marketed in blister packs. Each pack contains 100 capsules.

Ingredients

Nupentin

The active ingredient in Nupentin is gabapentin.

- Each Nupentin 100 capsule contains 100 mg of gabapentin.
- Each Nupentin 300 capsule contains 300 mg of gabapentin.
- Each Nupentin 400 capsule contains 400 mg of gabapentin.

The capsules also contain the following inactive ingredients:

- lactose monohydrate
- maize starch
- purified talc
- gelatin

- titanium dioxide (E171)
- quinoline yellow CI47005 (E104) [Nupentin 300 only]
- allura red AC CI16035 (E129) [Nupentin 300 only]
- sunset yellow FCF CI15985 (E110) [Nupentin 400 only]
- iron oxide red CI77491 (E172) [Nupentin 400 only]
- iron oxide yellow CI77492 (E172) [Nupentin 400 only]
- Tek Print black ink.

Nupentin capsules also contain sulfites (present in trace amounts) and sugars (as lactose). The capsules are gluten free.

Manufacturer

Nupentin is made in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

Australian registration numbers:

Nupentin 100 (100 mg capsule blister pack): AUST R 101694

Nupentin 300 (300 mg capsule blister pack): AUST R 101696

Nupentin 400 (400 mg capsule blister pack): AUST R 101698

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