

NEW ZEALAND CONSUMER MEDICINE INFORMATION

NUPENTIN

Gabapentin 100mg, 300mg & 400mg Capsules



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 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 Nupentin is used for

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

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

Nupentin contains the active ingredient gabapentin. Gabapentin belongs to a group of medicines called anticonvulsants. These medicines work by controlling brain chemicals which send signals to nerves to help control seizures or neuropathic pain.

Your doctor may prescribe Nupentin in addition to your current therapy when your treatment is no longer working as well.

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.

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

There is no evidence that Nupentin is addictive.

Use in Children

Nupentin is not recommended for use in children under the age of:

- 3 years to control epilepsy
- 18 years for the treatment of neuropathic pain.

The safety and effectiveness of Nupentin in children of these age groups have not been established.

Before you take Nupentin

When you must not take it:

Do not take Nupentin if you have an allergy to:

- any medicine containing gabapentin
- 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 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.

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

- Kidney problems
- Mixed seizure disorders, including absence seizures
- Mood disorders or depression.

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 important to control your seizures while you are pregnant. Your doctor can discuss with you the risks and benefits of taking Nupentin during pregnancy.

Tell your doctor if you are breast-feeding or wish to breast-feed.

Nupentin is not recommended for use when breastfeeding as it passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking Nupentin when breastfeeding.

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

If your baby develops a skin rash, becomes sleepy or has unusual symptoms speak to your doctor.

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

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.

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

- Opioids, medicines such as morphine, used to relieve severe pain
- Cimetidine, a medicine to reduce stomach acid and/or prevent stomach or duodenal ulcers.

These medicines may be affected by Nupentin or may affect how well Nupentin works. You may need different amounts of your medicines, or you may need to take different medicines.

Antacids, medicines used for heartburn or indigestion (e.g. Gaviscon, Mylanta) may reduce the absorption of Nupentin. **If you need to take an antacid, take it at least 2 hours before, or 2 hours after taking your dose of Nupentin.**

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

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

The amount of medicine to take varies from person to person.

Your doctor will tell you how many capsules you need to take each day and when to take them. This depends on your age, 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 condition.

People with kidney problems and/or on dialysis may need smaller doses.

How to take it

Swallow the capsules whole with a full glass of water. Do not open the capsules.

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

When to take it

Take your medicine at about the same time(s) each day.

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

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

How long to take it

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.

If you forget to take it

If you have missed a dose by more than 4 hours, skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine 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 your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (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.

If you take too much Nupentin, you may feel drowsy, tired, dizzy, have diarrhoea, slurred speech or double vision.

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 this medicine.

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

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

Tell your doctor immediately if you have any suicidal or self-harming thoughts, other mental/mood changes or show signs of depression.

Nupentin may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Patients and caregivers should be alert and monitor for these effects.

If you or someone you know is showing any of the following warning signs of suicide while

taking Nupentin, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment.

Signs and symptoms of suicide 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 onset or increase in aggressive behaviour, irritability, agitation, or any other unusual changes in behaviour or mood.
- New onset or worsening of depression.

Any mention of suicide or violence must be taken seriously.

If you are about to have any blood or urine tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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

Your doctor may want you to have some tests from time to time. This helps to prevent unwanted side effects.

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.

Things you must not do

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

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

Do not stop taking your medicine or change the dosage without checking with your doctor. Do not let yourself run out of

medicine over weekends or during holidays.

If you stop taking Nupentin suddenly, your condition may become worse. You may also feel anxious, sick (nauseous), have pains, sweat or have trouble sleeping. Your doctor will tell you how to gradually reduce your dose before you can stop taking Nupentin completely.

Things to be careful of

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

This medicine may cause drowsiness, dizziness, lightheadedness, tiredness or affect alertness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. 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 this medicine.

Combining Nupentin and alcohol can make you more sleepy, dizzy or lightheaded. **Your doctor may suggest you avoid alcohol while you are taking Nupentin.**

If you have diabetes, be aware that Nupentin may affect your blood glucose readings.

Side effects

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

Like all medicines, Nupentin may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking Nupentin, effects 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 changes to your condition.

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

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

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

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

- Dizziness or lightheadedness
- Feeling tired or drowsy
- Unfriendliness
- Pain - for example back, muscle or joint pain
- Forgetfulness, loss of concentration or confusion
- Difficulty speaking
- Changes in appetite or weight
- Nausea and/or vomiting, indigestion
- Constipation, diarrhoea
- Dry mouth
- Red swollen gums
- Swelling of the hands or feet
- Headache
- Runny or blocked nose
- Sore throat, discomfort when swallowing, coughing
- Bronchitis, lung infection
- Breast enlargement in men and women
- Sexual dysfunction, including changes in sexual drive, abnormal ejaculation or inability to achieve orgasm.

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

- Weakness, unsteadiness when walking, reduced coordination or slowed reactions
- Uncontrollable twitching, jerking or writhing movements of the body
- Unusual changes in mood or behavior such as restlessness or nervousness
- Signs of new onset of, or increased irritability or agitation
- Signs of depression or thoughts of suicide
- Seeing or hearing things that are not there, irrational thinking
- Yellowing of the skin and/or eyes, also called jaundice

- Unusual bleeding or bruising under the skin, or itching
- Blurred or double vision, uncontrollable jerky eye movements, difficulty seeing
- Frequent infections with symptoms such as fever, severe chills, sore throat or mouth ulcers
- Severe stomach pain, often with nausea and vomiting
- Passing little or no urine.

The above list includes serious side effects that may require medical attention.

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

- More frequent or more severe seizures (fits)
- Signs of an allergic reaction such as rash, itching or hives; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or difficulty breathing
- Chest pain or fast heart rate
- Severe blisters and bleeding of the lips, eyes, mouth, nose and genitals
- Pink or red itchy spots on the skin which may blister and progress to form raised, red, pale-centered marks.

The above list includes 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.

Some side effects (for example, changes in blood pressure or changes in numbers of blood cells) can only be found when your doctor does tests from time to time to check your progress.

After taking Nupentin

Storage

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 it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep medicines where children cannot reach them.

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

Ingredients

The active ingredient in Nupentin is gabapentin. Nupentin capsules are available in 3 strengths.

- 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:

- Lactose
- 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.

This medicine does not contain sucrose or gluten.

What it looks like

Nupentin 100:

A white capsule, with "GP100" printed on one half and "G" on the other half.

Nupentin 300:

A yellow capsule, with "GP300" printed on one half and "G" on the other half.

Nupentin 400:

An orange capsule, with "GP400" printed on one half and "G" on the other half.

Each pack contains 100 capsules.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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