

Nupentin

contains the active ingredient gabapentin

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Nupentin.

It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Nupentin against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your 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 severe type of pain caused by damage to the nerves.

Nupentin 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 Nupentin has been prescribed for you.

Your doctor may have prescribed Nupentin for another reason.

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.

Nupentin is available only with a doctor's prescription.

There is no evidence that Nupentin is addictive.

Before you take Nupentin

When you must not take it

Do not take Nupentin if you are allergic to medicines containing gabapentin (eg. Neurontin, Pendine) or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Nupentin if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date it may not work as well.

Do not take Nupentin if the packaging shows signs of tampering or the capsules do not look quite right.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you are allergic to:

- * any other medicines, especially barbiturates, or other medicines for epilepsy
- * any other substances, such as foods, dyes or preservatives.

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 fits while you are pregnant. Your doctor will discuss the risks and benefits of taking Nupentin during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

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.

Tell your doctor if you have any medical conditions, especially the following:

- * kidney problems
- * mixed seizure disorders, including absence seizures.

Your doctor may want to take special care if you have any of these conditions.

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

Taking other medicines

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

Some medicines may be affected by Nupentin, or may affect how well it works. These include:

- * some medicines used to treat stomach or duodenal ulcers, such as cimetidine (eg. Tagamet, Magicul)
- * morphine, a medicine used to relieve severe pain
- * antacids, medicines used to relieve heartburn and indigestion.

Avoid taking antacids at the same time as Nupentin.

Antacids may reduce the absorption of Nupentin.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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 and 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 dose 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 undergoing haemodialysis may need smaller doses.

How to take Nupentin

Swallow the capsules whole with a full glass of water.

When to take Nupentin

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 to 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.

If you need to take an antacid, take it at least 2 hours before, or 2 hours after taking your dose of Nupentin.

The absorption of Nupentin may be reduced if taken with antacids.

Nupentin can be taken with or without food.

If you forget to take Nupentin

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 you missed.

This may increase your chance of 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.

How long to take Nupentin for

Keep taking Nupentin for as long as your doctor recommends.

Nupentin helps control your condition, but does not cure it. Therefore, to properly control your condition, Nupentin must be taken every day.

If you take too much (overdose)

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 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, weak, unsteady when walking, have diarrhoea, slurred speech or double vision.

While you are taking Nupentin

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Nupentin.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Nupentin.

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

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

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:

- * thoughts or talk of death or suicide
- * thoughts or talk of self-harm or harm to others
- * any recent attempts of 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.

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 plan to have surgery, including dental surgery, tell your doctor or dentist that you are

taking Nupentin.

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

Nupentin may affect the results of some tests.

Visit your doctor regularly so they can check on your progress.

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

Things you must not do

Do not stop taking Nupentin, or lower the dose, 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.

Do not use Nupentin to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

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

Nupentin may cause drowsiness, dizziness, lightheadedness or affect alertness in some people. If any of these occur, 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 taking Nupentin.

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 are a diabetic, 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 other 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 treatment if you get some of the side effects.

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

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

You may not experience any of them.

Some side effects not listed below (eg. changes in thyroid function, structure of bones, high cholesterol or blood pressure) may also occur in some people. These side effects can only be found when your doctor does blood tests from time to time to check your progress.

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 you notice any of the following and they worry you:

- * dizziness or lightheadedness
- * feeling tired or drowsy
- * unsteadiness when walking, reduced coordination or slowed reactions
- * back pain, muscle pain

- * forgetfulness, loss of concentration
- * difficulty speaking
- * changes in appetite
- * changes in weight
- * nausea and/or vomiting, indigestion
- * constipation, diarrhoea
- * dry mouth
- * runny nose
- * fever
- * sore throat, coughing, bronchitis
- * breast enlargement in men and women.

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

- * yellowing of the skin and/or eyes, also called jaundice
- * unusual bleeding or bruising under the skin
- * swelling of hands, ankles or feet
- * mood changes such as nervousness, restlessness, agitation, irritability or depression
- * thinking abnormal or irrationally, seeing, feeling or hearing things that are not there
- * uncontrollable twitching, jerking or writhing movements of the body
- * blurred or double vision, uncontrollable jerky eye movements, difficulty seeing
- * frequent infections 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, which may require medical attention.

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

- * more frequent or more severe seizures
- * fast heart beats or chest pain
- * 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

- * 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 if you notice anything that is making you feel unwell.

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

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 degrees 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 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 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.

Each pack contains 100 capsules.

Ingredients

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:

- * 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.

The capsules are gluten free.

Manufacturer

Nupentin is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

www.alphapharm.com.au

Australian registration numbers:

Nupentin 100 - AUST R 101694

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Nupentin 400 - AUST R 101698

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