NEURONTIN®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking 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 NEURONTIN?

NEURONTIN contains the active ingredient gabapentin. NEURONTIN is used to control epilepsy and treat neuropathic pain. For more information, see Section 1. Why am I taking NEURONTIN? in the full CMI.

2. What should I know before I take NEURONTIN?

Do not take if you have ever had an allergic reaction to gabapentin 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 details, see Section 2. What

should I know before I take NEURONTIN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NEURONTIN 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 NEURONTIN?

Your doctor will tell you how many NEURONTIN capsules/tablets you need to take each day.

Swallow NEURONTIN whole with a full glass of water. **NEURONTIN tablets** can be divided in half along the breakline, if advised by your doctor or pharmacist. More instructions can be found in Section 4. How do I take NEURONTIN? in the full CMI.

5. What should I know while taking NEURONTIN?

Things you must do	• Remind any doctor, dentist or pharmacist, surgeon, or anaesthetist you visit that you are taking NEURONTIN. • 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.
Things you must not do	• Do not stop taking NEURONTIN or lower the dose without checking with your doctor. They will tell you how to do this, usually by reducing the dose gradually so that any withdrawal effects are kept to a minimum. Stopping your medicine may take a period of several weeks or even months.
Driving or using machines	• Do not drive, operate machinery, ride a bike as NEURONTIN may cause drowsiness, dizziness, light-headedness or sleepiness in some people.
Drinking alcohol	• Avoid alcohol as it can make you more sleepy, dizzy or light-headed.

Looking after your medicine	• Store below 30°C for capsules and store below 25°C for tablets. • Keep your capsules/ tablets in the pack until it is time to take them.

For more information, see Section 5. What should I know while taking NEURONTIN? in the full CMI.

6. Are there any side effects?

Common side effects include dizziness, light-headedness, headache, sleeplessness, feeling tired, drowsy, unfriendliness, unusually overactive, forgetfulness, loss of concentration, confusion, difficulty speaking, weight change, constipation, diarrhoea, nausea, vomiting, indigestion, dry mouth, red swollen gums, muscle pain, cramps, back pain, swelling hand or feet, runny or blocked nose, fever, bronchitis, lung infection, sore throat, coughing. Serious side effects include unusual changes in mood or behaviour, increased irritability or agitation, depression, seeing or hearing things that are not there, blurred or double vision, uncontrollable jerky eye movements, difficulty seeing, fever, severe chills, sore throat or mouth ulcers, trouble breathing, loss of consciousness, severe seizures, chest pain, fast heart rate, sudden signs of allergy, severe skin rash, high body temperature enlarged lymph nodes. 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: Before taking NEURONTIN, tell your doctor if you have a history of drug abuse. NEURONTIN poses risks of abuse and dependence. Taking NEURONTIN 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.

NEURONTIN®

Active ingredient: *gabapentin*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking NEURONTIN. **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 NEURONTIN.**

Where to find information in this leaflet:

1. Why am I taking NEURONTIN?
2. What should I know before I take NEURONTIN?
3. What if I am taking other medicines?
4. How do I take NEURONTIN?

5. What should I know while taking NEURONTIN?
6. Are there any side effects?
7. Product details

1. Why am I taking NEURONTIN?

NEURONTIN contains the active ingredient gabapentin. NEURONTIN belongs to a group of medicines called anticonvulsants.

NEURONTIN 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.

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

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

NEURONTIN also has pain relieving effects.

Your doctor may have prescribed NEURONTIN 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 NEURONTIN for another reason.

NEURONTIN may lead to dependence on this medicine.

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

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.

2. What should I know before I take NEURONTIN?

Warnings

When you must not take NEURONTIN

Do not take NEURONTIN if:

- you are allergic to gabapentin, or 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.
- Always check the ingredients to make sure you can take this medicine.
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have allergies to any other medicines, especially barbiturates or any other anticonvulsant medicines or any other substances, such as foods, preservatives or dyes.
- have any other medical conditions:
  - kidney problems
  - mixed seizure disorders that include absence seizures
  - myasthenia gravis.
- take any medicines for any other condition.
- have a history of drug abuse and/or psychiatric disorders.
  - NEURONTIN poses risks of abuse and dependence. Your body may become used to you taking NEURONTIN and this may result in physical dependence. It means that you may experience withdrawal symptoms if you stop taking NEURONTIN suddenly. So it is important to strictly follow the directions given by your doctor. They will tell you how to do this, usually by reducing the dose gradually so that any withdrawal effects are kept to a minimum. Stopping your medicine may take a period of several weeks or even months.
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed.
- if you notice any of the symptoms related to serious skin reactions described in Section 6 under table titled

"Serious side effects", stop taking NEURONTIN and seek medical attention immediately.

- Serious skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with gabapentin.

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

Pregnancy

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

If you are pregnant or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the medicine you are taking might pose to your unborn baby.

If you are planning to become pregnant you should discuss your treatment with your doctor as early as possible before you become pregnant. Effective contraception must be used by women of childbearing potential.

NEURONTIN should not be taken during pregnancy, unless you are told otherwise by your doctor. NEURONTIN may affect your developing baby if you take it during pregnancy. Some medicines used to treat

epilepsy have reported an increased risk of harm to the developing baby.

You should not stop your treatment without discussing this with your doctor.

Do not suddenly discontinue taking this medicine.
If taken during pregnancy, gabapentin may lead to withdrawal symptoms in newborn infants. This risk might be increased when gabapentin is taken together with opioid analgesics (medicines for treatment of severe pain).

It is also very important to control your fits while you are pregnant. If it is necessary for you to take NEURONTIN, your doctor can help you decide whether or not to take it during pregnancy.

Breastfeeding

Gabapentin, the active substance of NEURONTIN, is passed on through breast milk. Because the effect on baby is unknown, tell your doctor if you are breastfeeding or intend to breastfeed.

If you do breastfeed, watch your baby carefully.

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

Your doctor can discuss the risks and benefits of breastfeeding with you.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with NEURONTIN and affect how it works.

Some medicines may be affected by NEURONTIN 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.

NEURONTIN and certain other medicines may influence each other.

Taking NEURONTIN 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NEURONTIN.
Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking NEURONTIN.

4. How do I take NEURONTIN?

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/tablets 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 NEURONTIN and slowly increase the dose to the lowest amount needed to control your epilepsy/ convulsions or neuropathic pain.

- Follow the instructions provided and take NEURONTIN until your doctor tells you to stop.

How to take NEURONTIN

- Swallow NEURONTIN whole with a full glass of water.
- NEURONTIN tablets can be divided in half along the breakline, if advised by your doctor or pharmacist.

When to take NEURONTIN

- **NEURONTIN should be taken at about the same time each day.**
- Taking NEURONTIN at the same time each day will have the best effect. It will also help you remember when to take the capsules/tablets.
- If you are taking NEURONTIN three times a day, do not allow more than 12 hours between doses.
- It does not matter if you take NEURONTIN before or after food.

How long to take NEURONTIN

- **Continue taking your medicine for as long as your doctor tells you to.**
- NEURONTIN 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 NEURONTIN, or lower the dose, without checking with your doctor. Do not let yourself run out of medicine over the weekend or holidays.**

- Stopping NEURONTIN suddenly may worsen your condition or increase your chance of experiencing withdrawal symptoms, such as anxiety, difficulty sleeping, feeling sick (nausea), pain, excessive sweating, shaking, headache, depression, feeling abnormal, dizziness, feeling generally unwell, and diarrhoea (runny stools). These effects usually occur within 48 hours after stopping NEURONTIN and may also occur during and after reducing the dose. If you experience withdrawal effects, you should contact your doctor. If you want to stop taking NEURONTIN, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so that any withdrawal effects are kept to a minimum. Stopping your medicine may take a period of several weeks or even months.

If you forget to take NEURONTIN

NEURONTIN should be taken regularly at the same time each day.

If you miss your dose at the usual time, and 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 NEURONTIN as you would normally.

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, ask your doctor or pharmacist.

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

If you take too much NEURONTIN

If you think that you or anyone else may have taken too much NEURONTIN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.

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

5. What should I know while taking NEURONTIN?

Things you must do

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

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

If you are going to have surgery, procedure or emergency treatment (including dental surgery), tell the doctor, dentist, surgeon or anaesthetist that you are taking NEURONTIN.

If you feel NEURONTIN is not helping your condition, tell your doctor. Your doctor may need to change your medicine.

If, for any reason, you have not taken NEURONTIN exactly as prescribed, tell your doctor. Otherwise, your doctor may change your treatment unnecessarily.

If you need to have any medical tests while you are taking NEURONTIN, tell your doctor. It may interfere with the results of some tests.

Call your doctor straight away 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 anti-epileptics, such as NEURONTIN, 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.

Any mention of suicide or violence must be taken seriously.

- **you or someone you know is demonstrating these warning signs and symptoms of suicide while taking NEURONTIN, contact your doctor or a mental health professional right away.**
- **you become pregnant while taking NEURONTIN.**

Remind any doctor, dentist, pharmacist or surgeon you visit that you are taking NEURONTIN.

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 NEURONTIN to treat any other complaints unless your doctor tells you to.**
- **Do not give NEURONTIN to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.**
- **Do not stop taking NEURONTIN or lower the dose without checking with your doctor.**

Stopping NEURONTIN 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. Stopping your medicine may take a period of several weeks or even months.

Driving or using machines

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

As with other anticonvulsant medicines, NEURONTIN may cause drowsiness, dizziness, light-headedness or sleepiness in some people. Make sure you know how you react to NEURONTIN 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while you are taking NEURONTIN.

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

Looking after your medicine

- Capsules: Store below 30°C.
- Tablets: Store below 25°C.
- Keep your capsules/tablets in the pack until it is time to take them. If you take the capsules/tablets out of the pack, they may not keep well.

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.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to take this medicine, your doctor or pharmacist tells you to stop taking, it is out of date or damaged, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

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

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.

It can be difficult to tell whether side effects are the result of taking NEURONTIN; 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.

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

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

Less serious side effects

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

Less serious side effects	What to do
• dizziness* or light-headedness • headache • sleeplessness • 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	**Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• fever* • bronchitis*, lung infection* • sore throat and discomfort when swallowing, coughing.	

Serious side effects

Serious side effects	What to do
• weakness, unsteadiness when walking including falling, reduced co-ordination or slowed reactions (tremor) • weakness in neck, arms and legs • drooping eyelids • hard to control facial expressions; or to speak, swallow, or chew • unusual changes in mood* or behaviour such as restlessness, nervousness, or excitement	**Tell your doctor as soon as possible and seek medical attention immediately if you notice any of the serious side effects.**

Serious side effects	What to do
• 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	

Serious side effects	What to do
• 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. These serious	**Stop taking NEURONTIN and seek medical attention immediately if you notice any of the serious skin rashes symptoms occurred.**

Serious side effects	What to do
skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis). • widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).	

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

Very serious side effects

Very serious side effects	What to do
• 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	**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.**

Very serious side effects	What to do
breath, wheezing or difficulty breathing.	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 may be making you feel unwell.

Other side effects not listed here may 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.

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 NEURONTIN contains

Active ingredient **(main ingredient)**	**Capsules:** NEURONTIN 100 mg, 300 mg and 400 mg **Tablets:** NEURONTIN 600 mg and 800 mg
Other ingredients **(inactive ingredients)**	**Other capsule ingredients:** • Lactose monohydrate • Purified talc • Maize starch • Gelatin • Titanium dioxide • Iron oxide yellow (300 mg and 400 mg only) • Iron oxide red (400 mg only). • Opacode Blue S-1-4118 (ID 2703; contains shellac, titanium

	dioxide, indigo carmine aluminium lake, butan-1-ol, ethanol, methanol) **Other tablet ingredients:** • Poloxamer • Copovidone • Maize starch • Magnesium stearate • Candelilla wax • Opadry White YS-1-18111 (ID 3289; contains hyprolose, purified talc).
Potential allergens	Capsules: contain sugars as lactose.

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

What NEURONTIN looks like

Capsules

NEURONTIN 100 mg is white opaque hard gelatin capsule, imprinted in blue ink with "Neurontin 100mg" and an interlocking "VLE". (AUST R 74067).

NEURONTIN 300 mg is yellow opaque hard gelatin capsule, imprinted in grey with "Neurontin 300mg" and an interlocking "VLE". (AUST R 66008).

NEURONTIN 400 mg is orange opaque hard gelatin capsule, imprinted in grey with "Neurontin 400mg" and an interlocking "VLE". (AUST R 66005).

Tablets

NEURONTIN 600 mg is white, elliptical, film-coated tablet, with bisecting score on both sides and debossed with "NT" and "16" on one side (AUST R 71793).

NEURONTIN 800 mg is white, elliptical film-coated tablet with bisecting score on both sides and debossed with 'NT" and "26" on one side (AUST R 71791).

Each pack contains 100 capsules/tablets.

Not all packs are available.

Who distributes NEURONTIN

Viatris Pty Ltd

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Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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