

# Douglas Gabapentin

*Gabapentin (gab-a-PEN-tin)*

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about gabapentin.

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 to you of taking gabapentin 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.

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### What Douglas Gabapentin is used for

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Gabapentin belongs to a group of medicines called anticonvulsants. These medicines are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

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

Gabapentin is also used to treat neuropathic pain (pain due to nerves being damaged or affected).

Your doctor may have prescribed gabapentin for another reason.

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

There is no evidence that gabapentin is addictive.

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

Gabapentin is not recommended for use in children under the age of 3 years to control epilepsy, as its safety and effectiveness in that age group have not been established. Also, the safety and effectiveness of gabapentin for the treatment of neuropathic pain in children under the age of 18 years have not been established.

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### Before you take Douglas Gabapentin

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*When you must not take it*

**Do not take gabapentin if you have an allergy to gabapentin or any of the inactive ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction to gabapentin 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 gabapentin after the expiry date (EXP) printed on the pack.**

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

**Do not take gabapentin if the packaging is torn or shows signs of tampering.**

If you are not sure whether you should start taking gabapentin, 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 medical conditions, especially the following:**

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

**Tell your doctor if you are pregnant or intend to become pregnant.**

Gabapentin 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 there is a need to consider gabapentin during your pregnancy, your doctor can discuss the risks and benefits of using it whilst you are pregnant. You may have to take folic acid supplements.

### **Tell your doctor if you are breast-feeding or plan to breast-feed.**

It is recommended that you do not breastfeed while taking gabapentin, as it may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected. If there is a need to consider gabapentin whilst you are breastfeeding your doctor can discuss with you the possible risks to your baby.

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

#### *Taking other medicines*

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

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

- **cimetidine, a medicine used to treat stomach or duodenal ulcers or reflux**
- **antacids, medicines used to treat heartburn or reflux.**
- **morphine**

These medicines may be affected by gabapentin, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

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

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## How to take Douglas Gabapentin

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### *How much to take*

Your doctor will tell you how many capsules you will 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 gabapentin and slowly increase the dose to the lowest amount needed to control your convulsions or neuropathic pain.

### **Follow all directions given to you by your doctor carefully.**

They may differ from the information contained in this leaflet.

### **If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

### *How to take it*

**Swallow the prescribed dose of Douglas Gabapentin capsules with a full glass of water.**

### *When to take it*

### **Take gabapentin at about the same time each day.**

Taking gabapentin 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 gabapentin three times a day, do not allow more than 12 hours between doses.

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

### *If you forget to take it*

**If you have missed a dose by not more than 4 hours, take it as soon as you remember, and then go back to taking your medicine as you would normally. However, if you have missed a dose by more than 4 hours, you should skip the dose and continue taking the next dose when you are meant to.**

### **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.**

### *How long to take it*

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

### **Continue taking gabapentin for as long as your doctor tells you to.**

### *If you take too much (overdose)*

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to the Accident and Emergency department at your nearest hospital, if you think that you or anyone else may have taken too much gabapentin. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of an overdose with gabapentin include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

If you take too much gabapentin, you may feel drowsy, weak, unsteady when walking, have double vision, slurred speech or diarrhoea.

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## While you are using Douglas Gabapentin

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### *Things you must do*

**Tell any other doctors, dentists, or pharmacists who are treating you that you are taking gabapentin.**

**If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking gabapentin.**

**If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking gabapentin.**

**Tell your doctor if you feel gabapentin is not helping your condition.**

Your doctor may need to change your medicine.

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

Otherwise, your doctor may change your treatment unnecessarily.

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

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

Gabapentin may affect the results of some tests.

**Be sure to 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 stop taking gabapentin, or lower the dosage, without checking with your doctor.**

Stopping gabapentin suddenly may cause unwanted effects, you may experience anxiety, insomnia, nausea, pain and sweating or it can make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

**Do not let yourself run out of medicine over the weekend or on holidays.**

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

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

### *Things to be careful of*

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

As with other anticonvulsant medicines, gabapentin may cause dizziness, light-headedness or drowsiness in some people. Make sure you know how you react to gabapentin before you drive a car, operate potentially dangerous machinery, or do anything else that could be dangerous if you are dizzy, drowsy or light-headed. If this occurs do not drive or operate potentially dangerous machinery.

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

Gabapentin may cause drowsiness, dizziness or sleepiness in some people and affect alertness.

**Be careful when drinking alcohol while taking gabapentin.**

Combining gabapentin and alcohol can make you more sleepy, dizzy or lightheaded. Your doctor may suggest you avoid alcohol while you are being treated with gabapentin.

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## Side effects

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

Gabapentin helps most people with epilepsy, but it may have unwanted side effects in a few people. All medicines can have side effects. 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.

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

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

**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\***
- **changes in appetite**
- **indigestion**
- **changes in your weight\***
- **nausea and/or vomiting\***
- **constipation**
- **dry mouth, red swollen gums**
- **coughing**
- **muscle pain or cramps**
- **swollen ankles**
- **runny or blocked nose**
- **fever\***
- **bronchitis\*, lung infection\***
- **impaired or decreased sensitivity (hypoesthesia)**
- **thinking abnormally**
- **impaired sleep patterns**
- **mild hypotension**
- **diarrhoea**

These are the more common side effects of gabapentin. Mostly these are mild and short-lived.

Antiepileptics, such as gabapentin may increase the risk of suicidal thoughts and behaviour.

**If you or someone you know is demonstrating any of the following warning signs, contact your doctor or a mental health professional right away or go to your nearest hospital for treatment:**

- **thoughts or talk of death or suicide**
- **thoughts or talk of self-harm or harm to others**
- **any recent attempts at 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 or pharmacist immediately if you notice any of the following:**

- **weakness, unsteadiness when walking, reduced coordination or slowed reactions**
- **mood changes\* such as restlessness, agitation, nervousness, irritability**
- **forgetfulness, confusion or loss of concentration**
- **difficulty speaking or slurred speech**
- **blurred or double vision, uncontrollable jerky eye movements, difficulty seeing.**
- **signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers**
- **Excessive growth of the breast tissues in males and females.**
- **Yellowish discoloration of the eyes and skin.**

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

The side effects in the above lists marked \* have been specifically reported in children taking gabapentin

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

- **more frequent or more severe seizures (fits)**
- **sudden signs of allergy 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, a very fast heart rate**

These are very serious side effects. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Other side effects not listed above may happen in some people. Some of these side effects (for example, changes in thyroid function, structure of bones, high cholesterol or blood pressure) can only be found when your doctor does tests from time to time to check your progress.

**Tell your doctor if you notice anything else that is making you feel unwell.**

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

You may not experience any of them.

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## After using Douglas Gabapentin

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### Storage

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

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

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

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

**Do not leave it in on a windowsill or in the car on hot days.**

Heat and dampness can destroy some medicines.

**Keep it 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.

### Disposal

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

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## Product description

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### What it looks like

Douglas Gabapentin capsules are available in 300 mg & 400 mg strengths.

Douglas Gabapentin 300 mg capsules are opaque with a white body and a yellow cap. There are 100 capsules in each pack.

Douglas Gabapentin 400 mg capsules are opaque with a white body and an orange cap. There are 100 capsules in each pack.

### Ingredients

Active ingredient:

- **gabapentin.**

Other ingredients:

- **Croscarmellose sodium**
- **Magnesium stearate**
- **Purified talc**
- **Titanium dioxide**
- **Gelatin**
- **Iron oxide yellow (CI 77492)**
- **Black printing ink**
- **Iron oxide red (CI 77491)**

(400 mg capsules only).

Douglas Gabapentin capsules do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

### Sponsor

Genepharm Pty Ltd.  
3/10 Inglewood Place  
Norwest Business Park  
Baulkham Hills NSW 2153

Douglas Gabapentin 300 mg capsules: AUST R 81811

Douglas Gabapentin 400 mg capsules: AUST R 81812

This leaflet was amended in January 2009