

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about GANTIN.

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 GANTIN 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 Gantin is used for

GANTIN 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.

GANTIN is also used to treat neuropathic pain.

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

GANTIN also has analgesic effects.

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

Your doctor may have prescribed GANTIN for another reason. Ask your doctor if you have any questions about why GANTIN has been prescribed for you.

There is no evidence that GANTIN is addictive.

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

GANTIN 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 GANTIN for the treatment of neuropathic pain in children under the age of 18 years have not been established.

Before you take Gantin

When you must not take it

Do not take GANTIN if you have an allergy to:

- gabapentin, the active ingredient in GANTIN and NEURONTIN® or any of the ingredients listed at the end of this leaflet.

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

Do not take GANTIN 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 GANTIN, 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.

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

GANTIN 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 GANTIN, your doctor can help you decide whether or not to take it during pregnancy.

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

Your doctor will discuss the possible risks and benefits of using GANTIN during breastfeeding.

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.

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

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 GANTIN may interfere with each other. These include:

- some medicines used to treat stomach or duodenal ulcers, such as cimetidine
- antacids, medicines used to treat heartburn or reflux
- morphine, a medicine used to treat severe pain.

These medicines may be affected by GANTIN, 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 and pharmacist may have more information on medicines to be careful with or avoid while taking GANTIN.

How to take Gantin

How much to take

Your doctor will tell you how many capsules/tablets 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 GANTIN and slowly increase the dose to the lowest amount needed to control your epilepsy/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 GANTIN whole with a full glass of water.

When to take it

Take GANTIN at about the same time each day.

Taking GANTIN at the same time each day will have the best effect. It will also help you remember when to take the capsules/tablets. It does not matter if you take GANTIN before or after food.

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 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.

How long to take it

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

Stopping GANTIN suddenly may cause unwanted effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

If you take too much (overdose)

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

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

While you are taking Gantin

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking GANTIN.

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

Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking GANTIN.

Tell your doctor if you feel GANTIN is not helping your condition. Your doctor may need to change your medicine.

Tell your doctor if, for any reason, you have not taken GANTIN exactly as prescribed. Otherwise, your doctor may change your treatment unnecessarily.

If you become pregnant while taking GANTIN, tell your doctor.

If you need to have any medical tests while you are taking GANTIN, tell your doctor. GANTIN 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 give GANTIN to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.

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

Do not stop taking it unless your doctor tells you to.

Things to be careful of

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

As with other anticonvulsant medicines, GANTIN may cause dizziness, light-headedness, tiredness, drowsiness in some people. Make sure you know how you react to GANTIN 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. If you drink alcohol, dizziness or light-headedness may be worse.

Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or sleepy. GANTIN may cause drowsiness, dizziness or sleepiness in some people and affect alertness.

Be careful when drinking alcohol while taking GANTIN.

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

Side effects

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

GANTIN helps most people with epilepsy or neuropathic pain, 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 GANTIN 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
- weakness, unsteadiness when walking, reduced co-ordination or slowed reactions
- decreased feeling in the skin or sensitivity
- mood changes such as restlessness, agitation, nervousness, irritability or excitement
- forgetfulness, loss of concentration or confusion
- difficulty speaking
- changes in appetite
- indigestion
- changes in your weight
- constipation, diarrhoea
- dry mouth
- coughing
- rash
- muscle pain or cramps
- swelling of the hands, ankles and feet
- blurred or double vision, uncontrollable jerky eye movements, difficulty seeing.

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

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)
- 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
- severe stabbing or throbbing pain in the head
- nausea, vomiting, loss of appetite and feeling generally unwell, together with fever, itching and yellowing of the eyes and skin
- dark coloured urine.

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

All of these side effects are very rare.

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

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 blood tests from time to time to check your progress.

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

You may not experience any of them.

After using Gantin

Storage

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 will not keep well.

Keep your capsules in a cool dry place where the temperature stays below 30°C.

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

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

Do not leave it on a window sill 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 GANTIN or the capsules/tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

300 mg - Yellow capsule
400 mg - Orange capsule

A pack contains 100 capsules.

800 mg - White, elliptical, film-coated tablet, marked "800 mg" in orange ink.

A pack contains 100 tablets.

Ingredients

Capsules:

Active ingredients:

- GANTIN 300 mg - 300 mg gabapentin
- GANTIN 400 mg - 400 mg gabapentin.

Other ingredients

- lactose
- talc-purified
- starch maize
- gelatin
- titanium dioxide
- iron oxide - yellow (300 mg/400 mg)
- iron oxide - red (400 mg).

Tablets:

Active ingredients:

- GANTIN 800 mg - 800 mg gabapentin.

Other ingredients:

- poloxamer
- copovidone
- starch-maize
- magnesium stearate
- candelilla wax
- Opadry White YS-1-18111
- Opacode Orange NS-78-13007.

GANTIN does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Arrow Pharmaceuticals Limited
24 Rothschild Avenue
Rosebery NSW 2018
Australia

Australian Registration Numbers:

300 mg capsules: AUST R 78624
400 mg capsules: AUST R 78625
800 mg tablets: AUST R 78626

Date of preparation:
September 2004