

Pendine

contains the active ingredient gabapentin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Pendine.

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 Pendine 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 Pendine is used for

Pendine 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.

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

Pendine 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 Pendine 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 Pendine has been prescribed for you.

Your doctor may have prescribed Pendine for another reason.

Pendine 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 Pendine in children of these age groups have not been established.

Pendine is available only with a doctor's prescription.

There is no evidence that Pendine is addictive.

Before you take Pendine

When you must not take it

Do not take Pendine if you are allergic to medicines containing gabapentin (eg. Neurontin) 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 Pendine 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 Pendine if the packaging shows signs of tampering or the capsules or tablets 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.

Pendine 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 Pendine during pregnancy.

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

Pendine 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 Pendine 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 Pendine.

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 Pendine, 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 Pendine.

Antacids may reduce the absorption of Pendine.

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 Pendine.

How to take Pendine

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 or tablets 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 Pendine 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 Pendine

Swallow the capsules or tablets whole with a full glass of water.

When to take Pendine

Take Pendine at about the same time each day.

Taking Pendine 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 Pendine 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 Pendine.

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

Pendine can be taken with or without food.

If you forget to take Pendine

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 Pendine for

Keep taking Pendine for as long as your doctor recommends.

Pendine helps control your condition, but does not cure it. Therefore, to properly control your condition, Pendine 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 Pendine.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking Pendine

Things you must do

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

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

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

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

Pendine 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 Pendine, 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 Pendine is not helping your condition.

Your doctor may need to change your medicine.

Tell your doctor if, for any reason, you have not taken Pendine 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 Pendine.

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

Pendine 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 Pendine, 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 Pendine 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 Pendine completely.

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

Do not give Pendine 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 Pendine affects you.

Pendine 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 Pendine.

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

If you are a diabetic, be aware that Pendine 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 Pendine.

Like all other medicines, Pendine 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 Pendine 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
- sore throat, coughing, bronchitis

- fever
- 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 Pendine

Storage

Keep Pendine 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 medicine in the pack until it is time to take them.

If you take the capsules or tablets out of the pack, they may 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 Pendine or any other medicine in the bathroom or near a sink.

Do not leave Pendine in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

Pendine is available in 3 strengths:

- Pendine 300mg - yellow capsule. Each pack contains 100 capsules.
- Pendine 400mg - orange capsule. Each pack contains 100 capsules.
- Pendine 800mg - white elliptical, film-coated tablets, with bisecting score on both sides and debossed with "NT" and "26" on one side. Each pack contains 100 tablets.

Ingredients

The active ingredient in Pendine is gabapentin.

- Each Pendine 300mg capsule contains 300mg of gabapentin.
- Each Pendine 400mg capsule contains 400mg of gabapentin.
- Each Pendine 800mg tablet contains 800mg of gabapentin.

Capsules also contain:

- lactose
- maize starch
- purified talc
- gelatin
- titanium dioxide (E171)
- iron oxide yellow CI77492 (E172)
- iron oxide red CI77491 (E172) [Pendine 400mg only].

Tablets also contain:

- poloxamer
- copovidone
- maize starch
- magnesium stearate
- candelilla wax
- Opadry White YS-1-18111

Pendine does not contain sucrose or gluten.

Supplier

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:

Pendine 300mg - AUST R 80335

Pendine 400mg - AUST R 80336

Pendine 800mg - AUST R 80337

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