GABAPENTIN ZENTIVA 100MG, 300MG & 400MG CAPSULES

(Gabapentin)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

1. Keep this leaflet. You may need to read it again.
2. If you have any further questions, ask your doctor or pharmacist.
3. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
4. If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is this leaflet?
1. What gabapentin is and what it is used for
2. What you need to know before you take gabapentin
3. How to take gabapentin
4. Possible side effects
5. How to store gabapentin
6. Contents of the pack and other information

1. WHAT GABAPENTIN IS AND WHY YOU ARE TAKING IT

This medicine is called Gabapentin Zentiva and it contains the active substance Gabapentin (also called gabapentin throughout this leaflet).

Gabapentin belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain (pain lasting pain caused by damage to the nerves).

Gabapentin is used to treat:
- Various forms of epilepsy (attacks that are initially limited to certain parts of the brain, whether the seizure spreads to other areas or not), which may be severe and frequent. The doctor treating you may be able to increase your dose until the seizures are controlled.
- The doctor treating you may start you on 6 years of age and upwards. The dose may then be increased slowly and this will often take several weeks or months. This is because gabapentin is not easily absorbed and may take longer to reach the effective level.
- Peripheral neuropathic pain (pain lasting pain caused by damage to the nerves). A variety of different diseases can cause pain in the nerves, for example, disease occurring in the legs and hands, painful polyneuropathies, peripheral neuropathies, skin sensations may be described as burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles, etc.

2. BEFORE YOU TAKE GABAPENTIN

Do not take gabapentin:
- If you are allergic (hypersensitive) to the active substance of gabapentin (Gabapentin) or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
- Talk to your doctor or pharmacist before taking gabapentin:
- If you suffer from kidney problems your doctor may prescribe a different dosage schedule
- If you have kidney disease (renal impairment), to remove waste products because of kidney failure, tell your doctor if you develop muscle pain and weakness
- If you develop signs such as persistent stomach pain, feeling sick and being sick contact your doctor immediately as these may be symptoms of acute pancreatitis (an inflamed pancreas)
- If you have nervous system disorders, respiratory disorders, or you are more than 65 years old, your doctor may prescribe you a different dosage regimen
- Gabapentin treatment has been associated with dizziness and sleepiness, which could increase the likelihood of falls in older people. There have also been reports of loss of consciousness and confusion (see section 4).

- Causes of abuse and dependence have been reported for gabapentin. Talk to your doctor if you have a history of abuse or dependence.

A small number of people being treated with antiepileptic such as gabapentin have had thoughts of harming or killing themselves. If you are feeling depressed, immediately contact your doctor.

Important information about potentially serious reactions
- A small number of people taking gabapentin get an allergic reaction or potentially serious skin reaction, which may develop into a rash. You need to stop taking the medicine and see your doctor immediately. A rash is a red, itchy, scaly skin condition that can develop in the first few weeks after starting taking the medicine. Read the description of these symptoms in section 4 of this leaflet under 'Tell your doctor straight away'.

- Muscle weakness, tiredness, weight loss and appetite, all at the same time, you feel unwell or have a high temperature it may be caused by an infection. Contact your doctor immediately. It may also cause an increased risk of developing heart failure, particularly in patients over the age of 50 years or with pre-existing heart disease.

- Muscle wasting, tiredness, pain and particularly, if it is the same time, you feel unwell or have a high temperature it may be caused by an infection. Contact your doctor immediately. It may also cause an increased risk of developing heart failure, particularly in patients over the age of 50 years or with pre-existing heart disease.

- Muscle wasting, tiredness, pain and particularly, if it is the same time, you feel unwell or have a high temperature it may be caused by an infection. Contact your doctor immediately. It may also cause an increased risk of developing heart failure, particularly in patients over the age of 50 years or with pre-existing heart disease.

Children and adolescents

- There is limited data available on the effects of long-term gabapentin therapy (> 36 weeks); therefore the benefits must be weighed against the potential risks.

- Gabapentin is not recommended for use in children under 6 years old.

Other medicines and gabapentin
- Talk to your doctor or pharmacist if you are taking, have recently taken or may take any other medicines, including medicines obtained without prescription. In particular, tell your doctor (or pharmacist) if you are taking or have been recently taking any medicines for depression, anxiety, Parkinson's disease, Parkinson's-like conditions, other movement disorders, or any other neurological or psychiatric conditions.

- Medicines containing opioids such as morphine
- If you are taking any medication containing opioids (such as morphine), please tell your doctor or pharmacist as opioids may increase the effect of gabapentin. In addition, combination of gabapentin with opioids may cause symptoms like sleeplessness and/or decrease in breathing.

- Alcohol

- The effects of gabapentin from the stomach may be reduced if you are taking any medicines used to treat ulcer (antacids containing aluminium and magnesium) at the same time. It is therefore recommended that gabapentin is taken at the earliest two hours after taking an antacid.

- Gabapentin is not expected to interact with other drugs against epilepsy or your oral contraceptive pill.

- Gabapentin may interfere with some laboratory tests, so you may need to take a urine test for the drug you are taking.

- Gabapentin with food

- Gabapentin can be taken with or without food.
- Pregnancy, breast-feeding and fertility
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Pregnancy

- Gabapentin should not be taken during pregnancy, unless you are told otherwise by your doctor. Effective contraception must be used by women of childbearing age.

- No specific studies in pregnant women have been done with this medicine. However other medicines used to treat seizures have reported an increased risk of harm to the developing baby, particularly in the first trimester of pregnancy. Therefore, if you are planning to become pregnant or breastfeed, ask your doctor or pharmacist for advice before taking this medicine.

- Contact your doctor immediately if you become pregnant. If you think you might be pregnant or are planning to become pregnant while taking gabapentin, do not suddenly discontinue taking this medicine. The seizures may reappear, which could have serious consequences for you and your baby.

- Breast-feeding

- Gabapentin is excreted in human milk. Because the effect on the baby is unknown, it is not recommended to breast-feed while using gabapentin.

- Fertility

- There is no effect on fertility in animal studies.

- Driving and using machines

- Gabapentin may produce dizziness, drowsiness and tiredness. You should not drive, operate complex machinery or take part in any potentially hazardous activities, until you know whether this medicine affects your ability to perform these activities. The dose of gabapentin is increased at a personal cost and only under the advice of your doctor.

- Children

- Children aged 6 years and above

- The dose is to be given your child will be decided by your doctor as it is calculated against your child's weight. The treatment is started at a dose that is increased over a period of approximately 10 days.

- The usual dose to control epilepsy is 25-50 mg/kg/day. It is usually given in 3 divided doses, by taking the capsules() each day, usually once in the morning, once in the afternoon and once in the evening.

- Gabapentin is not recommended for use in children below 6 years of age.

- If you take gabapentin to relieve peripheral neuropathic pain the recommended dose is:

- Adults

- Take the number of capsules as instructed by your doctor. Your doctor will usually build up your dose gradually.

- The starting dose will generally be between 200mg and 600mg per day.

- Thereafter, the dose may be increased progressively up to a maximum of 3600mg per day. Your doctor will tell you to take the dose in 3 divided doses, i.e. once in the morning, once in the afternoon and once in the evening.

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- If you have kidney problems or are receiving haemodialysis

- Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys or are undergoing haemodialysis.

- If you are an elderly patient (over 65 years old), you should take gabapentin as indicated unless you have problems with your kidneys. Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.
If you have the impression that the effect of gabapentin is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

Method of administration

Gabapentin is for oral use. Always swallow the capsules with plenty of water.

Do not crush gabapentin if your doctor tells you to stop. You should not stop taking this medicine without medical advice.

If you take more gabapentin than you should

Higher than recommended dosage may result in an increase in side effects including loss of consciousness, dizziness, double vision, skin rash, drowsiness and diarrhoea. Call your doctor or go to the nearest hospital emergency unit immediately if you think you have taken too much than your doctor prescribed. Take along any capsules that you have not taken. Together with the container and the tablet to the hospital can help identify what medicine you have taken.

If you forget to take gabapentin

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking gabapentin

Do not stop taking gabapentin unless your doctor tells you to. If your treatment is stopped, it should be done gradually over a period of 10-14 days. Stopping gabapentin suddenly or before your doctor tells you so can cause an increased risk of seizures.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Use of medicine, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine and see a doctor straight away if you experience any of the following symptoms as they are serious:

- Stevens Johnson reactions that require immediate attention, swelling of the lips and face, skin rash and redness or hot and red eyes, or symptoms of a serious allergic reaction;
- Blistering, peeling or bleeding of the skin among the lips, eyes, mouth, nose and genitals. You may also have flu-like symptoms;
- Oedema, swelling of the hands and feet. These would be symptoms of a severe allergic reaction;
- Vomiting, diarrhoea or watery eyes, breathlessness and fever. This may be due to inflammation of the liver or changes in the way your liver is working;
- Persistent stomach pain, feeling sick and being sick. These may be symptoms of acute pancreatitis (inflamed pancreas);
- Infection persisting such as fever, severe cold or sore throat or ulcers. This may be due to a lower than normal white blood cell count (shown by a blood test);
- Development of blood clotting cells;
- Bruising more easily than usual. This could be because of a blood problem (thrombocytopenia);
- Seeing or hearing things which are not there (hallucinations);
- Problems with abnormal movements such as writhing, jerking movements and stiffness;
- Ringing in the ears (tinnitus);
- Serious kidney disease (acute kidney failure). Symptoms may include an increase in the need to pass water, passing of very small amounts of water, feeling tired, swelling of the hands and feet and a feeling of breathlessness.

If you have these side effects, call your doctor straight away.

These symptoms may be the first signs of a serious reaction. A doctor should examine you to decide if you should continue taking gabapentin.

If you are on haemodialysis, tell your doctor if you develop muscle pain and/or weakness.

Other side effects include:

- Very common (may affect more than 1 in 10 people):
  - dizziness;
  - feeling tired;
  - dizziness, dizzy, lack of coordination;
  - feeling hot, fever;
- Common (may affect up to 1 in 10 people):
  - dizziness, unusual taste, headache, feeling hot, nausea, headache, skin rash, depression, anxiety, nervousness, change in weight;
  - dry mouth, drowsiness, difficulty speaking, loss of memory, anxiety, depression;
  - loss of appetite, changes in weight, tiredness, forgetfulness, confusion, dry mouth or mouth ulcers, flu-like symptoms;
  - facial swelling, bruising, rash, itch, tone;
  - joint pain, muscle pain, back pain, tenderness;
  - difficult in breathing (hyperventilation);
  - swelling in the legs and arms, difficulty in walking, weakness, pain, feeling unwell, flu-like symptoms;
  - increase in weight;
  - accidental injury, fracture, abrasion;
- Uncommon (may affect up to 1 in 100 people):
  - depression, anxiety;
  - mental impairment;
  - racing heart beat;
  - swelling that may involve the face, body and limbs;
- Atrophic blood test results suggesting problems with the liver;
  - increase in blood glucose levels (most often observed in patients with diabetes);
  - agitation (a state of extreme restlessness and unintentional and purposeless movements);
  - difficulty swallowing.

Rare (may affect up to 1 in 1000 people):

- loss of consciousness;
- decrease in blood glucose levels (most often observed in patients with diabetes);
- trouble breathing, shallow breathing (respiratory depression);
- Not known (cannot be estimated from available data):
  - A group of side effects that could include swelling of the body, swollen arms or legs;
  - abnormal blood test results suggesting problems with the liver;
  - increase in blood glucose levels (most often observed in patients with diabetes);

5. HOW TO STORE GABAPENTIN

Keep out of sight and reach of children.

Do not store above 25°C.

Do not use these capsules after the expiry date which is stated on the carton. The expiry date refers to the last day of that month, Do not use these medicine in a household waste bin. Ask your pharmacist how to throw away medicines you no longer use. Those measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Gabapentin Zentiva Capsules contain

The active substance is gabapentin. Each capsule contains either 100mg, 200mg or 400mg of gabapentin.

The other ingredients and Gabapentin Zentiva 100 Capsules: lactose monohydrate, maize starch, talc; titanium dioxide (E171) and gelatin.

Gabapentin Zentiva 200 Capsules: lactose monohydrate, maize starch, talc; titanium dioxide (E171) and gelatin.

Gabapentin Zentiva 400 Capsules: lactose monohydrate, maize starch, talc; titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172) and gelatin.

The new pregelatinised starch used in the capsule contains: shellac (E104), titanium (E171) and FD&C Blue 1,FD&C Red 40 FCF Lake (E139).

What Gabapentin Zentiva Capsules look like and contents of the pack

Gabapentin Zentiva 100 Capsules are white, hard capsules marked S101 on one side.

Gabapentin Zentiva 200 Capsules are yellow, hard capsules marked S102 on one side.

Gabapentin Zentiva 400 Capsules are orangeyellow, hard capsules marked S103 on one side.

Pack size 100.

Marketing Authorisation Holder and Manufacturer:

Zentiva, One Olivine Street, Guildford, Surrey, GU1 4YS, UK

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