

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.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.
- 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 in this leaflet

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1. WHAT GABAPENTIN IS AND WHAT IT IS USED FOR

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

Gabapentin is used to treat:

• **Various forms of epilepsy (*seizures that are initially limited to certain parts of the brain, whether the seizure spreads to other parts of the brain or not*).** Your doctor will prescribe gabapentin if your current treatment is no longer fully controlling your epilepsy. You should take gabapentin in addition to your current treatment. If your doctor considers that it is necessary, gabapentin can also be used on its own to treat adults and children over 12 years of age.

• **Peripheral neuropathic pain (*long lasting pain caused by damage to the nerves*).** A variety of different diseases can cause this type of pain (primarily occurring in the legs and/or arms), such as diabetes (high blood sugar) or shingles (disease caused by the varicella virus). These pains may be felt as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles etc.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE GABAPENTIN**Do not take gabapentin**

- if you are allergic (hypersensitive) to the active substance of this medicine (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 dosing schedule
- if you are on haemodialysis (to remove waste products because of kidney failure), tell your doctor if you develop muscle pain and/or 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 dosing 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).

Cases 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 anti-epileptics such as gabapentin have had thoughts of harming or killing themselves. If at any time you have these thoughts, 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 more serious problems if they are not treated. You need to know the symptoms to look out for while you are taking gabapentin.

Read the description of these symptoms in section 4 of this leaflet under 'Tell your doctor straight away'.

Muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown which can be life-threatening and lead to kidney problems. You may also experience discolouration of your urine, and a change in blood test results (notably blood creatine phosphokinase increased). If you experience any of these signs or symptoms, please contact your doctor immediately.

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

Tell your doctor or pharmacist if you are taking, have recently taken or might 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 convulsions, sleeping disorders, depression, anxiety, or any other neurological or psychiatric problems.

Medicines containing opioids such as morphine

If you are taking any medicines 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 sleepiness and/or decrease in breathing.

Antacids for indigestion

The absorption 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, if you require a urine test tell your doctor or hospital what 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 child-bearing age.

No specific studies in pregnant women have been done with this medicine. However other medications used to treat seizures have reported an increased risk of harm to the developing baby, particularly when more than one seizure medication is taken at the same time. Therefore, whenever possible, you should try to take only one seizure medication during pregnancy and only under the advice of your doctor.

Contact your doctor immediately if you become pregnant, 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 passed on through 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 other potentially hazardous activities, until you know whether this medicine affects your ability to perform these activities.

Gabapentin Zentiva Capsules contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE GABAPENTIN

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will determine what dose is appropriate for you.

If you take gabapentin to treat epilepsy the recommended dose is*Adults and adolescents*

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 300mg and 900mg each day.

Thereafter, the dose may be increased progressively up to a maximum of 3600mg each 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.

Children aged 6 years and above

The dose to be given to your child will be decided by your doctor as it is calculated against your child's weight. The treatment is started with a low initial dose which is gradually increased over a period of approximately 3 days.

The usual dose to control epilepsy is 25-35 mg/kg/day.

It is usually given in 3 divided doses, by taking the capsule(s) 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 300mg and 900mg each day.

Thereafter, the dose may be increased progressively up to a maximum of 3600mg each 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.

If you have kidney problems or are receiving haemodialysis

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

If you are an elderly patient (over 65 years old), you should take gabapentin as indicated unless if 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.

Continue taking gabapentin until 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 doses may result in an increase in side effects including loss of consciousness, dizziness, double vision, slurred speech, drowsiness and diarrhoea. Call your doctor or go to the nearest hospital emergency unit immediately if you take more gabapentin than your doctor prescribed. Take along any capsules that you have not taken, together with the container and the label so that the hospital can easily tell 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 minimum of 1 week. If you stop taking gabapentin suddenly or before your doctor tells you, there is 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

Like all medicines, 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 can be serious:

- severe skin reactions that require immediate attention, swelling of the lips and face, skin rash and redness and/or hair loss (these may be symptoms of a serious allergic reaction).
- blistering, peeling or bleeding of the skin around the lip, eyes, mouth, nose and genitals. You may also have flu-like symptoms and a high temperature. These could be symptoms of Stevens-Johnson syndrome.
- yellowing of your skin or whites of your eyes, tiredness 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 (an inflamed pancreas).
- frequent infections such as fever, severe chills, sore throat or mouth ulcers. This may be due to a lower than normal white blood cell count (shown by a blood test).
- decreased platelets (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 shortness of breath.
- difficulty breathing, swelling of the lips, throat and tongue or dizziness, lightheadedness or fainting (due to low blood pressure) requiring emergency treatment. These may be signs of a serious, possibly life threatening allergic reaction (anaphylaxis)
- breathing problems, which if severe you may need emergency and intensive care to continue breathing normally.
- Gabapentin may cause a serious or life-threatening allergic reaction that may affect your skin or other parts of your body such as your liver or blood cells. You may or may not have rash when you get this type of reaction. It may cause you to be hospitalized or to stop gabapentin.

Call your doctor right away if you have any of the following symptoms:

- skin rash
- hives
- fever
- swollen glands that do not go away
- swelling of your lip and tongue
- yellowing of your skin or of the whites of the eyes
- unusual bruising or bleeding
- severe fatigue or weakness
- unexpected muscle pain
- frequent infections

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):

- viral infection
- feeling drowsy, dizzy, lack of coordination
- feeling tired, fever

Common (may affect up to 1 in 10 people):

- pneumonia, respiratory infections, urinary tract infections, inflammation of the ear or other infections
- anorexia, increase in appetite
- anger towards others, confusion, mood changes, depression, anxiety, nervousness, strange or unusual thoughts
- convulsions, jerky movements, difficulty speaking, loss of memory, tremor, difficulty sleeping, headache, sensitive skin, decreased sensation (numbness), difficulty with coordination, unusual eye movements, increased, decreased or absent reflexes
- blurred vision, double vision
- vertigo
- high blood pressure, flushing or dilation of blood vessels
- difficulty breathing, bronchitis, sore throat, cough, dry nose
- vomiting (being sick), nausea (feeling sick), problems with teeth, inflamed gums, diarrhoea, stomach pain, indigestion, constipation, dry mouth or throat, flatulence
- facial swelling, bruises, rash, itch, acne
- joint pain, muscle pain, back pain, twitching
- difficulties with erection (impotence)
- 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):

- decreased movement
- fall,
- mental impairment
- racing heart beat
- swelling that may involve the face, body and limbs
- abnormal blood test results suggesting problems with the liver
- increase in blood glucose levels (most often observed in patients with diabetes)
- agitation (a state of chronic restlessness and unintentional and purposeless motions)

Rare (may affect up to 1 in 1,000 people):

- loss of consciousness
- decrease in blood glucose levels (most often observed in patients with diabetes)
- trouble breathing, shallow breaths (respiratory depression)

Not known (cannot be estimated from available data):

- a group of side effects that could include swollen lymph nodes (isolated small raised lumps under skin), fever, rash, and inflammation of liver occurring together,
- incontinence (leakage of urine which you cannot control),
- increased breast tissue, breast enlargement
- side effects following the sudden stopping of gabapentin (anxiety, difficulty in sleeping, feeling sick, pain, sweating), chest pain,
- breakdown of muscle fibres (rhabdomyolysis),
- low blood sodium level (hyponatraemia),
- change in blood test results (creatinine phosphokinase increased),
- problems with sexual functioning including inability to achieve a sexual climax, delayed ejaculation.

Additional side effects in children and adolescents

In clinical studies in children, aggressive behaviour and jerky movements were reported commonly.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

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 throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These 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, 300mg or 400mg of gabapentin.

The other ingredients are:

Gabapentin Zentiva 100mg Capsules: lactose monohydrate, maize starch, talc, titanium dioxide (E171) and gelatin.

Gabapentin Zentiva 300mg Capsules: lactose monohydrate, maize starch, talc, titanium dioxide (E171), yellow iron oxide (E172) and gelatin.

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

The printing ink used on the capsule contains: shellac (E104), titanium (E171) and FD&C Blue 1/Brilliant blue FCF Lake (E133).

What Gabapentin Zentiva Capsules look like and contents of the pack

Gabapentin Zentiva 100mg Capsules are white, hard capsules marked S154 on one side.

Gabapentin Zentiva 300mg Capsules are yellow, hard capsules marked S155 on one side.

Gabapentin Zentiva 400mg Capsules are orange-yellow, hard capsules marked S156 on one side.

Pack size:100.

Marketing Authorisation Holder and Manufacturer:

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

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