### Gabapentin Capsules

**100, 300 & 400mg x 100’s (UK)**

- **IDE No:** 50899691
- **Dimensions:** 296x210 (Reel Fed)
- **Component:** Leaflet for Blisters
- **Pharmacode:** 4155

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**Contents of the pack and other information**

What Gabapentin capsules contain

The active substance (the ingredient that makes the medicine work) is gabapentin. Each capsule contains either 100mg, 300mg or 400mg gabapentin.

The other ingredients in the capsules are lactose monohydrate, maize starch, talc. The capsule shell contains titanium dioxide (E171) and gelatin, yellow iron oxide (E172) (300mg and 400mg capsules) and red iron oxide (E172) (400mg capsules only). The printing ink contains Shellac (E904), propylene glycol (E1520), black iron oxide (E172) and potassium hydroxide (E525).

What Gabapentin capsules looks like and contents of the pack

Gabapentin 100mg Capsules are white, the 300mg capsules are yellow and the 400mg capsules are orange. The packs contain: 100 capsules.

**Marketing Authorisation Holder and Manufacturer**

Actavis, Barnstaple, EX32 8NS, UK

Revision date June 2016

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**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 these symptoms to look out for while you are taking gabapentin.

Read the description of these symptoms in section 4 of this leaflet under 'Contact your doctor immediately if you experience any of the following symptoms after taking this medicine as they can be serious'.

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**How to store Gabapentin capsules**

Keep out of the sight and reach of children. Do not store above 25°C. Do not use Gabapentin capsules after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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**Who is this leaflet for?**

People who need to take Gabapentin capsules.
Driving and using machines
When taking Gabapentin capsules you may become drowsy, dizzy or feel tired, especially at the start of treatment or after a dose increase. Make sure you are not affected before driving or operating machinery.

Gabapentin capsules contain lactose
The capsules contain lactose monohydrate. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

How to take Gabapentin capsules
Always take Gabapentin capsules exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Gabapentin capsules are usually taken three times a day (morning, afternoon and evening). Always swallow the capsules whole with plenty of water, with or without food. Your doctor will determine what dose is appropriate for you. If you are an elderly patient (over 65 years old), have kidney disease or are having haemodialysis you should take Gabapentin capsules as prescribed by your doctor.

Continue taking Gabapentin capsules until your doctor tells you to stop.

Dosage
Epilepsy:
Adults and children aged 12 years or over:
The usual starting dose is between 300mg and 900mg each day. The dose may then be increased gradually to a maximum of 3600mg each day.
Children aged 6 years and above:
The dose depends on the body weight of your child. The treatment is started with a low initial dose which is gradually increased over a period of about 3 days. The usual dose to control epilepsy is 25-35mg per kg per day. Gabapentin capsules are not recommended for use in children below 6 years of age.

Peripheral neuropathic pain:
The usual starting dose is between 300mg and 900mg each day. The dose may then be increased gradually to a maximum of 3600mg each day.

If you take more Gabapentin capsules than you should
If you or someone else accidentally takes too many capsules, or if you think a child has swallowed any, contact your doctor or go to your nearest hospital casualty department immediately. As Gabapentin capsules may make you drowsy, it is recommended that you ask someone else to drive you to the doctor or hospital, or that you call an ambulance. Symptoms of an overdose are dizziness, double vision, slurred speech, drowsiness or tiredness, loss of consciousness and mild diarrhoea. Overdose of gabapentin, particularly in combination with other CNS depressant medications, may result in coma.

If you forget to take Gabapentin capsules
If you miss 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 capsules
Do not stop taking this medicine suddenly, as your symptoms may get worse. Your doctor will reduce the dose gradually, you may experience anxiety, difficulty sleeping, feeling sick, pain, sweating.

Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor immediately if you experience any of the following symptoms after taking this medicine 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)
- persistent stomach pain, feeling sick and being as these may be symptoms of acute pancreatitis (an inflamed pancreas)
- Gabapentin capsules 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 capsules.

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 Capsules.

- 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, dizziness, lack of coordination
- feeling tired, fever

Common (may affect up to 1 in 10 people):
- pneumonia, respiratory infections, urinary tract infection, inflammation of the ear or other infections
- low white blood cell counts
- anorexia, increased appetite
- anger towards others, confusion, mood changes, depression, anxiety, nervousness, difficulty with thinking
- convulsions, jerky movements, difficulty with speaking, loss of memory, tremor, difficulty sleeping, headache, sensations such as pins and needles, decreased sensation (numbness), difficulty with coordination, unusual eye movement, 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, runny 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, itchy skin, acne
- joint pain, muscle pain, back pain, twitching
- difficulties with erection (impotence)
- swelling in the legs and arms, difficulty with walking, weakness, pain, feeling unwell, flu-like symptoms
- decrease in white blood cell, increase in weight
- accidental injury, fracture, abrasion

Additionally in clinical studies in children, aggressive behaviour and jerky movements were reported commonly. Respiratory tract infections, inflammation of the middle ear and ear drum, convulsions and bronchitis were also reported.

Other medicines and Gabapentin capsules
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular:
- 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 capsules. In addition, combination of Gabapentin capsules with opioids may cause symptoms like sleepiness and/or decrease in breathing.
- antacids containing aluminium and magnesium (used to reduce stomach acid) - if taken at the same time, absorption of Gabapentin capsules from the stomach may be reduced. It is therefore recommended that Gabapentin capsules are taken at least two hours after taking an antacid.

Urinary Tests
Gabapentin capsules may interfere with urine tests. If you require a urine test, tell your doctor or hospital that you are taking Gabapentin capsules.

Pregnancy, breastfeeding and fertility
Pregnancy:
Gabapentin capsules should not be taken during pregnancy, unless advised by your doctor.

Contact your doctor immediately if you become pregnant, think you might be pregnant or are planning to become pregnant while taking Gabapentin capsules. Other medicines used to treat seizures may increase the risk of harm to the foetus, particularly when more than one seizure medication is taken at the same time. Therefore, whenever possible and only under the advice of your doctor, you should try to take only one seizure medication during pregnancy.

Do not suddenly stop taking this medicine as this may lead to breakthrough seizures, which could have serious consequences for you and your baby.

Breastfeeding:
If you are taking Gabapentin capsules, do not breastfeed, unless advised to by your doctor, as this medicine will pass into breast milk and may harm the baby.

Fertility:
There is no effect on fertility in animal studies.