

## **What is in this leaflet?**

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## **What Gabata 300/400 is used for**

### **Epilepsy:**

Gabata is used as adjunctive therapy in the treatment of partial seizures (affects a small area of the brain) with and without secondary generalization (spread to both sides of the brain) in adults and children age 3 years and above. Safety and effectiveness for adjunctive therapy in pediatric patients below the age of 3 years have not been established.

### **Neuropathic pain:**

Gabata is used for the treatment of neuropathic pain (long lasting pain caused by damage to the nerves), in adults age 18 years and above. Safety and effectiveness in patients below the age of 18 years have not been established.

## **How Gabata 300/400 works**

It works by changing the way the nerves send messages to the brain. Brain cells need to work at a certain rate to function normally. During a seizure, brain cells are forced to work more rapidly than normal. Gabapentin is used to control epilepsy and works by reducing the abnormal electrical activity in the brain.

## **Before you use Gabata 300/400**

### **- When you must not use it**

If you are allergic (hypersensitive) to Gabata or any of the other ingredients of this medicine if you have ever had epilepsy

### **- Before you start to use it**

#### ***Important information about potentially serious reactions***

A small number of people taking Gabata 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 Gabata.

Read the description of these symptoms in Section "Side Effects".

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

Gabata should not be taken during pregnancy, unless you are told otherwise by your doctor. Effective contraception must be used by women of child-bearing potential. There have been no studies specifically looking at the use of gabapentin in pregnant women, but 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 Gabata. Do not suddenly discontinue taking this medicine as this may lead to a breakthrough seizure, which could have serious consequences for you and your baby.

Gabapentin, the active substance of Gabata, is passed on through human milk. Because the effect on the baby is unknown, it is not recommended to breast-feed while using Gabata.

Important information about some of the ingredients of Gabata

Gabata hard capsules contain lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **- Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- If you are taking any medicines containing morphine, please tell your doctor or pharmacist as morphine may increase the effect of Gabata.

- If Gabata and antacids containing aluminium and magnesium are taken at the same time, absorption of Gabata

from the stomach may be reduced. It is therefore recommended that Gabata is taken at the earliest two hours after taking an antacid.

Gabata:

- is not expected to interact with other anti-epileptic drugs or the oral contraceptive pill

- may interfere with some laboratory tests, if you require a urine test tell your doctor or hospital what you are taking.

## **How to use Gabata 300/400**

### **How much to use**

Always take Gabata exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

*Epilepsy*, the usual dose is:

- Adults and adolescents:

Take the number of capsules or tablets as instructed. Your doctor will usually build up your dose gradually. The starting dose will generally be between 300mg and 900 mg each day. Thereafter, the dose may be increased as instructed by your doctor, up to a maximum of 3600mg each day.

- Children aged 3 – 12 years:

The starting dose should range from 10 to 15 mg/kg/day given in equally divided doses (three times a day), and the effective dose reached by upward titration over a period of approximately three days. The effective dose of gabapentin in patients age 5 years and older is 25 to 35 mg/kg/day given in equally divided doses (three times a day). The effective dose in pediatric patients ages 3 to less than 5 years is 40 mg/kg/day given in equally divided doses (three times a day). The maximum time interval between doses should not exceed 12 hours.

*Peripheral Neuropathic Pain*, the usual dose is:

- Adults: Take the number of capsules or tablets as instructed. Your doctor will usually build up your dose gradually. The starting dose will generally be between 300mg and 900 mg each day. Thereafter, the dose may be increased as instructed by your doctor, up to a maximum of 3600mg each day.

- If you have kidney problems or are receiving haemodialysis: Your doctor may prescribe a different dosing schedule and/or dose if you have

# GABATA 300/400

Consumer Medication Information Leaflet (RiMUP)

Gabapentin Capsules USP 300mg/400mg

problems with your kidneys or are undergoing haemodialysis.

## - When to use it

Your doctor will tell you to take the recommended dose for each treatment in 3 separate doses, i.e. once in the morning, once in the afternoon and once in the evening. If you are an elderly patient (over 65 years of age), your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

## - How long to use it

Do not stop taking Gabata unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of one (1) week. If you stop taking Gabata suddenly or before your doctor tells you to, there is an increased risk of seizures. If you have further questions on the use of this medicine, ask your doctor or pharmacist.

## - If you forget to use it

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 use too much (overdose)

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 Gabata than your doctor prescribed. Take along any capsules or tablets that you have not taken, together with the container and the label so that the hospital can easily tell what medicine you have taken.

## While you are using it:

### - Things you must do

- Read all this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not

listed in this leaflet, please tell your doctor or pharmacist.

## - Things you must not do

### Driving and using machines

Gabata 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 medication affects your ability to perform these activities.

## - Things to be careful of:

Take special care with Gabata:

- 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)
- 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

## Side Effects

Like all medicines, Gabata 300/400 can cause side effects, although not everybody gets them. Tell your doctor about any of the following side effects:

- 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 sick as these may be symptoms of acute pancreatitis (an inflamed pancreas)
  - Gabata 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 Gabata.
- 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 Gabata.

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

Very common side effectsL

- Viral infection
- Feeling drowsy, dizziness, lack of coordination
- Feeling tired, fever

Common side effects:

- 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, sensitive skin, 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, 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 with walking, weakness, pain, feeling unwell, flu-like symptoms
- Decrease in white blood cells, increase in weight
- Accidental injury, fracture, abrasion

You may report any side effects or adverse drug reactions directly to the

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Gabapentin Capsules USP 300mg/400mg

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National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) (Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

## **Storage and disposal Of Gabata**

### **300/400:**

#### **Storage**

Keep out of the reach and sight of children. Keep the tablets in their packet and store them in a dry place at a temperature not exceeding 30°C

#### **Disposal**

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.

## **Product Description**

*What it looks like and contents of the pack*

### **GABATA 300**

White to off white crystalline powder filled in size "1" yellow coloured hard gelatin capsule imprinted "215" on body with blue ink.

The capsules are available in PVC/PE/PVDC Film/ Aluminium foil blister pack. Each blister contain 10 capsules. Such 5 blisters & 10 blisters are packed in outer carton with insert.

### **GABATA 400**

White to off white crystalline powder filled in size "0" Orange coloured hard gelatin capsule imprinted "214" on body with blue ink.

The capsules are available in PVC/PE/PVDC Film/ Aluminium foil blister pack. Each blister contain 10 capsules. Such 5 blisters & 10 blisters are packed in outer carton with insert.

## **What Gabata 300/400 contains**

### **Active ingredients**

Gabapentin

### **Excipients**

Maize Starch, Anhydrous Lactose, Talc

### **- MAL number**

Gabata 300 - MAL19016037AZ Gabata

400 - MAL19016036AZ

## **Manufacturer**

Alkem Laboratories Ltd.  
Plot No. 167/2, 164, 165/1, 165/2, 165/3,  
Mahatma Gandhi Udyog Nagar, Village  
Dabhel, Daman - 396 210, India  
HO: ALKEM HOUSE, Senapati Bapat  
Marg, Lower Parel, Mumbai 400 013, India

## **Product Registration Holder**

Ascend Laboratories Sdn Bhd Level 25,  
Menara Hong Leong, No. 6, Jalan  
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Bukit Damansara,  
50490 Kuala Lumpur, Malaysia.

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