

# DYNA GABAPENTIN CAPSULE 300MG

Gabapentin (300mg)

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### 1. What *GABAPENTIN* is used for

Epilepsy:

Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization 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:

Gabapentin is indicated for the treatment of neuropathic pain which includes diabetic neuropathy, post-herpetic neuralgia and trigeminal neuralgia in adults age 18 years and above. Safety and effectiveness in patients below the age of 18 years have not been established.

### 2. How *GABAPENTIN* works

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

### 3. Before you use *GABAPENTIN*

- When you must not use it

DO NOT TAKE this medication if you are allergic (hypersensitive) to gabapentin or any of the other ingredients.

Take special care with 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).

- 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.

### Pregnancy and lactation

Pregnancy:

Due to lack of adequate, well-controlled studies, hence it is recommended that gabapentin should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus.

Lactation:

Gabapentin is excreted in human milk. Because the effect on the nursing infant is unknown, caution should be exercised when gabapentin is administered to a nursing mother. Gabapentin should be used in nursing mothers only if the benefits clearly outweigh the risks.

- Before you start to use it

If you have kidney problems, nervous system disorders, respiratory disorders or you are more than 65 years old, your doctor may prescribe a different dosing regimen.

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.

- 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 gabapentin.

If gabapentin and antacids containing aluminium and magnesium are taken at the same time, absorption of gabapentin from the stomach may be reduced. 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 anti-epileptic drugs or the oral contraceptive pill.

Some medicines and gabapentin may interfere with each other:

- Ginkgo
- Evening Primrose
- Ketorolac
- Hydrocodone

### 4. How to use *GABAPENTIN*

Take orally with or without food.

Swallow whole with a glass of water.

- How much to use

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 label, ask your doctor or pharmacist for help.

**Epilepsy, the usual dose is:**

- **Adults and adolescents:**

Take the number of capsules as instructed. Your doctor will usually build up your dose gradually. The starting dose will generally be between 300 mg and 900 mg each day.

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

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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.

Dyna Gabapentin Capsule is available in strength of 300 mg. It is not able to deliver all approved dose regimens of gabapentin; other approved dosage forms and strengths of gabapentin should be used in such cases.

**- When to use it**

Use as directed by your doctor or pharmacist.

**- How long to use it**

Continue taking *GABAPENTIN* for as long as your doctor recommends.

**- If you forget to use it**

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

**- If you use too much (overdose)**

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many capsules may cause sedation, ataxia, slurred speech, nystagmus, movement disorders, and gastrointestinal upset. In more severe cases, patients may present with mild hypotension and profound central nervous system depression requiring intubation.

**5. While you are using it**

**- Things you must do**

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *GABAPENTIN*.

Tell your doctor immediately if you become pregnant while taking this medication.

**- Things you must not do**

Do not abruptly discontinue or stop taking *GABAPENTIN* unless advised by your doctor. If need to, he will discontinue gradually over a minimum of 1 week.

Do not take any new medicines without consulting your doctor.

Do not give *GABAPENTIN* to anyone else, even if they have the same symptoms or condition as you.

**- Things to be careful of**

**Driving and using machines**

Gabapentin may impair the ability to drive a car or operate potentially dangerous machinery. Do not drive or operate potentially dangerous machinery, until it is known that this medication does not affect your ability to engage in these activities.

**6. Side effects**

Like all medicines, *GABAPENTIN* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

The most commonly reported adverse effects are somnolence (sleepiness), dizziness, ataxia (lack of voluntary coordination), and fatigue.

Common psychiatric effects include confusion, depression, and nervousness, and, more rarely, hallucinations and psychoses (mental disorder characterized by symptoms, such as delusions or hallucinations).

Other adverse effects include acute renal failure, allergic reactions, alopecia (hair loss), angioedema (rapid swelling of the dermis), chest pain, hepatitis, jaundice, movement disorders such as choreoathetosis (the occurrence of involuntary movements in a combination of chorea (irregular migrating contractions) and athetosis (twisting and writhing)), dyskinesia (difficulty or distortion in performing voluntary movements) and dystonia (neurological movement disorder, in which sustained muscle contractions cause twisting and repetitive movements or abnormal postures), palpitations (feelings or sensations that the heart is pounding or racing), thrombocytopenia (abnormally low amount of platelets), and tinnitus (ringing in the ears).

Contact your doctor immediately or go to the Emergency Department of your nearest hospital if you experience breathing problems such as slow, shallow or weak breathing after taking this medicine as this can be a sign of respiratory depression.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npa.gov.my](http://npa.gov.my) (*Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)*).

**7. Storage and Disposal of GABAPENTIN**

**- Storage**

Keep out of reach of children  
Protect from light  
Do not store above 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.

**8. Product Description**

**- What it looks like**

Yellow cap & yellow body hard gelatin capsule of size '1' containing white to off-white powder

**- Ingredients**

- Active ingredient(s)  
Gabapentin

- Inactive ingredients  
Magnesium Stearate, Lactose Powder & Corn Starch

**- MAL number(s):**

MAL17055007AZ

**9. Manufacturer & Product**

**Registration Holder:**

DYNAPHARM (M) SDN. BHD.  
2497, Mk. 1, Lorong Perusahaan Baru 5,  
Kawasan Perusahaan Perai 3,  
13600 Perai, Pulau Pinang,  
MALAYSIA

**10. Date of revision**

01/04/2022

**11. Serial number**

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