PMS-GABAPENTIN CAPSULE

Gabapentin (300mg, 400mg)

What is in this leaflet

- 1. What pms-Gabapentin is used for
- 2. How pms-Gabapentin works
- 3. Before you use pms-Gabapentin
- 4. How to use pms-Gabapentin
- 5. While you are using pms-Gabapentin
- 6. Side effects
- 7. Storage & disposal of pms-Gabapentin
- 8. Product description
- 9. Manufacturer and Product Registration Holder
- 10. Date of Revision

What pms-Gabapentin is used for

pms-Gabapentin is indicated 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 12 years and above.

How pms-Gabapentin works

pms-Gabapentin belongs to a group of medicines used to treat epilepsy.

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. pms-Gabapentin is used to control epilepsy and works by reducing the abnormal electrical activity in the brain.

Before you use pms-Gabapentin

When you must not use it

Do not take pms-Gabapentin capsules if you are:

• allergic (hypersensitive) to

gabapentin or any of the other ingredients of pms-Gabapentin capsule (see ingredient list)

Pregnancy and breastfeeding.
Tell your doctor if you are
pregnant or planning to become
pregnant. Gabapentin is excreted in
breast milk. It should only be used
during pregnancy or breastfeeding
if the potential benefit outweighs
the potential risks.

Ask your doctor or pharmacist for advice before taking any medicine.

If you have one of these conditions, do not take this medicine and inform your doctor.

Before you start to use it

Inform your doctor if you have any of the following conditions:

- kidney disease
- you are taking other medicines containing gabapentin.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken 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 pms-Gabapentin.

If pms-Gabapentin and antacids containing aluminium and magnesium are taken at the same time, absoption of pms-Gabapentin may be reduced.

If you are taking cimetidine (for gastric ulcer), naproxen (to treat pain or inflammation) or hydrocodone (an opioid pain medication).

How to use pms-Gabapentin

How much to use

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

Your doctor will determine what dose is appropriate for you. 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 in three equally divided doses 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.

The maximum time between doses in the three times a day schedule should not exceed 12 hours to prevent breakthrough convulsions.

When to use it

pms-Gabapentin is for oral use. Always swallow the capsules with plenty of water. pms-Gabapentin can be taken with or without food.

How long to use it

Take pms-Gabapentin capsules for the time your doctor recommends. Do not stop taking this medicine unless told to do so by your doctor.

<u>If you forget to use it</u>

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)

If you accidentally take an overdose of pms-Gabapentin, contact your doctor or hospital immediately; if possible, show them the pack of capsules. Medical treatment may be required.

Taking too many capsules may cause:

- dizziness
- double vision
- slurred speech
- drowsiness
- lethargy
- mild diarrhea

While you are using pms-Gabapentin

Things you must do

Follow the instructions for the administration of pms-Gabapentin exactly as your doctor tells you. Ask your doctor or pharmacist if you have any doubts.

Tell all the doctors, dentists and pharmacists treating you that you are taking pms-gabapentin.

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

Things you must not do

- Do not stop taking pms-Gabapentin unless told to do so by your doctor.
- Do not use pms-Gabapentin to treat any other conditions unless your doctor tells you to.
- Do not give or recommend pms-Gabapentin to anyone else, even if they have the same condition as you.

Things to be careful of

Driving and using machines:

pms-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 medication affects your ability to perform these activities.

Take special care with pms-Gabapentin:

- if you suffer from kidney problems your doctor may prescribe a different dosing schedule
- if you are on haemodialysis

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 drugs, pms-Gabapentin can produce adverse effects, although not everyone suffers from them.

The side effects include:

- Body as a whole: fatigue, increased weight, back pain
- Cardiovascular: vasodilation (dilatation of blood vessels)
- Digestive system: indigestion, dry mouth or throat, constipation
- Hematologic and lymphatic system: leukopenia (reduction in the number of white blood cells)
- Musculoskeletal system: muscle pain, fracture
- Nervous system: sleepiness, dizziness, depression
- Respiratory system: inflammation of the mucous membrane inside the nose, coughing
- Skin and appendages (body parts): abrasion, itching
- Urogenital system: impotence

- Special sense: double vision, amblyopia (lazy eye)

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

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

This is not a complete list of side effects. If any of the side effects gets serious, please tell your doctor.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and disposal of pms-Gabapentin

Storage

Store below 25°C in a dry cool place and protected from light. Keep out of reach of children.

Disposal

If your doctor tells you to stop taking pms-Gabapentin capsules or your capsules have passed their expiry date, ask your pharmacist or doctor what to do with any that are left over.

Do not simply throw the leftover or expired products into the dustbin.

Product description

What it looks like

300mg - Yellow opaque capsule. Printed 'Gabapentin 300 mg' on cap & 'P' logo on body in blue ink. Capsule filled with white powder.

400g - Orange opaque capsule. Printed 'Gabapentin 400 mg' on cap & 'P' logo on body in blue ink. Capsule filled with white powder.

<u>Ingredient</u>

Active Ingredient:

Gabapentin

Inactive Ingredients:

Corn starch, lactose, talc.

MAL number:

300mg - MAL08021473AR

400mg - MAL08021474AR

Manufacturer

Pharmascience Inc. 6111 Royalmount Avenue, Suite 100, H4P2T4 Montreal Quebec, Canada

Product Registration Holder

Medicell Pharmaceutical (Malaysia) Sdn Bhd (898390-M) Suite 16-03, Menara AmFIRST, 1, Jalan 19/3, 46300 Petaling Jaya, Selangor, Malaysia

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