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MEDICATION GUIDE
Gabapentin Tablets (Once-Daily)
(gab-a-pen-tin)

Read this Medication Guide before you start taking gabapentin tablets (Once-Daily) and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. If you have any questions about gabapentin tablets (Once-Daily), ask your healthcare provider or pharmacist.

What is the most important information I should know about gabapentin tablets (Once-Daily)?

Do not stop taking gabapentin tablets (Once-Daily) without first talking with your healthcare provider. Stopping gabapentin tablets (Once-Daily) suddenly can cause serious problems.

Like other antiepileptic drugs, gabapentin, the active ingredient in gabapentin tablets (Once-Daily), may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. This can happen while you take gabapentin tablets (Once-Daily) or after stopping. However, it is not known if gabapentin tablets (Once-Daily) are safe and effective in people with seizure problems (epilepsy). Therefore, gabapentin tablets (Once-Daily) should not be used in place of other gabapentin products.

Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- serious breathing problems
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Serious breathing problems

- Serious breathing problems can occur when gabapentin tablets (Once-Daily) are taken with other medicines that can cause severe sleepiness or decreased awareness, or when it is taken by someone who already has breathing problems. Watch for increased sleepiness or decreased breathing when starting gabapentin tablets (Once-Daily) or when the dose is increased. Get help right away if breathing problems occur.

Do not stop taking gabapentin tablets (Once-Daily) without first talking with your healthcare provider.

- Stopping gabapentin tablets (Once-Daily) suddenly can cause serious problems.

What are gabapentin tablets (Once-Daily)?

Gabapentin tablets (Once-Daily) are a prescription medicine used in adults, 18 years and older, to treat:

- pain from damaged nerves (neuropathic pain) that follows healing of shingles (a painful rash that comes after a herpes zoster infection).

It is not known if gabapentin tablets (Once-Daily) are safe and effective in people with seizure problems (epilepsy).

It is not known if gabapentin tablets (Once-Daily) are safe and effective in children under 18 years of age with postherpetic pain.

Gabapentin tablets (Once-Daily) are not substitutable with other gabapentin products.

Who should not take gabapentin tablets (Once-Daily)?

Do not take gabapentin tablets (Once-Daily) if you are allergic to gabapentin or any of the ingredients in gabapentin tablets (Once-Daily).

See the end of this Medication Guide for a complete list of ingredients in gabapentin tablets (Once-Daily).

What should I tell my healthcare provider before taking gabapentin tablets (Once-Daily)?

Before taking gabapentin tablets (Once-Daily), tell your healthcare provider if you:

- have or have had depression, mood problems or suicidal thoughts or behavior
- have breathing problems
- have seizures
- have kidney problems or get kidney dialysis
- **are pregnant or plan to become pregnant.** It is not known if gabapentin tablets (Once-Daily) can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking gabapentin tablets (Once-Daily). You and your healthcare provider will decide if you should take gabapentin tablets (Once-Daily) while you are pregnant.
- **are breastfeeding or plan to breastfeed.** Gabapentin passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with gabapentin tablets (Once-Daily).

Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins or herbal supplements. Especially tell your healthcare provider if you take any opioid pain medicine (such as oxycodone), or medicines for anxiety (such as lorazepam) or insomnia (such as zolpidem). You may have a higher chance for dizziness, sleepiness, or serious breathing problems if these medicines are taken with gabapentin tablets (Once-Daily).

Taking gabapentin tablets (Once-Daily) with certain other medicines can cause side effects or affect how well they work. Do not start or stop other medicines without talking to your healthcare provider.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take gabapentin tablets (Once-Daily)?

- Take gabapentin tablets (Once-Daily) exactly as prescribed. Your healthcare provider will tell you how much gabapentin tablets (Once-Daily) to take and when to take it. Take gabapentin tablets (Once-Daily) at the same time each day.

- **Do not change your dose or stop taking gabapentin tablets (Once-Daily) without talking with your healthcare provider.** If you stop taking gabapentin tablets (Once-Daily) suddenly, you may experience side effects. Talk with your healthcare provider about how to stop gabapentin tablets (Once-Daily) slowly.
- Take gabapentin tablets (Once-Daily) with food one time each day with your evening meal.
- Take gabapentin tablets (Once-Daily) tablets whole. Do not split, crush, or chew gabapentin tablets (Once-Daily) tablets before swallowing.
- Your healthcare provider may change your dose of gabapentin tablets (Once-Daily). Do not change your dose of gabapentin tablets (Once-Daily) without talking to your healthcare provider.
- If you miss a dose, take it as soon as you remember with food. If it is almost time for your next dose, just skip the missed dose. Take the next dose at your regular time. **Do not take two doses at the same time.**
- If you take too much gabapentin tablets (Once-Daily), call your healthcare provider or poison control center, or go to the nearest emergency room right away.
- If you are taking an antacid containing aluminum hydroxide and magnesium hydroxide, it is recommended that gabapentin tablets (Once-Daily) be taken at least 2 hours following administration of the antacid.

What should I avoid while taking gabapentin tablets (Once-Daily)?

- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking gabapentin tablets (Once-Daily) without first talking to your healthcare provider. Taking gabapentin tablets (Once-Daily) with alcohol or medicines that cause sleepiness or dizziness may make your sleepiness or dizziness worse.
- Do not operate heavy machines or do other dangerous activities until you know how gabapentin tablets (Once-Daily) affects you. Gabapentin tablets (Once-Daily) can slow your thinking and motor skills.

What are the possible side effects of gabapentin tablets (Once-Daily)?

The most common side effect of gabapentin tablets (Once-Daily) is:

- dizziness

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the possible side effects of gabapentin tablets (Once-Daily). For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store gabapentin tablets (Once-Daily)?

Store gabapentin tablets (Once-Daily) at 59°F to 86°F (15°C to 30°C)

- **Keep gabapentin tablets (Once-Daily) and all medicines out of the reach of children.**

General information about the safe and effective use of gabapentin tablets (Once-Daily)

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

Do not use gabapentin tablets (Once-Daily) for a condition for which it was not prescribed. Do not give gabapentin tablets (Once-Daily) to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about gabapentin tablets (Once-Daily). If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about gabapentin tablets (Once-Daily) that is written for health professionals.

For more information about gabapentin tablets (Once-Daily), call 1-855-724-3436.

What are the ingredients in gabapentin tablets (Once-Daily)?

Active ingredient: gabapentin, USP

Inactive ingredients:

300 mg tablet: Copovidone NF, Hypromellose USP, Magnesium Stearate NF, Microcrystalline Cellulose NF, Polyethylene Oxide NF, and white film coating (Polyethylene Glycol, Polyvinyl Alcohol, Talc, and Titanium Oxide).

600 mg tablet: Copovidone NF, Hypromellose USP, Magnesium Stearate NF, Polyethylene Oxide NF, and Beige film coating (Polyethylene Glycol, Polyvinyl Alcohol, Talc, Titanium Oxide, Iron Oxide Yellow, and Iron Oxide Red).

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This Medication Guide has been approved by the U.S. Food and Drug Administration