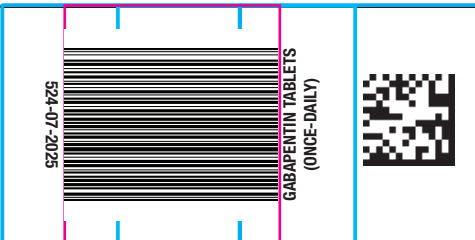


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Table with 3 columns: General Disorders, Infections and Infestations, Investigations, Musculoskeletal and Connective Tissue Disorders, Nervous System Disorders, and Adverse Reactions.

In addition to the adverse reactions reported in Table 4 above, the following adverse reactions with an uncertain relationship to gabapentin tablets (Once-Daily) were reported during the clinical development for the treatment of postherpetic neuralgia.

6.2 Postmarketing and Other Experience with other Formulations of Gabapentin
In addition to the adverse experiences reported during clinical testing of gabapentin, the following adverse experiences have been reported in patients receiving other formulations of marketed gabapentin.

There are postmarketing reports of withdrawal symptoms after discontinuation of gabapentin. Reported adverse reactions include, but are not limited to, seizures, depression, suicidal ideation and behavior, agitation, confusion, disorientation, psychotic symptoms, anxiety, insomnia, nausea, pain, sweating, tremor, headache, dizziness, and malaise.

There are postmarketing reports of life-threatening or fatal respiratory depression in patients taking gabapentin with opioids or other central nervous system (CNS) depressants, or in the setting of underlying respiratory impairment.

7.0 Drug Interactions
In vitro studies were conducted to investigate the potential of gabapentin to inhibit the major cytochrome P450 enzymes (CYP1A2, CYP2A6, CYP2C9, CYP2C19, CYP2D6, CYP2E1, and CYP3A4) that mediate drug and xenobiotic metabolism using isoform selective marker substrates and human liver microsomal preparations.

7.1 Phenytoin
In a single (400 mg) and multiple dose (400 mg three times daily) study of gabapentin immediate release in epileptic patients (N=8) maintained on phenytoin monotherapy for at least 2 months, gabapentin had no effect on the steady-state trough plasma concentrations of phenytoin and phenytoin had no effect on gabapentin pharmacokinetics.

7.2 Carbamazepine
Steady-state trough plasma carbamazepine and carbamazepine 10, 11 epoxide concentrations were not affected by concomitant gabapentin immediate release (400 mg three times daily; N=12) administration.

7.3 Valproic Acid
The mean steady-state trough serum valproic acid concentrations prior to and during concomitant gabapentin immediate release administration (400 mg three times daily; N=17) were not different and neither were gabapentin pharmacokinetic parameters affected by valproic acid.

7.4 Phenobarbital
Estimates of steady-state pharmacokinetic parameters for phenobarbital or gabapentin immediate release (300 mg three times daily; N=12) are identical whether the drugs are administered alone or together.

7.5 Naproxen
Coadministration of single doses of naproxen (250 mg) and gabapentin immediate release (125 mg) to 18 volunteers increased gabapentin absorption by 12% to 15%. Gabapentin immediate release had no effect on naproxen pharmacokinetics.

7.6 Hydrocodone
Coadministration of gabapentin immediate release (125 mg and 500 mg) and hydrocodone (10 mg) reduced the interaction of nax by 3% and 21%, respectively, and AUC by 4% and 22%, respectively. The mechanism of this interaction is unknown.

7.7 Morphine
When a single dose (60 mg) of controlled-release morphine capsule was administered 2 hours prior to a single dose (600 mg) of gabapentin immediate release in 12 volunteers, mean gabapentin AUC values increased by 44% compared to gabapentin immediate release administered without morphine.

7.8 Cimetidine
Cimetidine 300 mg decreased the apparent oral clearance of gabapentin by 14% and creatinine clearance by 10%. The effect of gabapentin immediate release on cimetidine was not evaluated.

7.9 Oral Contraceptives
Gabapentin immediate release (400 mg three times daily) had no effect on the pharmacokinetics of norethindrone (2.5 mg) or ethinyl estradiol (50 mcg) administered as a single tablet, except that the Cmax of norethindrone was increased by 13%. This interaction is not considered to be clinically significant.

7.10 Antacid (containing aluminum hydroxide and magnesium hydroxide)
An antacid containing aluminum hydroxide and magnesium hydroxide reduced the bioavailability of gabapentin immediate release by approximately 20%, but by only 5% when gabapentin immediate release was taken 2 hours after the antacid.

7.11 Probenecid
Gabapentin immediate release pharmacokinetic parameters were comparable with and without probenecid, indicating that gabapentin does not undergo renal tubular secretion by the pathway that is blocked by probenecid.

7.12 Drug/Laboratory Test Interactions
False positive readings were reported with the Ames-N-Multitest 50⁺ dipstick test for urine protein when gabapentin was added to other antiepileptic drugs; therefore, the more specific sulfosalicylic acid precipitation procedure is recommended to determine the presence of urine protein.

8.0 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Risk Summary
Available data from published prospective and retrospective cohort studies, and case reports over decades of use with gabapentin during pregnancy have not identified a drug-associated risk of major birth defects.

8.2 Lactation
Gabapentin is present in human milk following oral administration. Adverse effects on the breastfed infant have not been reported. There are no data on the effects of the drug on milk production.

8.3 Fertility
In a study of fertility and gonadal reproductive performance at 2,000 mg/kg/day with no effect at 1,000 mg/kg/day, in a teratology study at 1,000 mg/kg/day with no effect at 300 mg/kg/day, and in a perinatal and postnatal study at all doses studied (500, 1,000, and 2,000 mg/kg/day), the doses at which the effects occurred are approximately 3 to 11 times the maximum recommended dose of 1,800 mg on a mg/m² basis.

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8.15 Fertility
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When pregnant rabbits were treated with gabapentin during the period of organogenesis, an increase in embryofetal mortality was observed at 60, 300, and 1,500 mg/kg/day (0.6 to 16 times the MRHD on a mg/m² basis).

In a published study, gabapentin (400 mg/kg/day) was administered by intraperitoneal injection to neonatal mice during the first postnatal week, a period of synaptogenesis in rodents (corresponding to the last trimester of pregnancy in humans). Gabapentin caused a marked decrease in neuronal synapse formation in brains of intact mice and abnormal neuronal synapse formation in a mouse model of synaptic repair.

8.2 Lactation
Risk Summary
Gabapentin is present in human milk following oral administration. Adverse effects on the breastfed infant have not been reported. There are no data on the effects of the drug on milk production.

8.3 Fertility
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8.4 Pediatric Use
The safety and effectiveness of gabapentin tablets (Once-Daily) in the management of postherpetic neuralgia in patients less than 18 years of age has not been studied.

8.5 Geriatric Use
The total number of patients treated with gabapentin tablets (Once-Daily) in controlled clinical trials in patients with postherpetic neuralgia was 359, of which 63% were 65 years of age or older. The types and incidence of adverse events were similar across age groups except for peripheral edema, which tended to increase in incidence with age.

8.6 Hepatic Impairment
Because gabapentin is not metabolized, studies have not been conducted in patients with hepatic impairment.

8.7 Renal Impairment
Gabapentin tablets (Once-Daily) are known to be substantially excreted by the kidney. Dosage adjustment is necessary in patients with impaired renal function.

9.1 Controlled Substance
Gabapentin tablets (Once-Daily) contain gabapentin, which is not a controlled substance.

9.2 Dependence
Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug.

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HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use GABAPENTIN TABLETS (ONCE-DAILY) safely and effectively. See full prescribing information for GABAPENTIN TABLETS (ONCE-DAILY).

GABAPENTIN TABLETS (ONCE-DAILY), for oral use
Initial U.S. Approval: 1993
RECENT MAJOR CHANGES
Warnings and Precautions (5.1, 5.2) 04/2025

INDICATIONS AND USAGE
Gabapentin tablets are indicated for the management of Postherpetic Neuralgia (PHN).
Important Limitation: Gabapentin tablets (Once-Daily) are not substitutable with other gabapentin products because of differing pharmacokinetic profiles that affect the frequency of administration (See Warnings and Precautions).

DOSAGE AND ADMINISTRATION
Gabapentin tablets (Once-Daily) should be titrated to an 1,800 mg dose taken orally, once-daily, with the evening meal. Gabapentin (Once-Daily) tablets should be swallowed whole. Do not crush, split, or chew the tablets. (2.1)

Contraindications
Gabapentin tablets (Once-Daily) are contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients. (4)

Warnings and Precautions
Gabapentin tablets (Once-Daily) are not substitutable with other gabapentin products

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2 DOSAGE AND ADMINISTRATION
2.1 Postherpetic Neuralgia
2.2 Patients with Renal Impairment
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS

6.1 Clinical Trials Experience
6.2 Postmarketing and Other Experience with other Formulations of Gabapentin
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7.3 Valproic Acid
7.4 Phenobarbital
7.5 Naproxen
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7.7 Morphine
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14 CLINICAL STUDIES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION
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Antiepileptic drugs, including gabapentin, the active ingredient in gabapentin tablets (Once-Daily), increase the risk of suicidal thoughts or behavior (5.1)
Abrupt or rapid discontinuation may increase the risk for seizures. Withdrawal symptoms or suicidal behavior and ideation have been observed after discontinuation. Taper gabapentin tablets (Once-Daily) gradually over a minimum of 1 week. (5.2)
Respiratory depression may occur with gabapentin tablets (Once-Daily) when used with concomitant CNS depressants or in the setting of underlying respiratory impairment. Monitor patients and adjust dosage as appropriate. (5.3)

ADVERSE REACTIONS
The most common adverse reaction (greater than or equal to 5% and twice placebo) is dizziness. (6.1)
To report SUSPECTED ADVERSE REACTIONS, contact ScieGen Pharmaceuticals, Inc. at 1-855-724-3436 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS
An increase in gabapentin AUC values have been reported when administered with hydrocodone. (7.6)
An increase in gabapentin AUC values have been reported when administered with morphine. (7.7)
An antacid containing aluminum hydroxide and magnesium hydroxide reduced the bioavailability of gabapentin immediate release by about approximately 20%, but by only 5% when gabapentin was taken 2 hours after antacids. It is recommended that gabapentin tablets (Once-Daily) be taken at least 2 hours following antacid administration. (7.10)

USE IN SPECIFIC POPULATIONS
Elderly: Reductions in gabapentin tablets (Once-Daily) dose should be made in patients with age-related compromised renal function. (8.5)
Renal impairment: Dosage adjustment is necessary for patients with impaired renal function. (8.7)
See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

7.10 Antacid (containing aluminum hydroxide and magnesium hydroxide)
7.11 Probenecid
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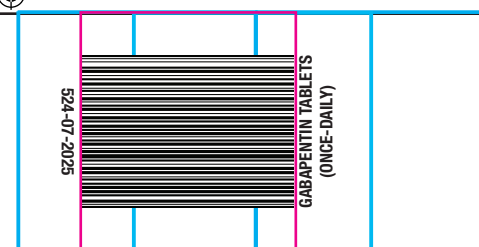
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Administration of gabapentin tablets (Once-Daily) with food increases the rate and extent of absorption of gabapentin compared to the fasted state. C_{max} of gabapentin increases 33-84% and AUC of gabapentin increases 33-118% with food depending on the fat content of the meal. Gabapentin tablets (Once-Daily) should be taken with food.

Distribution

Gabapentin is less than 3% bound to plasma proteins. After 150 mg intravenous administration, the mean \pm SD volume of distribution is 58 \pm 6 L.

Elimination

Gabapentin is eliminated by renal excretion as unchanged drug.

In patients with normal renal function given gabapentin immediate release 1,200 to 3,000 mg/day, the drug elimination half-life ($t_{1/2}$) was 5 to 7 hours. Elimination kinetics do not change with dose level or multiple doses.

Metabolism

Gabapentin is not appreciably metabolized in humans.

Excretion

Gabapentin elimination rate constant, plasma clearance, and renal clearance are directly proportional to creatinine clearance. In elderly patients and patients with impaired renal function, plasma clearance is reduced. Gabapentin can be removed from plasma by hemodialysis.

Dosage adjustment in patients with compromised renal function is necessary. In patients undergoing hemodialysis, gabapentin tablets (Once-Daily) should not be administered [see *Dosage and Administration* (2.2)].

12.4 Special Populations

Renal Insufficiency: As renal function decreases, renal and plasma clearances and the apparent elimination rate constant decrease, while C_{max} and $t_{1/2}$ increase.

In patients (N=60) with creatinine clearance of at least 60, 30 to 59, or less than 30 mL/min, the median renal clearance rates for a 400 mg single dose of gabapentin immediate release were 79, 36, and 11 mL/min, respectively, and the median $t_{1/2}$ values were 9.2, 14, and 40 hours, respectively.

Dosage adjustment is necessary in patients with impaired renal function [see *Dosage and Administration* (2.2)].

Hemodialysis: In a study in anuric adult subjects (N=11), the apparent elimination half-life of gabapentin on nondialysis days was about 132 hours; during dialysis the apparent half-life of gabapentin was reduced to 3.8 hours. Hemodialysis thus has a significant effect on gabapentin elimination in anuric subjects. Gabapentin tablets (Once-Daily) should not be administered in patients undergoing hemodialysis. Alternative formulations of gabapentin products should be considered in patients undergoing hemodialysis.

Elderly: Apparent oral and renal clearances of gabapentin decrease with increasing age, although this may be related to the decline in renal function with age. Reductions in gabapentin dose should be made in patients with age-related compromised renal function [see *Dosage and Administration* (2.2)].

Hepatic Impairment: Because gabapentin is not metabolized, studies have not been conducted in patients with hepatic impairment.

Pediatrics: The pharmacokinetics of gabapentin tablets (Once-Daily) have not been studied in patients less than 18 years of age.

Gender: Although no formal study has been conducted to compare the pharmacokinetics of gabapentin in men and women, it appears that the pharmacokinetic parameters for males and females are similar and there are no significant gender differences.

Race: Pharmacokinetic differences due to race have not been studied. Because gabapentin is primarily renally excreted and there are no important racial differences in creatinine clearance, pharmacokinetic differences due to race are not expected.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Gabapentin was given in the diet to mice at 200, 600, and 2,000 mg/kg/day and to rats at 250, 1,000, and 2,000 mg/kg/day for 2 years. A statistically significant increase in the incidence of pancreatic acinar cell adenoma and carcinomas was found in male rats receiving the high dose; the no-effect dose for the occurrence of carcinomas was 1,000 mg/kg/day. Peak plasma concentrations of gabapentin in rats receiving the high dose of 2,000 mg/kg/day were more than 10 times higher than plasma concentrations in humans receiving 1,800 mg per day and in rats receiving 1,000 mg/kg/day peak plasma concentrations were more than 6.5 times higher than in humans receiving 1,800 mg/day. The pancreatic acinar cell carcinomas did not affect survival, did not metastasize and were not locally invasive. The relevance of this finding to carcinogenic risk in humans is unclear.

Studies designed to investigate the mechanism of gabapentin-induced pancreatic carcinogenesis in rats indicate that gabapentin stimulates DNA synthesis in rat pancreatic acinar cells *in vitro* and, thus, may be acting as a tumor promoter by enhancing mitogenic activity. It is not known whether gabapentin has the ability to increase cell proliferation in other cell types or in other species, including humans.

Mutagenesis

Gabapentin did not demonstrate mutagenic or genotoxic potential in 3 *in vitro* and 4 *in vivo* assays. It was negative in the Ames test and the *in vitro* HGPRT forward mutation assay in Chinese hamster lung cells; it did not produce significant increases in chromosomal aberrations in the *in vitro* Chinese hamster lung cell assay; it was negative in the *in vivo* chromosomal aberration assay and in the *in vivo* micronucleus test in Chinese hamster bone marrow; it was negative in the *in vivo* mouse micronucleus assay; and it did not induce unscheduled DNA synthesis in hepatocytes from rats given gabapentin.

Impairment of Fertility

No adverse effects on fertility or reproduction were observed in rats at doses up to 2,000 mg/kg (approximately 11 times the maximum recommended human dose on an mg/m² basis).

14 CLINICAL STUDIES

The efficacy of gabapentin tablets (Once-Daily) for the management of postherpetic neuralgia was established in a double-blind, placebo-controlled, multicenter study. This study enrolled patients between the age of 21 to 89 with postherpetic neuralgia persisting for at least 6 months following healing of herpes zoster rash and a minimum baseline pain intensity score of at least 4 on an 11-point numerical pain rating scale ranging from 0 (no pain) to 10 (worst possible pain).

This 11-week study compared gabapentin tablets (Once-Daily) 1,800 mg once daily with placebo. A total of 221 and 231 patients were treated with gabapentin tablets (Once-Daily) or placebo, respectively. The study treatment including titration for all patients comprised a 10-week treatment period followed by 1-week of dose tapering. Double-blind treatment began with titration starting at 300 mg/day and titrated up to a total daily dose of 1,800 mg over 2 weeks, followed by 8 weeks fixed dosing at 1,800 mg once daily, and then 1 week of dose tapering. During the 8-week stable dosing period, patients took 3 active or placebo tablets each night with the evening meal. During baseline and treatment, patients recorded their pain in a daily diary using an 11-point numeric pain rating scale. The mean baseline pain score was 6.6 and 6.5 for gabapentin tablets (Once-Daily) and placebo-treated patients, respectively.

Treatment with gabapentin tablets (Once-Daily) statistically significantly improved the endpoint mean pain score from baseline. For various degrees of improvement in pain from baseline to study endpoint, Figure 1 shows the fraction of patients achieving that degree of improvement. The figure is cumulative, so that patients whose change from baseline is, for example, 50%, are also included at every level of improvement below 50%. Patients who did not complete the study were assigned 0% improvement.

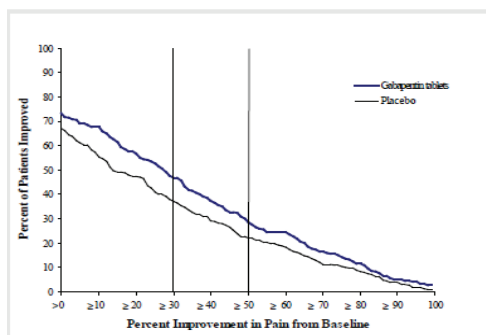


Figure 1: Percent of Patients Achieving Various Levels of Pain Relief

16 HOW SUPPLIED/STORAGE AND HANDLING

Gabapentin Tablets (Once-Daily) are supplied as follows:

- 300 mg tablets: Gabapentin tablets (Once-Daily) 300 mg are white, oval shape, film coated tablets, debossed with '523' on one side and plain on other side. NDC 50228-523-30 (Bottle of 30) NDC 50228-523-90 (Bottle of 90) NDC 50228-523-05 (Bottle of 500)

- 600 mg tablets: Gabapentin tablets (Once-Daily) 600 mg are beige, oval shape, film coated tablets, debossed with '524' on one side and plain on other side. NDC 50228-524-30 (Bottle of 30) NDC 50228-524-90 (Bottle of 90) NDC 50228-524-05 (Bottle of 500)

Storage

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Keep out of reach of children.

17 PATIENT COUNSELING INFORMATION

Advise patients of the availability of a Medication Guide, and instruct them to read the Medication Guide prior to taking gabapentin tablets (Once-Daily).

- Advise patients that gabapentin tablets (Once-Daily) are not substitutable with other formulations of gabapentin.
- Advise patients to take gabapentin tablets (Once-Daily) only as prescribed. Gabapentin tablets (Once-Daily) may cause dizziness, somnolence, and other signs and symptoms of CNS depression.
- Advise patients not to drive or operate other complex machinery until they have gained sufficient experience on gabapentin tablets (Once-Daily) to gauge whether or not it adversely affects their mental and/or motor performance. Advise patients who require concomitant treatment with morphine to tell their prescriber if they develop signs of CNS depression such as somnolence. If this occurs the dose of gabapentin tablets (Once-Daily) or morphine should be reduced accordingly.
- Advise patients that if they miss a dose of gabapentin tablets (Once-Daily) to take it with food as soon as they remember. If it is almost time for the next dose, just skip the missed dose and take the next dose at the regular time. Do not take two doses at the same time.
- Advise patients that if they take too much gabapentin tablets (Once-Daily), to call their healthcare provider or poison control center, or go to the nearest emergency room right away.

Suicidal Thoughts and Behavior

Counsel patients, their caregivers, and families that AEDs, including gabapentin, the active ingredient in gabapentin tablets (Once-Daily), may increase the risk of suicidal thoughts and behavior and of the need to be alert for the emergence or worsening of symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts about self-harm. Instruct patients, caregivers, and families to report behaviors of concern immediately to healthcare providers. Also inform patients who plan to or have discontinued gabapentin tablets (Once-Daily) that suicidal thoughts and behavior can appear even after the drug is stopped [see *Warnings and Precautions* (5.1)].

Respiratory Depression

Inform patients about the risk of respiratory depression. Include information that the risk is greatest for those using concomitant central nervous system (CNS) depressants (such as opioid analgesics) or in those with underlying respiratory impairment. Teach patients how to recognize respiratory depression and advise them to seek medical attention immediately if it occurs [see *Warnings and Precautions* (5.3)].

Dosing and Administration

Gabapentin tablets (Once-Daily) are not substitutable with other gabapentin products because of differing pharmacokinetic profiles that affect the frequency of administration.

The safety and effectiveness of gabapentin tablets (Once-Daily) in patients with epilepsy has not been studied.

Advise patients that gabapentin tablets (Once-Daily) should be taken orally once daily with the evening meal. Gabapentin tablets (Once-Daily) should be swallowed whole. Do not split, crush, or chew the tablets [see *Dosage and Administration* (2.1)].

Use in Pregnancy

Advise patients to notify their healthcare provider if they become pregnant or intend to become pregnant during treatment with gabapentin tablets (Once-Daily), and to notify their physician if they are breast feeding or intend to breast feed during therapy [see *Use in Specific Populations* (8.1) and (8.2)].

Manufactured by:

ScieGen Pharmaceuticals Inc

Hauppauge, NY 11788

USA

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Dispense the Medication Guide available at: <https://sciegenpharm.com/medication-guide/>

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<https://sciegenpharm.com/medication-guide/>

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).

Manufactured by:

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USA

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