



GABAPENTIN ORAL SOLUTION USP

250 mg per 5 mL



NDC
72888-0104-25

Description
Gabapentin Oral Solution

Strength
250 mg/5 mL

Package Size
470 mL

sales@advagenpharma.com

www.advagenpharma.com

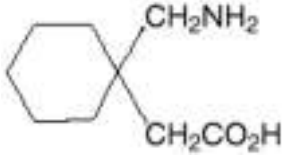
Gabapentin Oral Solution USP 250 mg per 5 mL

Advagen Pharma Ltd.

DESCRIPTION

The active ingredient in gabapentin oral solution is gabapentin, which has the chemical name 1-(aminomethyl) cyclohexanecarboxylic acid.

The molecular formula of gabapentin is C₉H₁₇NO₂ and the molecular weight is 171.24. The Structural formula of gabapentin is:



Gabapentin is a white to off-white crystalline solid with a pKa1 of 3.7 and a pKa2 of 10.7. It is freely soluble in water and both basic and acidic aqueous solutions. The log of the partition coefficient (noctanol/0.05M phosphate buffer) at pH 7.4 is -1.25.

Gabapentin oral solution contains 250 mg of gabapentin per 5 mL (50 mg per mL) and the following ingredients: acesulfame potassium, banana flavor NAT & ART, glycerin, methylparaben, propylparaben, propylene glycol, saccharin sodium and purified water. May also contain sodium hydroxide or hydrochloric acid for pH adjustment.

INDICATIONS AND USAGE

Gabapentin oral solution is indicated for:

Management of postherpetic neuralgia in adults

Adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy

DOSAGE AND ADMINISTRATION

1 Dosage for Postherpetic Neuralgia

In adults with postherpetic neuralgia, gabapentin oral solution may be initiated on Day 1 as a single 300 mg dose, on Day 2 as 600 mg/day (300 mg two times a day), and on Day 3 as 900 mg/day (300 mg three times a day). The dose can subsequently be titrated up as needed for pain relief to a dose of 1800 mg/day (600 mg three times a day). In clinical studies, efficacy was demonstrated over a range of doses from 1800 mg/day to 3600 mg/day with comparable effects across the dose range; however, in these clinical studies, the additional benefit of using doses greater than 1800 mg/day was not demonstrated.

2 Dosage for Epilepsy with Partial Onset Seizures

Patients 12 years of age and above

The starting dose is 300 mg three times a day. The recommended maintenance dose of gabapentin is 300 mg to 600 mg three times a day. Dosages up to 2400 mg/day have been well tolerated in long-term clinical studies. Doses of 3600 mg/day have also been administered to a small number of patients for a relatively short duration, and have been well tolerated. Administer gabapentin oral solution three times a day. The maximum time between doses should not exceed 12 hours.

Pediatric Patients Age 3 to 11 years

The starting dose range is 10 mg/kg/day to 15 mg/kg/day, given in three divided doses, and the recommended maintenance dose reached by upward titration over a period of approximately 3 days. The recommended maintenance dose of gabapentin in patients 3 to 4 years of age is 40 mg/kg/day, given in three divided doses. The recommended maintenance dose of gabapentin in patients 5 to 11 years of age is 25 mg/kg/day to 35 mg/kg/day, given in three divided doses. Gabapentin may be administered as the oral solution, capsule, or tablet, or using combinations of these formulations. Dosages up to 50 mg/kg/day have been well tolerated in a long-term clinical study. The maximum time interval between doses should not exceed 12 hours.

3 Dosage Adjustment in Patients with Renal Impairment

Dosage adjustment in patients 12 years of age and older with renal impairment or undergoing hemodialysis is recommended, as follows (see dosing recommendations above for effective doses in each indication):

DOSAGE FORMS & STRENGTHS/ STORAGE & HANDLING

250 mg per 5 mL (50 mg per mL) Oral Solution:

Clear colorless solution with banana aroma; each 5 mL of oral solution contains 250 mg of gabapentin; available in bottle containing 470 mL: **NDC 72888-104-25**

Store gabapentin oral solution refrigerated, at 2°C to 8°C (36°F to 46°F).

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OVERDOSAGE

Signs of acute toxicity in animals included ataxia, labored breathing, ptosis, sedation, hypoactivity, or excitation.

Acute oral overdoses of gabapentin have been reported. Symptoms have included double vision, tremor, slurred speech, drowsiness, altered mental status, dizziness, lethargy, and diarrhea. Fatal respiratory depression has been reported with gabapentin overdose, alone and in combination with other CNS depressants.

Gabapentin can be removed by hemodialysis.

If overexposure occurs, call your poison control center at **1-800-222-1222**.

MEDICATION GUIDE/FAQ'S

What is the most important information I should know about gabapentin oral solution?
Do not stop taking gabapentin oral solution without first talking to your healthcare provider.

Stopping gabapentin oral solution suddenly can cause serious problems.

Gabapentin oral solution can cause serious side effects including:

1. Suicidal Thoughts. Like other antiepileptic drugs, gabapentin oral solution may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. 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
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

What is gabapentin oral solution?

Gabapentin oral solution is a prescription medicine used to treat:

Pain from damaged nerves (postherpetic pain) that follows healing of shingles (a painful rash that comes after a herpes zoster infection) in adults.

Partial seizures when taken together with other medicines in adults and children 3 years of age and older with seizures.

Who should not take gabapentin oral solution?

Do not take gabapentin oral solution if you are allergic to gabapentin or any of the other ingredients in gabapentin oral solution. See the end of this Medication Guide for a complete list of ingredients in gabapentin oral solution.

What should I tell my healthcare provider before taking gabapentin oral solution?

Before taking gabapentin oral solution, tell your healthcare provider if you:

Have or have had kidney problems or are on hemodialysis
Have or have had depression, mood problems, or suicidal thoughts or behavior
Have diabetes
Have breathing problems

are pregnant or plan to become pregnant. It is not known if gabapentin can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking gabapentin oral solution. You and your healthcare provider will decide if you should take gabapentin oral solution while you are pregnant.

Pregnancy Registry: If you become pregnant while taking gabapentin oral solution, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy. You can enroll in this registry by calling 1-888-233-2334.

Are breast-feeding or plan to breast-feed. Gabapentin can pass into breast milk.

You and your healthcare provider should decide how you will feed your baby while you take gabapentin oral solution.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take any opioid pain medicine (such as oxycodone), any medicines for anxiety (such as lorazepam) or insomnia (such as zolpidem), or any medicines that make you sleepy.

You may have a higher chance for dizziness, sleepiness, or breathing problems if these medicines are taken with gabapentin oral solution.

Taking gabapentin oral solution 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.

What should I avoid while taking gabapentin oral solution?

Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking gabapentin oral solution without first talking with your healthcare provider. Taking gabapentin oral solution with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness or dizziness worse.

Do not drive, operate heavy machinery, or do other dangerous activities until you know how gabapentin affects you. Gabapentin can slow your thinking and motor skills.

What are the ingredients in gabapentin oral solution?

Active ingredient: gabapentin

Inactive ingredients: acesulfame potassium, banana flavor NAT & ART, glycerin, methylparaben, propylparaben, propylene glycol, saccharin sodium and purified water. May also contain sodium hydroxide or hydrochloric acid for pH adjustment. This Medication Guide has been approved by the U.S. Food and Drug Administration.

Keep gabapentin oral solution and all medicines out of the reach of children.

For more information about Gabapentin Oral Solution contact Advagen Pharma Ltd, at **866-488-0312**

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Revision: 07/2021