**Drug Enforcement Administration**
Diversion Control Division
*Drug & Chemical Evaluation Section*

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# GABAPENTIN

(Trade Name: Neurontin®)

## Introduction:

Gabapentin is a prescription medication approved by the United States Food and Drug Administration (FDA) for the treatment of neuropathic pain and epileptic disorders. This drug is currently marketed in capsule, tablet, and oral solution formulations. In recent years, however, gabapentin has been increasingly encountered by law enforcement, documented in national crime lab reports, reported to poison control centers, and diverted for illicit use.

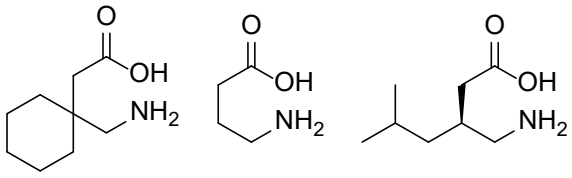
## Licit Uses:

According to the FDA-approved product label, gabapentin is used clinically for the management of postherpetic neuralgia in adults and as an adjunctive therapy for the treatment of partial onset seizures, with and without secondary generalization in adults and pediatric patients 3 years and older with epilepsy.

The annual total prescriptions dispensed for gabapentin in the United States steadily increased by approximately 150% over the past 15 years. According to the IQVIA National Prescription Audit™, total prescriptions dispensed for gabapentin in the United States were approximately 29.6 million in 2010, 56.9 million in 2015, 69.0 million in 2020, and 73.1 million in 2024. Gabapentin is available in various dosage forms and strengths, including 100, 300, and 400 milligram capsules; 600 and 800 milligram tablets; and 250 milligrams/5 mL oral liquid solution.

## Chemistry:

Gabapentin is chemically known as 2-[1-(aminomethyl) cyclohexaneacetic acid]. Gabapentin closely resembles pregabalin, a schedule V drug under the Controlled Substances Act in its chemical structure and pharmacological activity. The chemical structure of gabapentin is derived from the addition of a lipophilic cyclohexyl group to the backbone of gamma-aminobutyric acid (GABA). Gabapentin is a crystalline substance and freely soluble in water, alkaline and acidic solutions. The chemical structures for gabapentin, GABA, and pregabalin are shown below:




Gabapentin GABA Pregabalin

## Pharmacology:

The exact mechanisms through which gabapentin exerts its analgesic and antiepileptic actions are unknown; however, according to information on the FDA-approved label for the gabapentin, gabapentin has no effect on GABA binding, uptake, or degradation. In vitro studies have shown that gabapentin binds to auxiliary α2-δ subunits of voltage-gated $Ca^{2+}$ channels on neurons, thereby resulting in a decrease in neuronal excitability. At clinically therapeutic doses (900–3600 mg/day), gabapentin does not bind to $GABA_A$ or $GABA_B$ receptors, nor does it bind to benzodiazepine sites.

The FDA-approved product label for gabapentin mentions adverse reactions, such as dizziness, somnolence (drowsiness), peripheral edema (swelling), ataxia (incoordination), fatigue, and nystagmus (involuntary rapid eye movement). A published study analyzed information from 32 websites and reported that gabapentin use, similar to pregabalin, is associated with sedative and/or psychedelic effects.

## Illicit Uses:

Gabapentin has been encountered in postmortem toxicology reports, indicated by data from the American Association of Poison Control Centers (AAPCC). According to the AAPCC's National Poison Data System, gabapentin was detected in a total of 135 fatalities in 2020 alone, compared to 168 total fatalities between 2012 and 2016 combined. Of those cases, gabapentin was the primary cause of death in 23 individuals and among one of the most frequent analytes detected in 1,547 tissue samples. Of the 154 analytes detected, gabapentin accounted for 25 samples. Total exposure calls due to gabapentin stayed largely the same from 2017 to 2022: 22,088 calls were made in 2017; 21,423 in 2020; and 20,780 in 2022. Among cases classified as single substance pharmaceutical exposures (i.e., the number of human exposure cases that identified only one substance), gabapentin was identified as a single substance in 6,955 cases in 2022. With respect to medical outcomes associated with gabapentin calls to poison control centers in 2022, gabapentin was associated with 6 deaths, 164 outcomes classified as "major," 756 outcomes classified as "moderate," and 1359 outcomes classified as "minor."

## User Population:

The population likely to abuse gabapentin appears to be the same as those abusing sedative-hypnotic substances. In a cohort of 503 adults reporting nonmedical use of pharmaceuticals (and not enrolled in treatment facilities for such illicit use) in Appalachian Kentucky, 15% of respondents reported using gabapentin specifically to "get high." This number represented a 165% increase compared to the previous year and a 2,950% increase compared to respondents within the same cohort in 2008. In a 2013 online survey distributed to 1,500 respondents from the United Kingdom aged 16 to 59 years, 1.1% self-reported lifetime prevalence of gabapentin misuse.

## Illicit Distribution

The Drug Enforcement Administration's National Forensic Laboratory Information System (NFLIS) Drug database collects scientifically verified data on drug items and cases submitted to and analyzed by participating federal, state, and local forensic drug laboratories. NFLIS-Drug received 3,614 reports of gabapentin in 2019; 3,348 in 2020; 3,128 in 2021; 2,941 in 2022; 2,643 in 2023; and 2,182 in 2024 (reports still pending).

The Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS) System is a system that monitors prescription drug abuse, misuse, and diversion and collects geographically specific data. RADARS indicated that for gabapentin, 407 cases of diversion were reported in 41 states between 2002 and 2015. The diversion rate steadily increased from 0.0 in 2002 to 0.027 cases per 100,000 population in 2015.

Recent data from the FDA Adverse Event Reporting System found a higher proportion of abuse-related reports for pregabalin (10.2% of 571 reports and 26.1% of 97,813 reports) when compared to gabapentin (5.7% of 10,038 reports and 22.9% of 99,977 reports).

## Control Status:

Gabapentin is not controlled under the Controlled Substances Act.

Comments and additional information are welcomed by the Drug and Chemical Evaluation Section; Fax 571-362-4250, Telephone 571-362-3249, or Email DPE@dea.gov.