

# Winurina® Capsules (Gabapentin)

## DESCRIPTION:

Gabapentin is used with other medications to treat partial seizures and it can be used to relieve to burning nerve pain that sometimes persists for months or even years after an attack of shingles (Herpes zoster)

## COMPOSITION:

**Winurina® 100mg Capsules**  
Each capsule contains:  
Gabapentin USP .....100mg

**Winurina® 300mg Capsules**  
Each capsule contains:  
Gabapentin USP .....300mg

## CLINICAL PHARMACOLOGY:

### Mechanism of Action

Gabapentin is structurally related to the neurotransmitter GABA (Gamma - aminobutyric acid). Exact mechanism of its CNS depressant and anticonvulsant activity is not fully understood. In vitro studies with radio-labeled gabapentin have revealed a gabapentin site in areas of rat brain including neocortex & hippocampus

### Pharmacokinetics and Metabolism

All pharmacological actions following gabapentin administration are due to the activity of the parent compound; gabapentin is not appreciably metabolized in humans

### Oral Bio-availability

Gabapentin bioavailability is not dose proportional; i.e., as dose is increased, bioavailability decreases. Bioavailability of gabapentin is approximately 60%, 47%, 34%, 33%, and 27% following 900, 1200, 2400, 3600, and 4800 mg / day given in 3 divided doses, respectively. Food has only a slight effect on the rate and extent of absorption of gabapentin

### Distribution

Less than 3% of gabapentin is bound to plasma protein

### Elimination

Gabapentin is eliminated from the systemic circulation by renal excretion as unchanged drug. Its elimination half-life is 5 to 7 hours and is not altered by dose or following multiple dosing. In elderly patients, and in patients with impaired renal function, gabapentin plasma clearance is reduced

## INDICATIONS:

There are many evolving indications of gabapentin under trial. Its main indications are for the treatment of neuropathic pain and epilepsy

### Neuropathic pain

Gabapentin is recommended in neuropathic pain of:

- 1- Postherpetic neuralgia (Shingles)
- 2- Trigeminal neuralgias
- 3- Peripheral diabetic neuropathies

### Epilepsy

Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in patients over 12 years of age with epilepsy. It is also indicated as adjunctive therapy in the treatment of partial seizures in paediatric patients 3 – 12 years of age

## CONTRA-INDICATION:

Gabapentin is contra-indicated in patients who have demonstrated hypersensitivity to the drug or its ingredients

## PRECAUTIONS:

### Usage in Pregnancy

As the animal studies does not establish guidelines for its safe use in pregnancy, this drug should be used in pregnancy only if the potential benefits to the patients justifies the potential risk to fetus

### Usage in Nursing Mothers

Gabapentin is secreted into human milk. It should be used in nursing mothers only if the benefits clearly outweigh the risks

### Paediatric Use

Safety and effectiveness of gabapentin in the management of post-herpetic neuralgia have not been established. Effectiveness as adjunctive therapy in the treatment of partial seizures in paediatric patients below 3 years has not been established

### Geriatric Use

Gabapentin is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and dose should be adjusted based on creatinine clearance values in these patients

## ADVERSE REACTIONS:

In addition to commonly occurring adverse reactions (Dizziness, somnolence, ataxia, headache, nystagmus, tremor, fatigue, diplopia, nausea, vomiting and rhinitis), following table depicts the events occurred in descending order of frequency against different body systems:

SYSTEM	ADVERSE EVENTS
Nervous system	Dizziness, somnolence, ataxia, nystagmus, tremor, dysarthria, amnesia, confusion, insomnia, twitching, paresthesia, vertigo, abnormal coordination
Digestive system	Nausea, vomiting, abdominal pain, dyspepsia, dry mouth, constipation, diarrhea, and increased appetite
Respiratory system	Rhinitis, pharyngitis, cough, respiratory tract infection
Skin and appendages	Rash, pruritus, abrasion, acne, maculopapular rash
Special sense	Diplopia, amblyopia
Psychobiologic function	Nervousness, depression, emotional lability
Urogenital system	Impotence
Musculoskeletal system	Myalgia, fatigue
Cardiovascular system	Vasodilation
Blood and lymphatic system	Leucopenia, purpura
Body as whole	Fatigue, headache, weight increase, back pain, peripheral edema, viral infection, fever

There are reports of 8 sudden and unexplained deaths in a cohort of 2203 patients treated with gabapentin. However the incidence of deaths 0.0038 per patient per year with gabapentin is not much different from 0.0005 to 0.003 in a similar population of patients with epilepsy. Additional post-marketing adverse events reported include pancreatitis, erythema multiforme, Stevens-Johnson syndrome and elevated liver enzymes

## DRUG INTERACTIONS:

Gabapentin is not appreciably metabolized nor does it interfere with the metabolism of commonly co-administered antiepileptic drugs. Antacids containing magnesium and aluminium reduce gabapentin bioavailability almost by 24%, so it is recommended to use gabapentin at least after two hours following antacid administration

## OVER DOSAGE:

No specific information is available on the treatment of overdose with gabapentin, although hemodialysis has been shown to be effective in eliminating gabapentin. Treatment is symptomatic and supportive, consistent with established medical care. Overdose of gabapentin up to 49g ingested at one time have been reported in four people, all of whom recovered fully. Symptoms of overdose included dizziness, double vision, slurred speech, drowsiness, lethargy and mild diarrhea. In patients with renal impairment hemodialysis may be indicated. Reduced absorption of gabapentin at higher dose may limit drug absorption and hence minimize toxicity at the time of overdosing

## DOSAGE AND ADMINISTRATION:

Gabapentin is given orally with or without food

### Postherpetic Neuralgia

In adults with postherpetic neuralgia, the starting dose is 300mg three times a day. If necessary the dose may be increased up to 1800mg / day

### Epilepsy

Gabapentin is recommended as an adjunctive therapy in patients 3 years and above. Its effectiveness below 3 years has not been established

### Patients above 12 years of age

The usual effective starting dose of gabapentin is 900 to 1800 mg / day in two or three divided doses. The maximum time between the doses should not exceed 12 hours

### Paediatric patients age 3 to 12 years

The starting dose should range from 10-15 mg / kg / day in divided doses until the effective dosage is reached by upward titration over a period of approximately 3 days. The effective dose of gabapentin in paediatric patients age 3-4 years is 40 mg / kg / day given in divided doses. In patients 5 years or above the effective dose is 25-35 mg / kg / day given in divided doses. In any case the maximum time interval between the doses should not exceed 12 hours

If gabapentin is discontinued and/or an alternate anticonvulsant medication is added to the therapy, this should be done gradually over a minimum of 1 week

### Elderly and renal compromised patients

Care should be taken when prescribing gabapentin in elderly and renal compromised patients. Such patients may require dose adjustments depending upon state of creatinine clearance

OR

As directed by the physician

## STABILITY:

See expiry on the pack

## PRESENTATIONS:

**Winurina®** 100mg capsules in pack of 10's

**Winurina®** 300mg capsules in pack of 10's

## INSTRUCTIONS:

Do not chew or crush capsule contents. The capsule should be swallowed whole with water

Keep out of reach of children

Avoid exposure to heat, light and humidity

Store between 15 to 30°C

Improper storage may deteriorate the medicine



Manufactured by:  
SAMI Pharmaceuticals (Pvt.) Ltd.  
F-95, S.I.T.E., Karachi-Pakistan  
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وینورینا کپسول  
(گاباپینٹین)

خودک: ڈاکٹری ہدایت کے مطابق استعمال کریں  
کیپسول چبانے لہجیر پانی سے نگل لیں  
بچوں کی پہنچ سے دور رکھیں  
دوا کو دھوپ، گرمی اور نمی سے محفوظ رکھیں ۱۵°C سے ۳۰°C گرمی تک رکھیں  
کے درمیان میں رکھیں ورنہ دوا خراب ہو جائے گی