

# Epipen®

Gabapentin  
Tablet

## Description

Gabapentin (Epipen®) is a unique drug with unknown mechanism that was first approved as an anti-seizure medication. Together with its favorable side effect profile and lack of drug interactions, it is an attractive agent for the treatment of neuropathic pain. In addition, recent studies have demonstrated its effectiveness in headache syndromes, spasticity in spinal cord pathologies and bipolar disorders.

## Indications

*Epipen® (Gabapentin) tablet is indicated for*

- Epilepsy
- Neuropathic pain (e.g. postherpetic neuralgia) and other pain conditions
- Bipolar disorder
- Headache syndrome
- Spasticity in multiple sclerosis and spinal cord diseases

## Others:

Alcohol withdrawal  
Schizoaffective disorder  
Post-traumatic stress disorder  
Agitation and behavioural disturbances associated with dementia  
Lesch-Nyhan syndrome  
Essential tremor  
Restless legs syndrome  
Brachioradial pruritus  
Hemichorea/hemiballismus  
Hot Flashes

## Dosage and Administration

Epipen® (Gabapentin) is given orally with or without food.

The initial adult dose of Gabapentin for the treatment of epilepsy is 300 mg by mouth on the first day of treatment, 300 mg twice daily on the second day, and 300 mg three times daily on the third day; thereafter the dose may be increased in increments of 300 mg daily until

effective antiepileptic control is achieved, which is usually within the range of 0.9 to 1.2 g daily. Higher doses up to a maximum of 2.4 g daily may be required in some patients; doses of up to 3.6 g daily administered for a short period have been reported to be well tolerated. The total daily dose should be taken in three equally divided doses and the maximum dosage interval should not exceed 12 hours.

The initial dose for children 6 to 12 years of age for the treatment of epilepsy is 10 mg per kg body-weight on the first day of treatment, 20 mg per kg on the second day, and 25 to 35 mg per kg body weight on the third day. Recommended maintenance dose are 900 mg daily for children weighing 26 to 36 kg and 1200 mg daily for those weighing 37 to 50 kg. Epipen is used for adjunctive use in children from 3 years of age. An initial dose of 10 to 15 mg per kg daily is recommended, increased over about 3 days to doses of about 40 mg per kg daily in those aged 3 to 4, or 25 to 35 mg per kg daily in those 5 years of age or older. The total daily dose should be taken in three divided doses.

In the treatment of neuropathic pain in adults, doses should be titrated to a maximum of 1.8 g daily in three divided doses, in a similar manner to that recommended for the treatment of epilepsy in adults given above.

Reduced doses are recommended for patients with renal impairment. Suitable maintenance doses are: 600 to 1200 daily for patients with a creatinine clearance of 50 to 73 ml per minute; 300 to 600 mg daily for a clearance of 30 to 49 ml per minute; and 300 mg daily for a clearance of 15 to 29 ml per minute, and 300 mg on alternate days for a clearance of less than 15 ml per minute. The total daily doses should be given in 3 divided doses.

For other indications it has been approved for epilepsy as an adjunctive therapy and in

patients with postherpetic neuralgia.

## Contraindications

Epipen® (Gabapentin) is contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients.

## Side Effects

Epipen® (Gabapentin) is well tolerated but a few side effects like fatigue, dizziness, ataxia, weight gain, peripheral edema, dry mouth and somnolence, may occur. Rarely it may cause fulminate hepatic failure, or aplastic anemia.

## Precautions

Patients should be instructed to take Gabapentin only as prescribed.

Patients should be advised that Gabapentin may cause dizziness, somnolence and other symptoms and signs of CNS depression. Accordingly, they should be advised neither to drive a car nor to operate other complex machinery until they have gained sufficient experience on Gabapentin to gauge whether or not it affects their mental and/or motor performance adversely.

Patients who require concomitant treatment with morphine may experience increase in Gabapentin concentrations. Patients should be carefully observed for signs of CNS depression, such as somnolence, and the dose of Gabapentin or morphine should be reduced appropriately.

## Drug Interaction

Antacids may reduce the bioavailability of Gabapentin by up to 20%. Cimetidine may alter its renal excretion. Gabapentin does not interact with other antiepileptic agent or oral contraceptive preparation.

## Use in Pregnancy & Lactation

*Pregnancy:* Gabapentin is a pregnancy category C drug, it should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

*Lactation:* Gabapentin may be secreted through the breast milk like many other drugs, so it should be used in women who are nursing only if the benefits clearly outweigh the risks.

## Use in Children

Safety and effectiveness of Gabapentin in the management of neuropathic pain in pediatric patients have not been established. Safety and effectiveness of Gabapentin in the management of seizures in pediatric patients below the age of 3 years have not been established.

## Storage

Tablets should be stored below 25°C and protected from light & moisture.

## Commercial Pack

Epipen® 300 tablet: Box containing 30 tablets in blister strips. Each tablet contains Gabapentin INN 300 mg.



Manufactured by

**BEXIMCO PHARMACEUTICALS LTD.**

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