# GABAPENTIN

## MUZZAPEN - 300

Rx

300 mg Capsule

Anticonvulsant/Antiepileptic

**FORMULATION:**

Each capsule contains:

Gabapentin USP ..... 300mg

**PRODUCT DESCRIPTION:**

White/White hard gelatin capsule filled with white colour powder

**PHARMACOKINETICS:** Gabapentin is absorbed from the gastrointestinal tract by means of a saturable mechanism. After multiple dosing peak plasma concentrations are usually achieved within 1 to 2 days. Gabapentin is not appreciably metabolized and most of a dose is excreted unchanged in the urine with the remainder appearing in faces. Gabapentin is widely distributed throughout the body but binding to plasma proteins is minimal. The elimination half-life has been reported to be about 5 to 7 hours. Gabapentin is distributed into breast milk.

**INDICATION:** Gabapentin is antiepileptic used as monotherapy or adjunctive therapy in the treatment of partial seizures with or without secondary generalisation and for the treatment of neuropathic pain.

**DOSAGE AND ADMINISTRATION:** The initial oral dose of gabapentin for the treatment of epilepsy is 300 mg on the first day oftreatment 300 mg twice daily on the secondary day, and 300 mg 3 times daily on the third day; there after the dose may be increased in increments of 300 mg every 2 to 3 days until effective antiepileptic control is achieved, which is usually within the range of 0.9 to 3.6 g daily. Higher doses up to a maximum of 4.8 g daily 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. In the treatment of neuropathic pain, doses should be titrated to usual maximum of 1.8 g daily in three divided doses in a similar manner to that recommended above for the treatment of epilepsy. Higher doses have sometimes been given. As with other antiepileptics, withdrawal of gabapentin therapy or transition to or from another type of antiepileptic therapy should be made gradually to avoid precipitating an increase in the frequency of seizures. License product information recommends reducing the dose gradually over at least 7 days. For a discussion on whether or not to withdraw antiepileptic the spy in seizure free patients. Dosage of gabapentin should be reduced in patients with renal impairment.

**DRUG INTERACTIONS:**

The absorption of gabapentin from the gastrointestinal tract is reduced by antacids containing aluminium with magnesium; it is recommended that gabapentin is taken at least 2 hours after any such antacid. Morphine has been reported to reduce the clearance of gabapentin; patients receiving both drugs should be monitored for signs of CNS depression and doses should be reduced accordingly. Cimetidine has also been reported to reduce the renal clearance of gabapentin but licensed product information does not consider this to be of clinical importance. For references to possible interactions with other antiepileptics.

**ADVERSE EFFECTS:**

The most commonly reported adverse effects associated with gabapentin are somnolence, dizziness, ataxia, and fatigue. Nystagmus, tremor, diplopia, amblyopia, pharyngitis, rhinitis, dysarthria, nausea, and vomiting, weight gain, oedema, dyspepsia, amnesia, weakness, paraesthesia, arthralgia, purpura, leucopenia, anxiety, and urinary tract infection may occur less frequently. Rarely, pancreatitis, altered liver function tests, erythema multiform, Steven-Johnson syndrome, myalgia, headache, and blood glucose fluctuations in diabetics have been reported. Common psychiatric effects include confusion, depression, and nervousness, and, more rarely, hallucinations and psychoses. Other adverse effects include acute renal failure, allergic reactions, alopecia, angioedema, chest pain, hepatitis jaundice movement disorders such as chloreoathetosis, dyskinesia and dystonia, palpitations, thrombocytopenia, and tinnitus.

**REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS:**

To allow continued monitoring of benefit/risk balance of the medicinal product, reporting of adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to **FDA: www.fda.gov.ph.** Patients are advised to seek immediate medical attention at first signs of adverse reactions.

**PRECAUTIONS:**

Gabapentin should be used with caution in patients with renal impairment and in those undergoing haemodialysis. False positive readings have been reported with some urinary protein tests in patients taking gabapentin. Care is required when withdrawing gabapentin therapy.

**CAUTIONS:**

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

**STORAGE CONDITION:**

Store at temperatures not exceeding 30°C.

**AVAILABILITY:**

Alu/Alu Blister Pack x 10's (Box of 30's and 100's)

**FDA Registration Number:** DR-XY42591
**Date of First Authorization:** 31 October 2018
**Date of Revision of Package Insert:** 19 April 2023

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