# Levetiracetam

# Xolvecetam

500 mg Film-Coated Tablet Antiepileptic

## FORMULATION
Each film-coated tablet contains:
Levetiracetam 500mg

## PRODUCT DESCRIPTION
White to off white, elongated, biconvex, plain on both side and film-coated tablets.

## PHARMACODYNAMIC PROPERTIES
Pharmacotherapeutic group: antiepileptics, other antiepileptics.
The active substance, levetiracetam, Is a pyrrolidone derivative (S-enantiomer of ethyl-2-oxo-l-pyrrolidine acetamide), chemically unrelated to ex1stIngantiepileptic active substances.
(For complete details on its Pharmacology please refer to the product insert.)

## INDICATIONS
Levetiracetam is used as an adjunct in the treatment of partial seizures with or without secondary generalizations, myoclonic seizures and primary generalized tonic-clonic seizures.

## DOSAGE AND ADMINISTRATION
**Partial Onset Seizures:**
- *Adults 16 years and older-initial daily dose of 1000 mg/day given as twice-daily dosing (500mgtwice daily).*
- *l month to <6 months-initial daily dose of 14 mg/kg in two divided doses (7 mg/kg twice daily).*
- *6 months to < 4years-initial daily dose of 20mg/kg in 2 divided doses (10mg/kg twice daily). The daily dose should be increased in 2 weeks by an increment of 20mg/kg to the recommended daily dose of 50mg/kg (25 mg/kg twice daily)*
- *4 years to <16 years-initial daily dose of 20 mg/kg in 2 divided doses (10 mg/kg twice daily). The daily dose should be increased every 2 weeks by increments of 20 mg/kg to the recommended daily dose of 60mg/kg (30 mg/kg twice daily).*

**Myoclonic Seizures in patients 12 years of age and older:**
- *Treatment should be initiated with a dose of 1000 mg/day, given as twice-daily dosing (500 mg twice daily). Dosage should be increased by 1000mg/day every 2 weeks to the recommended daily dose of 3000mg*.

**Primary generalized tonic-clonic seizures:**
Adult 16 years and older - treatments should be initiated with a dose of 1000mg/day, given as twice-daily dosing (500 mg twice daily).
Pediatric patients ages 6 to < 16 years - Treatment should be initiated with a daily dose of 20 mg/kg in 2 divided doses (10 mg/kg twice daily).

## CONTRAINDICATIONS
Hypersensitivity to the active substance or other pyrrolidone derivatives or to any of the excipients.

## SPECIAL WARNINGS AND PRECAUTIONS FOR USE

### Renal impairment

The administration of levetiracetam to patients with renal impairment may require dose adjustment. In patients with severely impaired hepatic function, assessment of renal function is recommended before dose selection.

### Acute Kidney injury

The use of levetiracetam has been very rarely associated with acute kidney injury, with a time to onset ranging from a few days to several months.

### Blood cell counts

Rare cases of decreased blood cell counts (neutropenia, agranulocytosis, leucopenia, thrombocytopenia and pancytopenia) have been described in association with levetiracetam administration, generally at the beginning of the treatment. Complete blood cell counts are advised in patients experiencing important weakness, pyrexia, recurrent infections or coagulation disorders.

### Suicide

Suicide, suicide attempt, suicidal ideation and behaviour have been reported in patients treated with anti-epileptic agents including levetiracetam. A meta-analysis of randomized placebo-controlled trials of anti-epileptic medicinal products has shown a small increased risk of suicidal thoughts and behaviour. The mechanism of this risk is not known. Therefore, patients should be monitored for signs of depression and/or suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of depression and/or suicidal ideation or behaviour emerge.

**Pediatric population**

The tablet formulation is not adapted for use in infants and children under the age of 6 years. Available data in children did not suggest impact on growth and puberty. However, long term effects on learning, intelligence, growth, endocrine function, puberty and childbearing potential in children remain unknown

## PRECAUTION

Levetiracetam should be used with caution and in reduced doses in patients with renal impairment, those undergoing haemodialysis and in patients with severe hepatic impairment.
Breast feeding: Levetiracetam is transferred into breast milk in significant amounts, but serum concentrations in breast-fed infants are very low.
Pregnancy: The management of epilepsy during pregnancy may present problems for both the mother and the fetus. Evidence for any effect of the newer antiepileptic on the fetus is particular scanty. Limited data have not so far suggested a significant increase in risk with levetiracetam.

## ADVERSE DRUG REACTION

The most common adverse effects associated with levetiracetam are somnolence, weakness and dizziness. Anorexia, diarrhea, dyspepsia, nausea, ataxia, headache, amnesia, depression, emotional liability, insomnia, nervousness, tremor, vertigo, diplopia and rash may occur less frequently. A raised incidence of mild infections, such as the common cold and upper respiratory-tract infections has been reported.
Other effects reported include abnormal behavior, aggression, anger, anxiety, confusion, hallucinations, irritability, psychotic disorders, neutropenia, pancytopenia and thrombocytopenia.

## DRUG INTERACTIONS

Potential pharmacokinetic interactions of or with levetiracetam were assessed in clinical pharmacokinetic studies (phenytoin, valproate, warfarin, digoxin, Oral contraceptive, probenecid) and through pharmacokinetic screening in the placebo-controlled clinical studies in epilepsy patients. Symptoms of carbamazepine toxicity have been reported when levetiracetam was added to carbamazepine therapy; this interaction appeared to be due to pharmacodynamics mechanism as blood levels of carbamazepine and its metabolite were not altered.

## OVERDOSE ANDTREATMENT

**Symptoms**

Somnolence, agitation, aggression, depressed level of consciousness, respiratory depression and coma were observed with levetiracetam overdoses.

**Management of overdose**
After an acute overdose, the stomach may be emptied by gastric lavage or by induction of emesis. There is no specific antidote for levetiracetam. Treatment of an overdose will be symptomatic and may include haemodialysis. The dialyser extraction efficiency is 60 % for levetiracetam and 74 % for the primary metabolite

## CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction.

**STORAGE CONDITION**
Store at temperature snot exceeding 30'C. Keep all medicines out of reach of children.

## AVAILABILITY
Alu/Alu Blister Pack x 10's (Box of 10’s)

## DRP-4583-10
Date of First Authorization: March 16,2020
Date of Revision of Package Insert: November 16, 2022

(For complete Product information please refer to the product insert.)