Iracet™

Levetiracetam USP

Composition

Iracet™ 250 Tablet: Each tablet contains Levetiracetam USP 250 mg.
Iracet™ 500 Tablet: Each tablet contains Levetiracetam USP 500 mg.
Iracet™ **XR** 500 Tablet: Each extended release tablet contains Levetiracetam USP 500 mg.
Iracet™ Injection: Each 5 ml Ampoule contains Levetiracetam USP 500 mg.
Iracet™ Oral solution: Each 5 ml solution contains Levetiracetam USP 500 mg.

Pharmacology

Iracet™ (Levetiracetam) The exact mechanism of action is unknown but does not involve inhibitory and excitatory neurotransmission. Stereo-selective binding of Levetiracetam was confined to synaptic plasma membranes in the central nervous system with no binding occurring in peripheral tissue.

Indication

Iracet™ (Levetiracetam) is indicated as an adjunctive therapy for:
Partial Onset Seizures
Myoclonic Seizures In Patients with Juvenile Myoclonic Epilepsy
Primary Generalized Tonic-Clonic Seizures
Iracet™ (Levetiracetam) injection is an alternative for adult patients (16 years and older) when oral administration is temporarily not feasible.

Dosage & Administration

Iracet™ (Levetiracetam) can be initiated with either intravenous or oral administration.
For tablet and oral solution
Treatment should be initiated with a daily dose of 1000 mg/day, given as twice-daily dosing (500 mg twice daily). Additional dosing increments may be given (1000 mg/day additional every 2 weeks) to a maximum recommended daily dose of 3000 mg.
Use in Pediatric Patients

Age/weight	Initial dose (Daily)	Incremental dose (Daily)
1 Month To < 6 Months	7 mg/kg twice daily	21 mg/kg twice daily
6 Months To < 4 Years	10 mg/kg twice daily	25 mg/kg twice daily
4 Years To < 16 Years	10 mg/kg twice daily	30 mg/kg twice daily
Adolescent with 20- 40 kg body weight	250 mg twice daily	750 mg twice daily

*The daily dose should be increased every 2 weeks.
Iracet Oral Solution: Weight-Based Dosing Calculation For Pediatric Patients:

$$\text{Total daily dose (mL/day)} = \frac{\text{Daily dose (mg/kg/day) x patient weight (kg)}}{\text{100 mg/mL}}$$

Injection
Iracet™ (Levetiracetam) injection is for intravenous use only and must be diluted prior to administration. **Iracet**™ (Levetiracetam) injection (500 mg/5 mL) should be diluted in 100 mL of compatible diluents and administered intravenously as a 15-minute IV infusion. Product with particulate matter or discoloration should not be used.
Dosing Instructions: Preparation and Administration

Dose	Withdraw Volume	Volume of Diluent	Infusion Time
500 mg	5 ml (one 5 ml ampoule)	100 ml	15 minutes
1000 mg	10 ml (two 5 ml ampoules)	100 ml	15 minutes
1500 mg	15 ml (three 5 ml ampoules)	100 ml	15 minutes

For example, to prepare a 1000 mg dose, dilute 10 ml of **Iracet**™ (Levetiracetam) injection in 100 ml of a compatible diluents and administer intravenously as a 15-minute infusion.
Compatibility and Stability
Levetiracetam injection was found to be physically compatible and chemically stable when mixed with the following diluents and antiepileptic drugs for at least 24 hours and stored in polyvinyl chloride (PVC) bags at controlled room temperature 15-30°C (59-86°F).

Diluents
- Sodium chloride (0.9%) injection, USP
- Lactated Ringer's injection
- Dextrose 5% injection, USP

Other Antiepileptic Drugs
- Lorazepam
- Diazepam
- Valproate sodium

Adult Patients with Impaired Renal Function
Levetiracetam dosing must be individualized according to the patient's renal function status. Recommended doses and adjustment for dose for adults are shown in

Dosing Adjustment Regimen for Adult Patients with Impaired Renal Function

Group	Creatinine Clearance (mL/min)	Dosage (mg)	Frequency
Normal	> 80	500 to 1,500	Every 12 h
Mild	50 - 80	500 to 1,000	Every 12 h
Moderate	30 - 50	250 to 750	Every 12 h
Severe	< 30	250 to 500	Every 12 h
Patients using dialysis		500 to 1,000	Every 24 h*

*Following dialysis, a 250 to 500 mg supplemental dose is recommended.

Contraindication

None

Warnings & Precaution

Severe allergic reactions, abnormal thoughts; dark urine; decreased coordination; extreme dizziness, drowsiness, tiredness, or weakness; fever, chills, or persistent sore throat; hallucinations; memory loss; mouth sores; muscle or neck pain; new or worsening mental problem; mood or behavior changes; new or worsening seizures; pain, itching or redness at the injection site; suicidal thoughts or attempts; unusual bruising or bleeding; vision changes; yellowing of the skin or eyes.

Adverse Effect

Dizziness, drowsiness, irritability, sore throat, tiredness, weakness are some common adverse effects. In rare cases severe allergic reaction may happen.

Drug Interaction

No potential drug interaction has been reported

Use In Pregnancy And Lactation

Pregnancy: Pregnancy category C.
Lactation: No data on the use of Levetiracetam in breast-feeding women are available. Data from animals indicate that Levetiracetam is secreted into milk. Therefore Levetiracetam is contraindicated during breast-feeding.

Storage

Store in a cool and dry place, protected from light and moisture. Keep out of the reach of children.

How Supplied

Iracet™ 250 Tablet : Each box contains 30 tablets in blister pack.
Iracet™ 500 Tablet : Each box contains 20 tablets in blister pack.
Iracet™ **XR** 500 Tablet : Each box contains 12 tablets in blister pack.
Iracet™ Injection: Each box contains 6 ampoules in blister pack.
Iracet™ Oral solution: Each PET bottle contains 50 ml oral solution.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH