Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
Iracet Injection

2. Qualitative and quantitative composition
Each 5 mL Ampoule contains Levetiracetam USP 500 mg.

For a full list of excipients, see section 6.1

3. Pharmaceutical form
A clear colorless sterile solution having characteristic odor, free from any visible foreign particle, filled and sealed in transparent glass ampoule.

4. Clinical particulars

4.1 Therapeutic indications
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 injection is an alternative for adult patients (16 years and older) when oral administration is temporarily not feasible.

4.2 Posology and method of administration
Iracet (Levetiracetam) injection is for intravenous use only and must be diluted prior to administration.

Iracet 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.

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.

4.3 Contraindications
None.

4.4 Special warnings and precautions for use
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.

4.5 Interaction with other medicinal products and other forms of interaction
No potential drug interaction has been reported.

4.6 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 breastfeeding.

4.7 Effects on ability to drive and use machines
Levetiracetam has minor or moderate influence on the ability to drive and use machines. Due to possible different individual sensitivity, some patients might experience somnolence or other central nervous system related symptoms, especially at the beginning of treatment or following a dose increase.
Therefore, caution is recommended in those patients when performing skilled tasks, e.g. driving vehicles or operating machinery. Patients are

advised not to drive or use machines until it is established that their ability to perform such activities is not affected.

4.8 Undesirable effects

Dizziness, drowsiness, irritability, sore throat, tiredness, weakness are some common adverse effects.

In rare cases, severe allergic reaction may happen.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via National Pharmacovigilance Electronic Reporting Systems' to the respective National Regulatory Authorities.

4.9 Overdose

Symptoms

Somnolence, agitation, aggression, depressed level of consciousness, respiratory depression and coma.

Management of overdose

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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiepileptics

ATC Code: N03AX14

Mechanism of action

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.

Pharmacodynamic Effects

Levetiracetam induces seizure protection in a broad range of animal models of partial and primary generalized seizures without having a pro-convulsant effect. The primary metabolite is inactive. In man, an activity in both partial and generalized epilepsy conditions (epileptiform discharge/photoparoxysmal response) has confirmed the broad spectrum pharmacological profile of levetiracetam.

5.2 Pharmacokinetic properties

General pharmacokinetics

Levetiracetam is a highly soluble and permeable compound. The pharmacokinetic profile is linear with low intra- and inter-subject variability. There is no modification of the clearance after repeated administration. The time independent pharmacokinetic profile of levetiracetam was also confirmed following 1500 mg intravenous infusion for 4 days with twice daily dosing.

There is no evidence for any relevant gender, race or circadian variability. The pharmacokinetic profile is comparable in healthy volunteers and in patients with epilepsy.

Distribution
No tissue distribution data are available in humans.
Neither levetiracetam nor its primary metabolite are significantly bound to plasma proteins (< 10 %).
The volume of distribution of levetiracetam is approximately 0.5 to 0.7l/kg, a value close to the total body water volume.

Biotransformation
Levetiracetam is not extensively metabolised in humans. The major metabolic pathway (24% of the dose) is an enzymatic hydrolysis of the acetamide group.

Elimination
The plasma half-life in adults was 7±1 hours and did not vary either with dose, route of administration or repeated administration. The mean total body clearance was 0.96 mL/min/kg.
The major route of excretion was via urine, accounting for a mean 95% of the dose (approximately 93% of the dose was excreted within 48 hours). Excretion via faeces accounted for only 0.3% of the dose.
The cumulative urinary excretion of levetiracetam and its primary metabolite accounted for 66% and 24% of the dose, respectively during the first 48 hours.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, genotoxicity and carcinogenic potential.

Adverse effects not observed in clinical studies but seen in the rat and to a lesser extent in the mouse at exposure levels similar to human exposure levels and with possible relevance for clinical use were liver changes, indicating an adaptive response such as increased weight and centrilobular hypertrophy, fatty infiltration and increased liver enzymes in plasma.

6. Pharmaceutical Particulars

6.1 List of Excipients

Sodium Chloride

Sodium Acetate
Glacial Acetic Acid

6.2 Incompatibilities
Not applicable

6.3 Shelf-Life
24 months (2 years)

6.4 Special Precautions for storage
Store below 30°C, protect from light & moisture.

6.5 Nature and Content of container
Each box contains 6 ampoules in blister pack.

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing Authorization Holder
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8. Marketing Authorization Number
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