SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Iracet Oral Solution 50 ml

2. Qualitative and quantitative composition

Each ml of solution contains 100 mg Levetiracetam USP.

Excipients with known effect
Each ml of solution contains Aspartame

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

An orange colour solution having sweet orange flavour with slight bitter taste; free from any visible foreign particle. The solution is filled in a transparent PET bottle and sealed with a white colour PP cap overprinted with "SQUARE".

4. Clinical particulars

4.1 Therapeutic indications

Iracet (Levetiracetam) is indicated as adjunctive therapy for:

- Partial onset seizures.
- Myoclonic seizures in patients with juvenile myoclonic epilepsy.
- Primary generalized tonic-clonic seizures.

4.2 Posology and method of 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 paediatric patients

Dosing instructions: preparation and administration

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 Paediatric Patients:

Total daily dose (mL/day) = [Daily dose (mg/kg/day) × patient weight (kg)] / 100 mg/mL

Method of administration: For oral use.

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 behaviour 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 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.

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 and weakness are some common adverse effects. In rare cases, severe allergic reaction may happen.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS)
https://pv.pharmacyboardkenya.org

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

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 generalised seizures without having a pro-convulsant effect. The primary metabolite is inactive.

In man, an activity in both partial and generalised epilepsy conditions (epileptiform discharge/photoparoxysmal response) has confirmed the broad-spectrum pharmacological profile of levetiracetam.

5.2 Pharmacokinetic properties

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. 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.

Due to its complete and linear absorption, plasma levels can be predicted from the oral dose of levetiracetam expressed as mg/kg bodyweight. Therefore, there is no need for plasma level monitoring of levetiracetam.

A significant correlation between saliva and plasma concentrations has been shown in adults and children (ratio of saliva/plasma concentrations ranged from 1 to 1.7 for oral tablet formulation and after 4 hours post-dose for oral solution formulation).

Absorption

Levetiracetam is rapidly absorbed after oral administration. Oral absolute bioavailability is close to 100%.

Peak plasma concentrations (Cmax) are achieved at 1.3 hours after dosing. Steady state is achieved after two days of a twice daily administration schedule. Peak concentrations (Cmax) are typically 31 and 43 μg/ml following a single 1,000 mg dose and repeated 1,000 mg twice daily dose, respectively.

The extent of absorption is dose-independent and is not altered by food.

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 0.7 l/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. Production of the primary metabolite, ucb L057, is not supported by liver cytochrome P450 isoforms. Hydrolysis of the acetamide group was measurable in a large number of tissues including blood cells. The metabolite ucb L057 is pharmacologically inactive.

Two minor metabolites were also identified. One was obtained by hydroxylation of the pyrrolidone ring (1.6% of the dose) and the other one by opening of the

pyrrolidone ring (0.9% of the dose). Other unidentified components accounted only for 0.6% of the dose.

No enantiomeric interconversion was evidenced in vivo for either levetiracetam or its primary metabolite.

In vitro, levetiracetam and its primary metabolite have been shown not to inhibit the major human liver cytochrome P450 isoforms (CYP3A4, 2A6, 2C9, 2C19, 2D6, 2E1 and 1A2), glucuronyl transferase (UGT1A1 and UGT1A6) and epoxide hydroxylase activities. In addition, levetiracetam does not affect the in vitro glucuronidation of valproic acid.

In human hepatocytes in culture, levetiracetam had little or no effect on CYP1A2, SULT1E1 or UGT1A1. Levetiracetam caused mild induction of CYP2B6 and CYP3A4. The in vitro data and in vivo interaction data on oral contraceptives, digoxin and warfarin indicate that no significant enzyme induction is expected in vivo. Therefore, the interaction of levetiracetam with other substances, or vice versa, is unlikely.

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.

The renal clearance of levetiracetam and ucb L057 is 0.6 and 4.2 ml/min/kg respectively, indicating that levetiracetam is excreted by glomerular filtration with subsequent tubular reabsorption and that the primary metabolite is also excreted by active tubular secretion in addition to glomerular filtration.

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

- Glycerol
- Liquid Sorbitol (Non Crystalizing)
- Sodium Methyl Hydroxybenzoate
- Sodium Propyl Hydroxybenzoate
- Aspartame
- Sucralose
- Sodium Citrate

- Anhydrous Citric Acid
- FD&C Red No. 40
- D & C Yellow No. 10
- Orange Liquid (Sweet) Essence No. 1 NA.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture. Keep out of children's reach.

6.5 Nature and contents of container

Each PET bottle contains 50 ml solution.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing Authorization Holder

Square Pharmaceuticals Ltd.
Square Road, Salgaria, Pabna 6600
Bangladesh
Tel: +880 0731 66582-86
Cell: +88 01777712318
Fax: +880 2 8828768, 8828609

8. Marketing Authorization Number

H2025/CTD9290/20105

9. Date of first authorization/renewal of the authorization

12/08/2025

10. Date of revision of the text

12/08/2025