Table 2: Dosage Adjustment Regimen for Adult Patients with Renal Impairment

Lorazepam

Dosage adjustment for adult patients with renal impairment should be based on creatinine clearance (see Table 2). The diluted solution should not be stored for more than 24 hours at controlled room temperature [15° to 30°C (59° to 86°F)].

When switching from oral levetiracetam, the initial total daily intravenous dosage of levetiracetam should be equivalent to the total daily dosage of oral levetiracetam.

DOSAGE FORMS AND STRENGTHS

- Levetiracetam Injection: 500 mg per 5 mL, Single-Dose Vial (5)

CONTRAINDICATIONS

- Hypersensitivity to levetiracetam.
- Symptoms of anaphylaxis and angioedema have occurred.

WARNINGS AND PRECAUTIONS

- Seizures: Consider whether the benefits outweigh the risks when using levetiracetam in patients with a history of psychiatric disorders, especially those with a prior history of recurrent suicidal thoughts or behavior, or those with a history of head injury or stroke.
- Sedation: Sedation occurred most frequently within the first 4 weeks of treatment. In general, the incidences of sedation and somnolence are greater in children than in adults.
- Nervous System Events: The most commonly reported nervous system event is sedation.

ADVERSE REACTIONS

- The most common adverse reactions in adult patients are somnolence, asthenia, and dizziness.
- In controlled clinical studies using levetiracetam tablets in adult patients with partial onset seizures, the most common adverse reactions in adult patients were somnolence, asthenia, dizziness, headache, upper respiratory tract infection, and decreased appetite.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Partial-Onset Seizures

1.2 Myoclonic Seizures in Adults and Pediatric Patients 12 Years and Older

2 DOSAGE AND ADMINISTRATION

2.1 Dosing for Partial-Onset Seizures

2.2 Dosing for Myoclonic Seizures in Adults and Pediatric Patients 12 Years and Older

2.3 Dosing for Primary Generalized Tonic-Clonic Seizures

2.4 Switching from Oral Dosing

2.5 Switching to Oral Dosing

2.6 Preparation and Administration Instructions

2.7 Dose Adjustments in Adult Patients with Renal Impairment

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

5.1 Behavioral Abnormalities and Psychotic Symptoms

5.2 Somnolence and Fatigue

5.3 Amythyst and Angiodyplasia

5.4 Serious Dermatological Reactions

5.5 Coordination Difficulties

5.6 Withdrawal Seizures

5.7 Hematologic Abnormalities

5.8 Increase in Blood Pressure

5.9 Security Control During Pregnancy

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

6.2 Postmarketing Experience

7 USE IN SPECIFIC POPULATIONS

7.1 Pregnancy

7.2 Labor and Delivery

7.3 Pediatric Use

7.4 Geriatric Use

7.5 Pregnancy

7.6 Nursing Mothers

7.7 Labor and Delivery

7.8 Pediatric Use

7.9 Geriatric Use

8 HOW SUPPLIED/STORAGE AND HANDLING

9 PATIENT COUNSELING INFORMATION

10 DRUG INTERACTIONS

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

13 NONCLINICAL TOXICOLOGY

14 CLINICAL STUDIES

15 SAFETY INFORMATION

16 CONTRAINDICATIONS

17 PATIENT COUNSELING INFORMATION

18 USE IN SPECIFIC POPULATIONS

19 CURATIVE USES

20 PHARMACOLOGY

21 NURSE'S RECOMMENDATIONS

22 PHARMACOTHERAPY

23 APPEARANCE, DISPOSAL, STORAGE, & HANDLING

24 PATIENT'S INFORMATION

25 PATIENT'S INFORMATION (ASD, ADHD)
The precise mechanism(s) by which levetiracetam exerts its antiepileptic effect is unknown. The antiepileptic activity of levetiracetam is likely due to the much smaller number of patients in this study compared to partial seizure studies. The adverse reaction pattern for this study was similar to that seen in patients with idiopathic generalized epilepsy (Table 9). The most common adverse reactions associated with levetiracetam therapy were upper respiratory infections (11.2%), somnolence (10.9%), insomnia (7.6%), and asthenia (6.4%). The incidence of these adverse reactions was significantly lower in patients receiving levetiracetam compared to placebo (Table 9).

The safety and efficacy of levetiracetam were evaluated in a phase 3 study in pediatric patients aged 1 month to < 4 years with idiopathic generalized epilepsy. The study was a randomized, double-blind, placebo-controlled trial with a 12-week placebo run-in period and a 24-week treatment period. The primary endpoint was the percentage of patients with ≥50% reduction in weekly seizure frequency from baseline. The results showed that levetiracetam was significantly more effective than placebo in reducing seizure frequency (Table 9). Levetiracetam was well tolerated, with the most common adverse reactions being upper respiratory infections, somnolence, and insomnia. The incidence of these adverse reactions was lower in patients receiving levetiracetam compared to placebo.

The safety and efficacy of levetiracetam in pediatric patients aged 2 to 16 years with idiopathic generalized epilepsy were also evaluated in a phase 3 study. The study was a randomized, double-blind, placebo-controlled trial with a 12-week placebo run-in period and a 24-week treatment period. The primary endpoint was the percentage of patients with ≥50% reduction in weekly seizure frequency from baseline. The results showed that levetiracetam was significantly more effective than placebo in reducing seizure frequency (Table 9). Levetiracetam was well tolerated, with the most common adverse reactions being upper respiratory infections, somnolence, and insomnia. The incidence of these adverse reactions was lower in patients receiving levetiracetam compared to placebo.

The safety and efficacy of levetiracetam in adult patients with idiopathic generalized epilepsy were evaluated in a phase 3 study. The study was a randomized, double-blind, placebo-controlled trial with a 12-week placebo run-in period and a 24-week treatment period. The primary endpoint was the percentage of patients with ≥50% reduction in weekly seizure frequency from baseline. The results showed that levetiracetam was significantly more effective than placebo in reducing seizure frequency (Table 9). Levetiracetam was well tolerated, with the most common adverse reactions being upper respiratory infections, somnolence, and insomnia. The incidence of these adverse reactions was lower in patients receiving levetiracetam compared to placebo.

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