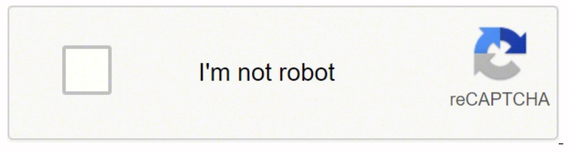

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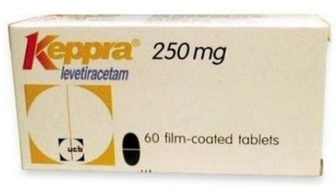

NDC 68180-116-01

Levetiracetam Oral Solution USP

100 mg/mL

Each mL of oral solution contains levetiracetam USP 100 mg.

PHARMACIST: Dispense in a tight, light-resistant container with a child-resistant closure along with medication guide provided separately.

Rx only

16 fl oz (473 mL)

LUPIN

Usual Dosage: See accompanying prescribing information.

Storage: Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Warning: Keep this and all medications out of the reach of children.

Manufactured for:
Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202
United States

Manufactured by:
Lupin Limited
Aurangabad 431 210 INDIA

Code No. MH/DRUGS/633

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No dose adjustment is needed for patients with hepatic impairment. Therefore, other controlled pediatric data, presented above, should also be considered to apply to this age group. Approximately 50% of the pool of levetiracetam in the body is removed during a standard 4-hour hemodialysis procedure [see Dosage and Administration (2.5)]. Levetiracetam dosing was determined by age and weight as follows: children 1 month to less than 6 months old were randomized to a target dose of 40 mg/kg/day, and children 6 months to less than 4 years old were randomized to a target dose of 50 mg/kg/day. Do not change your dose without talking to your healthcare provider. Do not take levetiracetam oral solution if you are allergic to levetiracetam. If you have suicidal thoughts or actions, your healthcare provider may check for other causes. Although no substantive differences were observed between the placebo and drug treated groups in the median change from baseline in this battery, the study was not adequate to assess formal statistical non-inferiority of the drug and placebo. In clinical studies in pediatric patients 1 month to < 4 years of age, irritability was reported in 12% of the levetiracetam-treated patients compared to 0% of placebo-treated patients. • primary generalized tonic-clonic seizures in people 6 years of age and older with certain types of generalized epilepsy. • Problems with muscle coordination (problems walking and moving) The most common side effects seen in people who take levetiracetam oral solution include: • sleepiness • weakness • infection • dizziness The most common side effects seen in children who take levetiracetam oral solution include, in addition to those listed above: • tiredness • acting aggressive • nasal congestion • decreased appetite • irritability Tell your healthcare provider if you have any side effect that bothers you or that does not go away. Do not start a new medicine without first talking with your healthcare provider. The body weight adjusted apparent clearance of levetiracetam was approximately 40% higher than in adults. Do not use a household teaspoon. The results of the analysis of Study 1 are displayed in Table 10. In these studies, 904 patients were randomized to placebo, 1000 mg, 2000 mg, or 3000 mg/day. Table 7 lists adverse reactions that occurred in at least 5% of juvenile myoclonic epilepsy patients experiencing myoclonic seizures treated with levetiracetam and were numerically more common than in patients treated with placebo. Table 3: Adverse Reactions in Pooled Placebo-Controlled, Add-On Studies in Adults Experiencing Partial Onset Seizures In controlled adult clinical studies, 15% of patients receiving levetiracetam and 12% receiving placebo either discontinued or had a dose reduction as a result of an adverse reaction. Reactions have included anaphylaxis and angioedema [see Warnings and Precautions (5.4)]. In this study, either levetiracetam or placebo was added to concurrent AED therapy. 1.3 Primary Generalized Tonic-Clonic Seizures Levetiracetam oral solution is indicated as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy. Alopecia has been reported with levetiracetam use; recovery was observed in majority of cases where levetiracetam was discontinued. The somnolence was considered serious in 0.3% of levetiracetam-treated patients, compared to 0% in the placebo group. Table 4: Adverse Reactions that Resulted in Discontinuation or Dose Reduction in Placebo-Controlled Studies in Adult Patients Experiencing Partial Onset Seizures Pediatric Patients 4 Years to < 16 Years The adverse reaction data presented below was obtained from a pooled analysis of two controlled pediatric clinical studies in pediatric patients 4 to 16 years of age with partial onset seizures. The 18-week treatment period consisted of a 6-week titration period, followed by a 12-week fixed dose evaluation period, during which concomitant AED regimens were held constant. A total of 3.2% of levetiracetam-treated and 1.8% of placebo-treated patients had at least one possibly significant (≤2.8 x 109/L) decreased WBC, and 2.4% of levetiracetam-treated and 1.4% of placebo-treated patients had at least one possibly significant (≤1.0 x 109/L) decreased neutrophil count. In 0.5% of levetiracetam-treated patients and in 0.2% of placebo-treated patients, the dose was reduced due to asthenia. Inform patients not to drive or operate machinery until they have gained sufficient experience on levetiracetam to gauge whether it adversely affects their ability to drive or operate machinery [see Warnings and Precautions (5.3)]. Levetiracetam oral solution does not contain lactose or gluten. Absorption and Distribution Absorption of levetiracetam is rapid, with peak plasma concentrations occurring in about an hour following oral administration in fasted subjects. There was no overt maternal toxicity at the doses used in this study. Secondary outcome variables included the responder rate (incidence of patients with ≥ 50% reduction from baseline in partial-onset seizure frequency per week). 12 CLINICAL PHARMACOLOGY 12.1 Mechanism of Action The precise mechanism(s) by which levetiracetam exerts its antiepileptic effect is unknown. 5.7 Withdrawal Seizures As with most antiepileptic drugs, levetiracetam should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus. These findings suggest that the interaction of levetiracetam with the SV2A protein may contribute to the antiepileptic mechanism of action of the drug. Drug Interactions In vitro data on metabolic interactions indicate that levetiracetam is unlikely to produce, or be subject to, pharmacokinetic interactions. 10 OVERDOSAGE 10.1 Signs, Symptoms and Laboratory Findings of Acute Overdosage in Humans The highest known dose of levetiracetam received in the clinical development program was 6000 mg/day. In the clinical trial, the mean daily dose was 44 mg/kg. Because of the shorter exposure period, incidences of adverse reactions are expected to be lower than in other pediatric studies in older patients. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Call your healthcare provider between visits as needed, especially if you are worried about symptoms. Pharmacokinetics of levetiracetam were also not affected by phenytoin. In a study where there was no titration, about 45% of patients receiving 4000 mg/day reported somnolence. No overall differences in safety were observed between these subjects and younger subjects. Patients should be monitored for these signs and symptoms and advised not to drive or operate machinery until they have gained sufficient experience on levetiracetam to gauge whether it adversely affects their ability to drive or operate machinery. It may harm them. The mean decreases from baseline in the levetiracetam-treated group were -0.4 × 109/L and -0.3 × 109/L, respectively, whereas there were small increases in the placebo group. Dermatological Adverse Reactions Advise patients that serious dermatological adverse reactions have occurred in patients treated with levetiracetam and instruct them to call their physician immediately if a rash develops [see Warnings and Precautions (5.5)]. 1200 mg/kg/day (4 times the MRHD) was a developmental no effect dose. There was no evidence of maternal toxicity in this study. Levetiracetam oral solution active ingredient: levetiracetam Inactive ingredients: acesulfame potassium, ammonium glycyrrhizinate, citric acid anhydrous, glycerin, maltitol solution, methylparaben, propylparaben, purified water, sodium citrate dihydrate and natural and artificial grape flavor. Levetiracetam should normally be gradually withdrawn to reduce the potential of increased seizure frequency and status epilepticus [see Warnings and Precautions (5.7)]. If withdrawal is needed because of a serious adverse reaction, rapid discontinuation can be considered. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function [see Clinical Pharmacology (12.3)]. Hepatic Impairment In subjects with mild (Child-Pugh A) to moderate (Child-Pugh B) hepatic impairment, the pharmacokinetics of levetiracetam were unchanged. Levetiracetam is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Following oral administration of twice-daily dosing for 10 days, total body clearance decreased by 38% and the half-life was 2.5 hours longer in the elderly compared to healthy adults. At the time of the study, patients were taking a stable dose regimen of at least one and could take a maximum of two AEDs. During the baseline period, patients had to have experienced at least two partial-onset seizures during each 4-week period. The major metabolite is inactive in animal seizure models. • If your healthcare provider has prescribed levetiracetam oral solution, be sure to ask your pharmacist for a medicine dropper or medicine cup to help you measure the correct amount of levetiracetam oral solution. The primary measure of effectiveness was a between group comparison of the percent reduction in weekly partial seizure frequency relative to placebo over the entire 14-week randomized treatment period (titration + evaluation period). In the clinical trial, the mean daily dose was 35 mg/kg in this age group. Table 13 displays the results of this study. The risk did not vary substantially by age (5-100 years) in the clinical trials analyzed. Levetiracetam oral solution is a prescription medicine taken by mouth that is used with other medicines to treat: • myoclonic seizures in people 12 years of age and older with juvenile myoclonic epilepsy. 10.2 Management of Overdose There is no specific antidote for overdose with levetiracetam. It is not known if the levetiracetam oral solution that passes into your breast milk can harm your baby. 12.2 Pharmacodynamics Effects on QTc Interval The effect of levetiracetam on QTc prolongation was evaluated in a randomized, double-blind, positive-controlled (moxifloxacin 400 mg) and placebo-controlled crossover study of levetiracetam (1000 mg or 5000 mg) in 52 healthy subjects. Pooled analyses of 199 placebo-controlled clinical trials (mono- and adjunctive therapy) of 11 different AEDs showed that patients randomized to one of the AEDs had approximately twice the risk (adjusted Relative Risk 1.8, 95% CI:1.2, 2.7) of suicidal thinking or behavior compared to patients randomized to placebo. Dosing was initiated at a dose of 20 mg/kg/day in two divided doses. There was a statistically significant decrease from baseline in PGTC frequency in the levetiracetam-treated patients compared to the placebo-treated patients. The primary measure of effectiveness was the responder rate (percent of patients with ≥ 50% reduction from baseline in average daily partial-onset seizure frequency) assessed by a blinded central reader using a 48-hour video EEG performed during the last two days of the 4-day maintenance period. In addition, the following adverse reactions were seen in other controlled adult studies of levetiracetam: balance disorder, disturbance in attention, eczema, memory impairment, myalgia, and blurred vision. Safety and effectiveness for the treatment of partial-onset seizures in pediatric patients below the age of 1 month; adjunctive therapy for the treatment of myoclonic seizures in pediatric patients below the age of 12 years; and adjunctive therapy for the treatment of primary generalized tonic-clonic seizures in pediatric patients below the age of 6 years have not been established. The pharmacokinetic results indicated that half-life was shorter (5.3 h) than for adults (7.2 h) and apparent clearance was faster (1.5 mL/min/kg) than for adults (0.96 mL/min/kg). 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. What is levetiracetam oral solution? Probenecid Probenecid, a renal tubular secretion blocking agent, administered at a dose of 500 mg four times a day, did not change the pharmacokinetics of levetiracetam 1000 mg twice daily. It is not known if levetiracetam oral solution is safe or effective in children under: • 1 month of age to treat partial-onset seizures • 12 years of age to treat myoclonic seizures • 6 years of age to treat primary generalized tonic-clonic seizures Before taking your medicine, make sure you have received the correct medicine. Manufactured by: Akorn, Inc. The study consisted of a 5-day evaluation period which included a 1-day titration period followed by a 4-day maintenance period. What should I tell my healthcare provider before starting levetiracetam oral solution? You can ask your pharmacist or healthcare provider information about levetiracetam oral solution that is written for health professionals. Table 5 lists adverse reactions from the pooled pediatric controlled studies (4 to 16 years of age) that occurred in at least 2% of pediatric levetiracetam-treated patients and were numerically more common than in pediatric patients treated with placebo. Table 15: Median Percent Reduction from Baseline in PGTC Seizure Frequency per Week in Study 7 *statistically significant versus placebo The percentage of patients (y-axis) who achieved ≥50% reduction in weekly seizure rates from baseline in PGTC seizure frequency over the entire randomized treatment period (titration + evaluation period) within the two treatment groups (x- is presented in Figure 6. Levetiracetam oral solution may make you dizzy or sleepy. 8.5 Geriatric Use There were 347 subjects in clinical studies of levetiracetam that were 65 and over. 5.3 Somnolence and Fatigue Levetiracetam may cause somnolence and fatigue. • If you take too much levetiracetam oral solution, call your local Poison Control Center or go to the nearest emergency room right away. Maternal toxicity was also observed at 1800 mg/kg/day. Recurrence of the serious skin reactions following rechallenge with levetiracetam has also been reported. In clinical studies, two (0.3%) levetiracetam-treated adult patients were hospitalized and their treatment was discontinued due to psychosis. Increase the daily dose every 2 weeks by increments of 14 mg/kg to the recommended daily dose of 42 mg/kg (21 mg/kg twice daily). oz. Ask your pharmacist for instructions on how to use the measuring device the right way. In addition, levetiracetam does not affect the in vitro glucuronidation of valproic acid. WARNING: Keep this and all medication out of the reach of children. The study consisted of an 8-week baseline period and 4-week titration period followed by a 10-week evaluation period. Table 4 lists the most common (>1%) adverse reactions that resulted in discontinuation or dose reduction and that occurred more frequently in levetiracetam-treated patients than in placebo-treated patients. Table 12 displays the results of the analysis of Study 3. The pharmacokinetics of levetiracetam are linear over the dose range of 500-5000 mg. 2 DOSAGE AND ADMINISTRATION 2.2 Dosing for Partial Onset Seizures The recommended dosing for monotherapy and adjunctive therapy is the same; as outlined below. Know the medicines you take. The finding of increased risk with AEDs of varying mechanisms of action and across a range of indications suggests that the risk applies to all AEDs used for any indication. Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worryyou: • thoughts about suicide or dying • attempts to commit suicide • new or worse depression • new or worse anxiety • feeling agitated or restless • panic attacks • trouble sleeping (insomnia) • new or worse irritability • acting aggressive, being angry, or violent • acting on dangerous impulses • an extreme increase in activity and talking (mania) • other unusual changes in behavior or mood Do not stop levetiracetam oral solution without first talking to a healthcare provider. The safety and effectiveness of levetiracetam as adjunctive therapy for the treatment of myoclonic seizures in adolescents 12 years of age and older with juvenile myoclonic epilepsy have been established [see Clinical Studies (14.2)]. 5.9 Increase in Blood Pressure In a randomized, placebo-controlled study in patients 1 month to

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