

**DR. REDDY'S LABORATORIES (PTY) LTD.
REDILEV 250/500/750
(FILM-COATED TABLETS)
APPROVED PROFESSIONAL INFORMATION**

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

REDILEV 250

REDILEV 500

REDILEV 750

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

REDILEV 250: Each film-coated tablet contains levetiracetam 250 mg.

REDILEV 500: Each film-coated tablet contains levetiracetam 500 mg.

REDILEV 750: Each film-coated tablet contains levetiracetam 750 mg.

Sugar free.

For the full list of excipients, see section 6.1.

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3. PHARMACEUTICAL FORM
Film-coated tablet
REDILEV 250: Blue, modified capsule-shaped, film-coated tablets debossed with 'LV250' on one side and plain on other side.
REDILEV 500: Yellow, modified capsule-shaped, film-coated tablets debossed with 'LV500' on one side and plain on other side.
REDILEV 750: Peach, modified capsule-shaped, film-coated tablets debossed with 'LV750' on one side and plain on other side.
4. CLINICAL PARTICULARS
4.1 THERAPEUTIC INDICATIONS
REDILEV is indicated in adults and adolescents (from 16 years of age): <ul style="list-style-type: none">• as monotherapy, for the treatment of newly diagnosed partial onset seizures with or without secondary generalisation.• as adjunctive therapy to treat partial onset seizures, with or without secondary generalisation.
REDILEV is also indicated as adjunctive therapy in the treatment of: <ul style="list-style-type: none">• myoclonic seizures in adults, and juvenile myoclonic epilepsy in adolescents (from 12 years of age).• primary generalised tonic-clonic seizures in adults, and idiopathic generalised epilepsy in adolescents (from 16 years of age).
4.2 POSOLOGY AND METHOD OF ADMINISTRATION
Posology
Monotherapy
<i>Adults and adolescents from 16 years of age:</i>

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The recommended starting dose is 250 mg twice daily which should be increased to an initial therapeutic dose of 500 mg twice daily after two weeks. The dose can be further increased by 250 mg twice daily every two weeks depending upon the clinical response. The maximum daily dose is 1 500 mg twice daily.

Add-on therapy

Adults (≥ 18 years) and adolescents (12 to 17 years) weighing 50 kg or more, when indicated (see section 4.2):

The initial therapeutic dose is 500 mg twice daily. The dose can be started on the first day of treatment. Depending upon the clinical response and tolerability, the daily dose can be increased up to 1 500 mg twice daily. Dose changes can be made in 500 mg twice daily increases or decreases every two to four weeks.

Adolescents (12 to 17 years) weighing less than 50 kg, when indicated (see section 4.2):

The initial therapeutic dose is 10 mg/kg twice daily. This dose can be started on the first day of treatment.

Depending upon the clinical response and tolerability, the dose can be increased up to 30 mg/kg twice daily. Dose changes should not exceed increases or decreases of 10 mg/kg twice daily every two weeks. The lowest effective dose should be used.

Dosage in children 50 kg or greater is the same as in adults.

The medical practitioner should prescribe the most appropriate formulation strength according to weight and dose.

Recommended dosage for children and adolescents with normal renal function:

Weight	Starting dose (10 mg/kg twice daily)	Maximum dose (30 mg/kg twice daily)
15 kg ⁽¹⁾	150 mg twice daily	450 mg twice daily
20 kg ⁽¹⁾	200 mg twice daily	600 mg twice daily
25 kg	250 mg twice daily	750 mg twice daily
From 50 kg ⁽²⁾	500 mg twice daily	1500 mg twice daily
⁽¹⁾ Another formulation of levetiracetam should be used.		
⁽²⁾ Dosage in children and adolescents 50 kg or more is the same as in adults.		

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Special populations

Elderly (65 years and older):

Adjustment of the dose is recommended in elderly patients with compromised renal function (see Patients with renal impairment below).

Patients with renal impairment:

The REDILEV daily dose must be individualised according to renal function. For adult patients refer to the following table and adjust the dose as indicated. To use this dosing table, an estimate of the patient's creatinine clearance (CL_{cr}) in ml/min is needed. The CL_{cr} may be estimated from serum creatinine (µmol/l) determination using the following formula:

Table: Dosing adjustment for patients with impaired renal function

$$CL_{cr} \text{ (ml/min)} = \frac{[140 - \text{age}] \times \text{Weight (kg)} \times \text{Constant}^*}{S_{cr} \text{ (}\mu\text{mol/l)}}$$

Constant* = 1,23 in males and = 1,04 in females.

Group	Creatinine clearance (ml/min)	Dosage and frequency
Normal	> 80	500 to 1 500 mg twice daily
Mild	50 – 79	500 to 1 000 mg twice daily
Moderate	30 – 49	250 to 750 mg twice daily
Severe	< 30	250 to 500 mg twice daily
End-stage renal disease patients undergoing dialysis ⁽¹⁾	-	500 to 1 000 mg once daily ⁽²⁾

(1) A 750 mg loading dose is recommended on the first day of treatment with REDILEV.

(2) Following dialysis, a 250 mg to 500 mg supplemental dose is recommended.

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Patients with hepatic impairment:

No dose adjustment is needed in patients with mild to moderate hepatic impairment.

In patients with severe hepatic impairment, the creatinine clearance may underestimate the degree of any accompanying renal insufficiency. Therefore a 50 % reduction of the daily maintenance dose is recommended when the creatinine clearance is < 70 ml/min. (see Patients with renal impairment and section 4.4).

Paediatric population

Infants and children younger than 12 years:

REDILEV should not be used in children younger than 12 years of age.

Method of administration

REDILEV must be taken orally, swallowed with liquid and may be taken with or without food. The daily dose is administered in two equally divided doses.

4.3 CONTRAINDICATIONS

- Hypersensitivity to levetiracetam or other pyrrolidone derivatives or any of the excipients of REDILEV.
- Pregnancy and lactation (see section 4.6).

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Behavioural abnormalities and psychotic symptoms

REDILEV may cause behavioural abnormalities and psychotic symptoms. Patients treated with REDILEV should be monitored for psychiatric signs and symptoms, suggesting important mood and/or personality changes. If such behaviours are noticed, treatment adaptation or gradual discontinuation should be considered. If discontinuation is considered, please refer to section 4.2.

Suicidal behaviour and ideation

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Antiepileptic drugs (AEDs), including REDILEV, increase the risk of suicidal thoughts or behaviour in patients taking these medicines. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behaviour, and/or any unusual changes in mood or behaviour.

Medical practitioners considering prescribing REDILEV or any other AED must balance the risk of suicidal thoughts or behaviours with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behaviour.

Should suicidal thoughts and behaviour emerge during treatment, the medical practitioner needs to consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

Somnolence and Fatigue

REDILEV may cause somnolence and fatigue. Patients should be monitored for these signs and symptoms and advised not to drive or operate machinery until they have gained sufficient experience on REDILEV to gauge whether it adversely affects their ability to drive or operate machinery.

Anaphylaxis and Angioedema

REDILEV can cause anaphylaxis or angioedema after the first dose or at any time during treatment. Signs and symptoms in cases reported in the post marketing setting have included hypotension, hives, rash, respiratory distress, and swelling of the face, lip, mouth, eye, tongue, throat, and feet. In some reported cases, reactions were life-threatening and required emergency treatment. If a patient develops signs or symptoms of anaphylaxis or angioedema, REDILEV should be discontinued and the patient should seek immediate medical attention.

REDILEV should be discontinued permanently if a clear alternative etiology for the reaction cannot be established.

Serious Dermatological Reactions

Serious dermatological reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in both paediatric and adult patients treated with REDILEV. The median time of onset is reported to be 14 to 17 days, but cases have been reported at least four months after initiation of treatment.

Recurrence of the serious skin reactions following rechallenge with REDILEV has also been reported. REDILEV should be discontinued at the first sign of a rash, unless the rash is clearly not drug-related. If signs or symptoms suggest SJS/TEN, use of this drug should not be resumed and alternative therapy should be considered.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan Hypersensitivity

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Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as multiorgan hypersensitivity, has been reported in patients taking antiepileptic medicines, including REDILEV. These events can be fatal or life-threatening, particularly if diagnosis and treatment do not occur as early as possible. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling, in association with other organ system involvement, such as hepatitis, nephritis, haematological abnormalities, myocarditis, or myositis, sometimes resembling an acute viral infection. Eosinophilia is often present. Because this disorder is variable in its expression, other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately. REDILEV should be discontinued if an alternative etiology for the signs or symptoms cannot be established.

Coordination difficulties

REDILEV may cause coordination difficulties. Patients should be monitored for these signs and symptoms and advised not to drive or operate machinery until they have gained sufficient experience on REDILEV to gauge whether it could adversely affect their ability to drive or operate machinery.

Withdrawal seizures

As with most antiepileptic medicines, REDILEV should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus. If withdrawal is needed because of a serious adverse reaction, rapid discontinuation can be considered.

Haematologic Abnormalities

REDILEV can cause hematologic abnormalities. Hematologic abnormalities included decreases in white blood cell (WBC), neutrophil, and red blood cell (RBC) counts; decreases in haemoglobin and haematocrit; and increases in eosinophil counts. Cases of agranulocytosis, pancytopenia, and thrombocytopenia have been reported in the post marketing setting. A complete blood count is recommended in patients experiencing significant weakness, pyrexia, recurrent infections, or coagulation disorders.

Seizure Control During Pregnancy

Physiological changes may gradually decrease plasma levels of levetiracetam throughout pregnancy. This decrease is more pronounced during the third trimester. It is recommended that patients be monitored carefully

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during pregnancy. Close monitoring should continue through the postpartum period especially if the dose was changed during pregnancy.

Renal impairment

The administration of levetiracetam to patients with renal impairment may require dose adjustment. In patients with severely impaired hepatic function, assessment of renal function is recommended before dose selection (see section 4.2).

Acute Kidney injury

The use of levetiracetam has been very rarely associated with acute kidney injury, with a time to onset ranging from a few days to several months.

Electrocardiogram QT interval prolongation

Rare cases of ECG QT interval prolongation have been observed during post-marketing surveillance. Levetiracetam should be used with caution in patients with QTc-interval prolongation, in patients concomitantly treated with drugs affecting the QTc-interval, or in patients with relevant pre-existing cardiac disease or electrolyte disturbances.

Worsening of seizures

As with other types of antiepileptic medicines, levetiracetam may rarely exacerbate seizure frequency or severity. This paradoxical effect was mostly reported within the first month after levetiracetam initiation or increase of the dose, and was reversible upon drug discontinuation or dose decrease. Patients should be advised to consult their physician immediately in case of aggravation of epilepsy. Lack of efficacy or seizure worsening has for example been reported in patients with epilepsy associated with sodium voltage-gated channel alpha subunit 8 (SCN8A) mutations.

REDILEV should be used with caution in patients with severe hepatic impairment. No dose adjustment is needed in patients with mild to moderate hepatic impairment. For patients with severe hepatic impairment, see section 4.2.

4.5 INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Antiepileptic medicines

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Levetiracetam did not influence the serum concentrations of existing antiepileptic medicines (phenytoin, carbamazepine, valproic acid, phenobarbital, lamotrigine, gabapentin and primidone) and that these antiepileptic medicines did not influence the pharmacokinetics of levetiracetam.

As in adults, there is no evidence of clinically significant medicine interactions in paediatric patients receiving up to 60 mg/kg/day levetiracetam.

A retrospective assessment of pharmacokinetic interactions in children and adolescents with epilepsy (4 to 17 years) confirmed that adjunctive therapy with orally administered levetiracetam did not influence the steady-state serum concentrations of concomitantly administered carbamazepine and valproate. However, data suggested a 20 % higher levetiracetam clearance in children taking enzyme-inducing antiepileptic medicines. Dose adjustment is not required.

Probenecid

Probenecid (500 mg four times daily), a renal tubular secretion blocking agent, has been shown to inhibit the renal clearance of the primary metabolite, but not of levetiracetam. Nevertheless, the concentration of this metabolite remains low.

Methotrexate

Concomitant administration of levetiracetam and methotrexate has been reported to decrease methotrexate clearance, resulting in increased/prolonged blood methotrexate concentration to potentially toxic levels. Blood methotrexate and levetiracetam levels should be carefully monitored in patients treated concomitantly with the two medicines.

Oral contraceptives and other pharmacokinetics interactions

Levetiracetam 1000 mg daily did not influence the pharmacokinetics of oral contraceptives (ethinyl-estradiol and levonorgestrel); endocrine parameters (luteinizing hormone and progesterone) were not modified. Levetiracetam 2000 mg daily did not influence the pharmacokinetics of digoxin and warfarin; prothrombin times were not modified. Co-administration with digoxin, oral contraceptives and warfarin did not influence the pharmacokinetics of levetiracetam.

Laxatives

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There have been isolated reports of decreased levetiracetam efficacy when the osmotic laxative macrogol has been concomitantly administered with oral levetiracetam. Therefore, macrogol should not be taken orally for one hour before and for one hour after taking levetiracetam.

Food and alcohol

The extent of absorption of levetiracetam was not altered by food, but the rate of absorption was slightly reduced. No data on the interaction of levetiracetam with alcohol are available.

No information on the influence of antacids on the absorption of levetiracetam is available.

4.6 FERTILITY, PREGNANCY AND LACTATION

Women of child bearing potential

Specialist advice should be given to women who are of childbearing potential. Treatment with levetiracetam should be reviewed when a woman is planning to become pregnant. As with all antiepileptic medicines, sudden discontinuation of levetiracetam should be avoided as this may lead to breakthrough seizures that could have serious consequences for the woman and the unborn child. Monotherapy should be preferred whenever possible because therapy with multiple antiepileptic medicines could be associated with a higher risk of congenital malformations than monotherapy, depending on the associated antiepileptics.

Pregnancy

There is no information on the use of levetiracetam during pregnancy. Animal studies have shown reproductive toxicity. Therefore, REDILEV is contraindicated in pregnancy and lactation (see section 4.3).

Breastfeeding

Levetiracetam is excreted in human breast milk and therefore patients using REDILEV should not breastfeed.

Fertility

No impact on fertility was detected in animal studies. No clinical data are available, potential risk for human is unknown.

4.7 Effects on ability to drive and use machines

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Due to possible different individual sensitivity, some patients might experience, at the beginning of treatment with REDILEV or following a dosage increase, somnolence or other CNS related symptoms. Therefore, caution is recommended in those patients when performing skilled tasks, eg. driving vehicles or operating machinery.

4.8 UNDESIRABLE EFFECTS

a. Summary of the safety profile

The most frequently reported adverse reactions were nasopharyngitis, somnolence, headache, fatigue and dizziness.

b. Tabulated list of adverse reactions

System Organ Class	Frequency	Adverse effect
Infections and infestations	Frequent	Nasopharyngitis
	Less frequent	Infection
Blood and lymphatic system disorders	Less frequent	Thrombocytopenia, leukopenia, pancytopenia, neutropenia, agranulocytosis
	Less frequent	Drug reaction with eosinophilia and systemic symptoms (DRESS), hypersensitivity (including angioedema and anaphylaxis)
Metabolism and nutrition disorders	Frequent	Anorexia
	Less frequent	Weight decreased, weight increase, hyponatremia
Psychiatric disorders	Frequent	Depression, hostility/aggression, anxiety, insomnia, nervousness/irritability
	Less frequent	Suicide attempt, suicidal ideation, psychotic disorder, abnormal behaviour, hallucination, anger, confusional state, panic attack, affect lability/mood swings, agitation, completed

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		suicide, personality disorder, thinking abnormal, delirium, obsessive compulsive disorder**
Nervous system disorders	Frequent	Somnolence, headache, convulsion, balance disorder, dizziness, lethargy, tremor
	Less frequent	Amnesia, memory impairment, coordination abnormal/ataxia, paraesthesia, disturbance in attention, choreoathetosis, dyskinesia, hyperkinesia, gait disturbance, encephalopathy, seizures aggravated
Eye disorders	Less frequent	Diplopia, vision blurred
Ear and labyrinth disorders	Frequent	Vertigo
Cardiac disorders	Less frequent	Electrocardiogram QT prolonged
Respiratory, thoracic and mediastinal disorders	Frequent	Cough
Gastrointestinal disorders	Frequent	Abdominal pain, diarrhoea, dyspepsia, vomiting, nausea
	Less frequent	Pancreatitis
Hepatobiliary disorders	Less frequent	Liver function test abnormal, hepatic failure, hepatitis
Renal and Urinary disorders	Less frequent	Acute kidney injury
Skin and subcutaneous tissue disorders	Frequent	Rash
	Less frequent	Alopecia, eczema, pruritus, Toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme

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Musculoskeletal and connective tissue disorders*	Less frequent	Muscular weakness, myalgia, rhabdomyolysis and blood creatine phosphokinase increased*
General disorders and administration site conditions*	Frequent	Asthenia/fatigue
Injury, poisoning and procedural complications	Less frequent	Injury

* Prevalence is significantly higher in Japanese patients when compared to non-Japanese patients. Evidence also suggests a possible predisposition of the Japanese population to neuroleptic malignant syndrome (NMS).

**Very rare cases of development of obsessive-compulsive disorders (OCD) in patients with underlying history of OCD or psychiatric disorders have been observed in post-marketing surveillance.

c. Description of selected adverse reactions

The risk of anorexia is higher when levetiracetam is co-administered with topiramate.

In several cases of alopecia, recovery was observed when levetiracetam was discontinued.

Bone marrow suppression was identified in some of the cases of pancytopenia.

Cases of encephalopathy generally occurred at the beginning of the treatment (few days to a few months) and were reversible after treatment discontinuation.

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Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

For any information about this medicine, including adverse reaction reporting, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100

4.9 OVERDOSE

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

In acute overdosage the stomach may be emptied by induction of emesis. There is no specific antidote for REDILEV. Treatment for an overdose will be symptomatic and may include haemodialysis. The dialyser extraction efficiency is 60 % for levetiracetam and 74 % for the metabolite ucb L057.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Antiepileptics, other antiepileptics

ATC code: N03AX14

Pharmacological classification: A 2.5 Anticonvulsants, including anti-epileptics

Levetiracetam has anti-seizure properties. Levetiracetam is a pyrrolidone derivative (S-enantiomer of α -ethyl-2-oxo-1-pyrrolidine acetamide), chemically unrelated to existing anti-epileptic active substances.

The precise mechanism of action by which levetiracetam induces seizure protection is unknown. *In vitro* and *in vivo* experiments suggest that levetiracetam does not alter basic cell characteristics and normal neurotransmission. The mechanism of action may relate to an interaction with a specific and stereoselective binding site that is only found within the central nervous system.

5.2 PHARMACOKINETIC PROPERTIES

The pharmacokinetic profile is dose linear with low intra- and inter-subject variability. 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.

Absorption

Levetiracetam is rapidly and almost completely absorbed after oral administration. Peak plasma concentrations (C_{max}) are achieved at 1,3 hours after dosing. The extent of absorption is dose-independent and is not altered by food. Steady-state is achieved after two days on a twice daily administration schedule. Peak concentrations (C_{max})

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are typically 31 and 43 µg/ml, following a single 1 000 mg dose and repeated 1000 mg twice-daily dose, respectively.

Distribution

No tissue distribution data are available in humans. Neither levetiracetam nor its major metabolite are significantly bound to plasma proteins (< 10 %). The volume of distribution of levetiracetam is approximately 0,5 to 0,7 litres/kg, a value close to the volume of distribution of intracellular and extracellular water.

Metabolism

The major metabolic pathway (24 % of the dose) is an enzymatic hydrolysis of the acetamide group. Production of this metabolite does not involve the liver cytochrome P450 isoforms. Hydrolysis of the acetamide group was measurable in a large number of tissues including whole blood but not plasma. 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 major metabolite.

Elimination

The plasma half-life in adults was 7 hours ± 1 hour and did not vary with dose, route of administration or repeated administration. The total body clearance was a mean of 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 major metabolite accounted for 66 % and 24 % of the dose, respectively during the first 48 hours. The renal clearance of levetiracetam and its metabolite 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 major metabolite is also excreted by active tubular secretion in addition to glomerular filtration. In the elderly the half-life is increased by about 40 % [10 to 11 hours]. This is related to the decrease in renal function in this population. Following single dose administration (20 mg/kg) to epileptic children 6 to 12 years, the half-life of levetiracetam was 6,0 hours.

The apparent clearance was approximately 30 % higher than in epileptic adults. The apparent body clearance of both levetiracetam and of its metabolite is correlated to the creatinine clearance. It is therefore recommended to

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adjust the maintenance daily dose of levetiracetam, based on creatinine clearance in patients with moderate and severe renal impairment. In anuric end-stage renal disease subjects, the half-life was approximately 25 and 3,1 hours during interdialytic and intradialytic periods respectively. The fractional removal of levetiracetam was 51 % during a typical 4-hour dialysis session. In subjects with mild and moderate hepatic impairment, there was no relevant modification of the clearance of levetiracetam. In most subjects with severe hepatic impairment, the clearance of levetiracetam was reduced by more than 50 % due to a concomitant renal impairment.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Tablet core:

Colloidal silicon dioxide, corn starch, hypromellose, macrogol, magnesium stearate, microcrystalline cellulose, povidone, purified talc, sodium starch glycolate and titanium dioxide.

Film-coating:

REDILEV 250 contains FD&C Blue #2/Indigo carmine aluminium lake and polysorbate 80.

REDILEV 500 contains iron oxide black and iron oxide yellow.

REDILEV 750 contains iron oxide red.

6.2 INCOMPATIBILITIES

Not applicable

6.3 SHELF LIFE

36 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store at or below 25 °C in a dry place.

Keep the tablets in the original bottle and keep well closed.

Keep the tablets in the blisters and the blisters in the carton until required for use.

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KEEP OUT OF THE REACH OF CHILDREN.

6.5 NATURE AND CONTENTS OF CONTAINER

REDILEV 250, 500 and 750:

30, 120, 240 or 500 film-coated tablets in white opaque HDPE bottles with white, opaque, ribbed plastic caps with pulp liners. Packed in printed outer cardboard cartons: 20, 30 or 50 tablets as 2, 3, or 5 blister strips of 10 tablets each. The blisters are comprised of clear, transparent PVC (PVdC coated on one side) and silver coloured (paper backed) aluminium foil.

Not all strengths and pack sizes may be marketed.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

Any unused product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Dr. Reddy's Laboratories (Pty) Ltd.

Block B, 204 Rivonia Road

Morningside

Sandton

2057

8. REGISTRATION NUMBER

REDILEV 250: 41/2.5/0460

REDILEV 500: 41/2.5/0461

REDILEV 750: 41/2.5/0462

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

25 November 2016

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10. DATE OF REVISION OF TEXT

02 December 2024