Concentrate for solution for infusion

Levetiracetam

What is in this leaflet:
1. What Desitrend is and what it is used for
2. What you need to know before you are given Desitrend
3. How Desitrend is given
4. Possible side effects
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1. What Desitrend is and what it is used for

Levetiracetam is an antiepileptic medicine (a medicine used to treat seizures in epilepsy).

Levetiracetam can be used during pregnancy, only if doctor for advice before taking this medicine.

If you are pregnant or breast-feeding, think you may recently taken or might take any other medicines, your seizures may rarely become worse or happen more often, mainly during the first month after the start of treatment.

Talk to your doctor before you are given Desitrend, see a doctor as soon as possible.

What is this leaflet:
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if the patient uses it for a different condition.

- If you have any further questions, ask your doctor or pharmacist.

Desitrend is used:
- as an add-on to other antiepileptic medicines to reduce the number of fits.
- on its own in adults and adolescents from 16 years of age with newly diagnosed epilepsy, to treat a certain form of epilepsy. Epilepsy is a condition where the patients have repeated fits (seizures). Levetiracetam is used for the epilepsy form in which the fits initially affect only one side of the brain (primary generalised tonic-clonic seizures) or on both sides of the brain (partial onset seizures with or without secondary generalisation).

Levetiracetam is given to you by your doctor to reduce the number of fits.

3. How Desitrend is given

A doctor or nurse will prescribe you a lower dose (500 mg each day) during 2 weeks before giving you the lowest general dose of 1,000 mg.

Desitrend contains sodium
This medicine contains 53 mg sodium (main component of cooking/table salt) in each maximum single dose.

The recommended dose must be diluted to 2.7 % of the recommended maximum daily intake of sodium for an adult.

Adults (≥18 years) and adolescents (12 to 17 years) weighing 50 kg or more: General dose between 250 mg and 3,000 mg each day. When you will first start taking Desitrend, your doctor will prescribe you a lower dose (500 mg each day) during 2 weeks before giving you the lowest general dose of 1,000 mg.

Dose in children (4 to 11 years) and adolescents (12 to 17 years) weighing less than 50 kg: General dose: between 20 mg per kg body weight and 60 mg per kg body weight each day.

Method and route of administration:
Desitrend is for intravenous use.

Desitrend must be administered twice a day, in the morning and once in the evening, at about the same time each day.

The intravenous formulation is an alternative to your intramuscular injection.

You should not stop your treatment without discussing this with your doctor. Risk of both detected or your unborn child cannot be completely excluded.

Feeding: is not recommended during treatment.

Driving and using machines:
Desitrend may impair your ability to drive or operate any tools or machinery, as it may make you feel sleepy. This is more likely at the beginning of treatment or after an increase in the dose. You should not drive or use machines until it is established that your ability to perform such activities is not affected.

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4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you stop using Desitrend:
Intravenous and oral Desitrend should be discontinued grad- ually over a period of 4 days.

If you experience any of the following symptoms while taking the antiepileptic oral Desitrend medicine is temporarily dose should be adjusted.

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• a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome);
• more severe form of rash causing skin peeling in more than 30% of the body surface (toxic epidermal necrolysis);
• signs of systemic mental changes or if someone around you notices signs of confusion, somnolence (smaller signs of mental confusion or impairment (forgetfulness), abnormal behaviour or other neurological signs including involuntary or uncontrolled movements. These could be symp-
toms of an encephalopathy.
• suicide attempt and suicidal ideation.

The most frequently reported adverse reactions were:
• lactated Ringer’s solution for injection.

Diluents:
• NaCl 0.9% injection (three 5 ml ampoules)

Volume Diluent Time Administration Dose
1,500 mg 15 ml 100 ml 15 minutes twice daily 3,000 mg/day
1,000 mg 10 ml 100 ml 15 minutes twice daily 2,000 mg/day
500 mg 5 ml 100 ml 15 minutes twice daily 1,000 mg/day

Table 1. Preparation and administration of Desitrend concentrate

The table presented above contains the following dosages for Desitrend:

• seizures may become worse or happen more frequently;
• uncontrollable muscle spasms affecting the head, limbs and lips; difficulty in controlling move-
mements, hyperkinesia (hyperactivity);
• change of the heart rhythm (Electrocardiogram);
• pancreatic enzyme deficiency;
• liver failure, hepatitis (with e.g. flu-like symptoms, jaundice, upper right abdominal pain, yellow skin and eyes);
• sudden decrease in kidney function;
• rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge (erythema multiforme)), a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form causing skin peeling in more than 35% of the body surface (toxic epidermal necrolysis);
• rhabdomyolysis (breakdown of muscle tissue) and associated blood creatine phosphokinase increase. Prevalence is significantly higher in Japa-
nese patients when compared to non-Japanese Desitrend users;
• imp or difficulty walking.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: Web-
site: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Desitrend
Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the ampoules and card box after D:

The expiry data refers to the last day of the month. Do not refrigerate.

Do not use this medicine if you notice particulate matter or discolouration.

6. Contents of the pack and other information
What Desitrend contains
This medicine contains 500 mg of levetiracetam.

The 5 ml ampoule contains 500 mg of levetiracetam.

The other ingredients are: sodium acetate trihydrate, glacial acetic acid, sodium chloride, water for injec-
tion.

Volume Diluent Time Administration Dose
250 mg 1.5 ml (half 5 ml ampoule) 150 ml 15 minutes twice daily 500 mg/day
500 mg 5 ml (one 5 ml ampoule) 150 ml 15 minutes twice daily 1,000 mg/day
1,000 mg 10 ml (two 5 ml ampoules) 150 ml 15 minutes twice daily 2,000 mg/day
1,500 mg 15 ml (three 5 ml ampoules) 150 ml 15 minutes twice daily 3,000 mg/day

This medicinal product is for single use only, any unused solution should be discarded.

In-use shelf life: Chemical and physical in-use stability has been demonstrated for 24 hours at 25 °C. From in-use shelf life: Chemical and physical in-use stability has been demonstrated for 24 hours at 25 °C.

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