



PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Desitrend[®] 100 mg/ml oral solution

Levetiracetam

Read all of this leaflet carefully before you or your child start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Desitrend is and what it is used for
2. What you need to know before you take Desitrend
3. How to take Desitrend
4. Possible side effects
5. How to store Desitrend
6. Contents of the pack and other information

1. What Desitrend is and what it is used for

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

Desitrend is used:

- 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, but could thereafter extend to larger areas on both sides of the brain (partial onset seizure with or without secondary generalisation). Levetiracetam has been given to you by your doctor to reduce the number of fits.
- as an add-on to other antiepileptic medicines to treat:
 - partial onset seizures with or without generalisation in adults, adolescents, children and infants from one month of age
 - myoclonic seizures (short, shock-like jerks of a muscle or group of muscles) in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy
 - primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in adults and adolescents from 12 years of age with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

2. What you need to know before you take**Desitrend****Do not take Desitrend**

- if you are allergic to levetiracetam, pyrrolidone derivatives or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before taking Desitrend

- If you suffer from kidney problems, follow your doctor's instructions. He/she may decide if your dose should be adjusted.
- If you notice any slow down in the growth or unexpected puberty development of your child, please contact your doctor.
- A small number of people being treated with anti-epileptics such as Desitrend have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.

Children and adolescents

Desitrend is not indicated in children and adolescents below 16 years on its own (monotherapy).

Other medicines and Desitrend

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take macrogol (a drug used as laxative) for one hour before and one hour after taking levetiracetam as this may result in a reduction of its effect.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Desitrend should not be used during pregnancy unless clearly necessary. A risk of birth defects for your unborn child cannot be completely excluded. Desitrend has shown unwanted reproductive effects in animal studies at dose levels higher than you would need to control your seizures. Breast-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.

Desitrend contains methyl parahydroxybenzoate, propyl parahydroxybenzoate and maltitol

Desitrend oral solution includes methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

Desitrend oral solution also contains maltitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Desitrend

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

Take the oral solution following your doctor's instructions.

Monotherapy**Dose in adults and adolescents (from 16 years of age):**

Measure the appropriate dosage using the **10 ml syringe**.

General dose: Desitrend is taken twice daily, in two equally divided doses, each individual dose being measured between 5 ml (500 mg) and 15 ml (1,500 mg).

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.

Add-on therapy**Dose in adults and adolescents (12 to 17 years) weighing 50 kg or more:**

Measure the appropriate dosage using the **10 ml syringe**.

General dose: Desitrend is taken twice daily, in two equally divided doses, each individual dose being measured between 5 ml (500 mg) and 15 ml (1,500 mg).

Dose in children 6 months and older:

For dosages of up to 2.5 ml (250 mg), use the 1 ml syringe.

For dosages of more than 2.5 ml (250 mg), use the 10 ml syringe.

Both syringes, **1 ml and 10 ml**, are included in the package.

General dose: Desitrend is taken twice daily, in two equally divided doses, each individual dose being measured between 0.1 ml (10 mg) and 0.3 ml (30 mg), per kg bodyweight of the child (see table below for dose examples).

Dose in children 6 months and older:

Weight	Starting dose: 0.1 ml/kg twice daily	Suitable syringe size		Maximum dose: 0.3 ml/kg twice daily	Suitable syringe size	
		1ml	10ml		1ml	10ml
6 kg	0.6 ml twice daily	yes	no	1.8 ml twice daily	yes	no
8 kg	0.8 ml twice daily	yes	no	2.4 ml twice daily	yes	no
10 kg	1 ml twice daily	yes	no	3 ml twice daily	no	yes
15 kg	1.5 ml twice daily	yes	no	4.5 ml twice daily	no	yes
20 kg	2 ml twice daily	yes	no	6 ml twice daily	no	yes
25 kg	2.5 ml twice daily	no	yes	7.5 ml twice daily	no	yes
From 50 kg	5 ml twice daily	no	yes	15 ml twice daily	no	yes

Dose in infants**(1 month to less than 6 months):**

For infants 1 month to less than 6 months, measure the appropriate dosage using the **1 ml syringe**.

General dose: Desitrend is taken twice daily, in two equally divided doses, each individual dose being measured between 0.07 ml (7 mg) and 0.21 ml (21 mg), per kg bodyweight of the infant (see table below for dose examples).

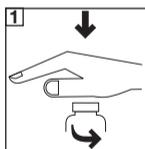
Dose in infants (1 month to less than 6 months):

Weight	Starting dose:		Maximum dose:	
	0.07 ml/kg twice daily		0.21 ml/kg twice daily	
4 kg	0.3 ml twice daily		0.85 ml twice daily	
5 kg	0.35 ml twice daily		1.05 ml twice daily	
6 kg	0.45 ml twice daily		1.25 ml twice daily	
7 kg	0.5 ml twice daily		1.5 ml twice daily	

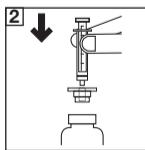
Method of administration:

After measuring the correct dose with an appropriate syringe, Desitrend oral solution may be diluted in a glass of water or baby's bottle. You may take Desitrend oral solution with or without food.

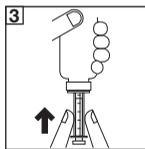
Instructions for use:



- Open the bottle: press the cap and turn it anticlockwise (figure 1).
- Choose the syringe and adaptor suitable for your dosage (see dosage information).

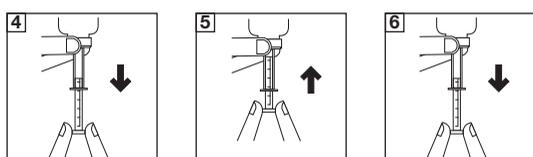


- Insert the syringe adaptor into the bottle neck (figure 2). Ensure it is well fixed.
- Take the syringe and put it in the adaptor opening (figure 2).

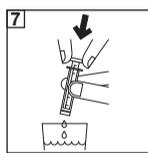


- Turn the bottle upside down (figure 3).



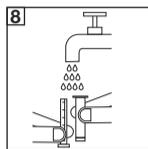


- Fill the syringe with a small amount of solution by pulling the piston down (figure 4), then push the piston upward in order to remove any possible bubble (figure 5). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 6).
- Turn the bottle the right way up.
- Remove the syringe from the adaptor.



- Empty the contents of the syringe in a glass of water or baby's bottle by pushing the piston to the bottom (figure 7).

- Drink the whole contents of the glass/baby's bottle.



- Close the bottle with the plastic screw cap.
- Wash the syringe with water only (figure 8).

Duration of treatment:

Desitrend is used as a chronic treatment. You should continue Desitrend treatment for as long as your doctor has told you.

Do not stop your treatment without your doctor's advice as this could increase your seizures.

If you take more Desitrend than you should:

The possible side effects of an overdose of Desitrend are sleepiness, agitation, aggression, decrease of alertness, inhibition of breathing and coma.

Contact your doctor if you took more Desitrend than you should. Your doctor will establish the best possible treatment of overdose.

If you forget to take Desitrend:

Contact your doctor if you have missed one or more doses. Do not take a double dose to make up for a forgotten dose.

If you stop taking Desitrend:

If stopping treatment, Desitrend should be discontinued gradually to avoid an increase of seizures.

Should your doctor decide to stop your Desitrend treatment, he/she will instruct you about the gradual withdrawal of Desitrend.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Tell your doctor immediately, or go to your nearest emergency department, if you experience:

- weakness, feel light-headed or dizzy or have difficulty breathing, as these may be signs of a serious allergic (anaphylactic) reaction
- swelling of the face, lips, tongue and throat (Quincke's oedema)
- flu-like symptoms and a rash on the face followed by an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes (Drug Reaction with Eosinophilia and Systemic Symptoms [DRESS])
- symptoms such as low urine volume, tiredness, nausea, vomiting, confusion and swelling in the legs, ankles or feet, as this may be a sign of sudden decrease of kidney function
- a skin rash which may form blisters and look 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*)
- a more severe form of rash causing skin peeling in more than 30% of the body surface (*toxic epidermal necrolysis*)
- signs of serious mental changes or if someone around you notices signs of confusion, somnolence (sleepiness), amnesia (loss of memory), memory impairment (forgetfulness), abnormal behaviour or other neurological signs including involuntary or uncontrolled movements. These could be symptoms of an encephalopathy.

The most frequently reported adverse reactions were nasopharyngitis, somnolence (sleepiness), headache, fatigue and dizziness. At the beginning of the treatment or at dose increase side effects like sleepiness, tiredness and dizziness may be more common. These effects should however decrease over time.

Very common: may affect more than 1 user in 10 people

- nasopharyngitis;
- somnolence (sleepiness), headache.

Common: may affect 1 to 10 users in 100 people

- anorexia (loss of appetite);
- depression, hostility or aggression, anxiety, insomnia, nervousness or irritability;
- convulsion, balance disorder (equilibrium disorder), dizziness (sensation of unsteadiness), lethargy (lack of energy and enthusiasm), tremor (involuntary trembling);
- vertigo (sensation of rotation);
- cough;
- abdominal pain, diarrhoea, dyspepsia (indigestion), vomiting, nausea;
- rash;
- asthenia/fatigue (tiredness).

Uncommon: may affect 1 to 10 users in 1,000 people

- decreased number of blood platelets, decreased number of white blood cells;
- weight decrease, weight increase;
- suicide attempt and suicidal ideation, mental disorder, abnormal behaviour, hallucination, anger, confusion, panic attack, emotional instability/mood swings, agitation;
- amnesia (loss of memory), memory impairment (forgetfulness), abnormal coordination/ataxia (impaired coordinated movements), paraesthesia (tingling), disturbance in attention (loss of concentration);
- diplopia (double vision), vision blurred;
- elevated/abnormal values in a liver function test;
- hair loss, eczema, pruritus;
- muscle weakness, myalgia (muscle pain);
- injury.

Rare: may affect 1 to 10 users in 10,000 people

- infection;
- decreased number of all blood cell types;
- severe allergic reactions (DRESS, anaphylactic reaction [severe and important allergic reaction], Quincke's oedema [swelling of the face, lips, tongue and throat]);
- decreased blood sodium concentration;
- suicide, personality disorders (behavioural problems), thinking abnormal (slow thinking, unable to concentrate);
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity);
- pancreatitis;
- liver failure, hepatitis;
- sudden decrease in kidney function;
- skin 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 30% of the body surface (*toxic epidermal necrolysis*);
- rhabdomyolysis (breakdown of muscle tissue) and associated blood creatine phosphokinase increase. Prevalence is significantly higher in Japanese patients when compared to non-Japanese patients.

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, website: www.mhra.gov.uk/yellowcard. 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 cardboard box and bottle after EXP:. The expiry date refers to the last day of the month. Do not use after 7 months of first opening the bottle.

Store in the original bottle, in order to protect from light.

Store in an upright position.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Desitrend contains

The active substance is levetiracetam. Each ml contains 100 mg of levetiracetam.

The other ingredients are: sodium citrate, citric acid monohydrate, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), ammonium glycyrrhizate, glycerol (E422), maltitol liquid (E965), acesulfame potassium (E950), grapefruit flavour, purified water.

What Desitrend looks like and contents of the pack

Desitrend 100 mg/ml oral solution is a clear liquid.

300 ml solution in an amber glass bottle with a white child resistant closure is packed in a cardboard box containing a 1 ml oral syringe (graduated every 0.05 ml) with adaptor and a 10 ml oral syringe (graduated every 0.25 ml) with adaptor.

Marketing Authorisation Holder

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Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom: Desitrend 100 mg/ml oral solution

This leaflet was last revised in 01/2017.