PATIENT INFORMATION LEAFLET

3174
09.11.23[10]

Desitrend® 250 mg coated granules in sachet

(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.

Your medicine is available using the above name but will be referred to as Desitrend throughout this leaflet. Desitrend is available in other strengths.

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 group or 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 antiepileptics such as levetiracetam have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.
- If you have a family or medical history of irregular heart rhythm (visible on an electrocardiogram), or if you have a disease and/or take a treatment that make(s) you prone to heartbeat irregularities or salt imbalances.

Tell your doctor or pharmacist if any of the following side effects gets serious or last longer than a few days:
- Abnormal thoughts, feeling irritable or reacting more aggressively than usually, or if you or your family and friends notice important changes in mood or behaviour.
- Aggravation of epilepsy
  Your seizures may rarely become worse or happen more often, mainly during the first month after the start of treatment or increase of the dose. If you experience any of these new symptoms while taking Desitrend, see a doctor as soon as possible.

Children and adolescents

Desitrend coated granules are not indicated in children and adolescents below 16 years on its own (monotherapy), and are not recommended in children under the age of 6 years as well as in the initial treatment of children weighing less than 25 kg.

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 loss of its effect.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Levetiracetam can be used during pregnancy, only if after careful assessment it is considered necessary by your doctor.

You should not stop your treatment without discussing this with your doctor. A risk of birth defects for your unborn child cannot be completely excluded.

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.

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.
Take the number of sachets following your doctor's instructions.
Desitrend must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

Adjunctive therapy and monotherapy (from 16 years of age)

Adults (≥18 years) and adolescents (12 to 17 years) weighing 50 kg or more:
- Recommended dose: between 1,000 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 daily dose of 1,000 mg.
Example: if your daily dose is intended to be 1,000 mg, your reduced starting dose is 1 sachet of 250 mg in the morning and 1 sachet of 250 mg in the evening, and the dose will be gradually incremented to reach 1,000 mg daily after 2 weeks.

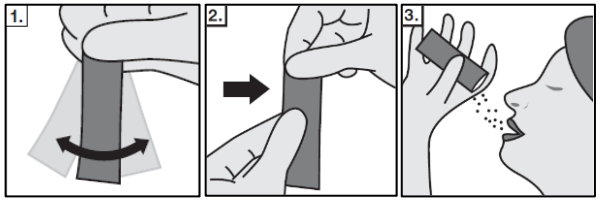
Adolescents (12 to 17 years) weighing 50 kg or less

Your doctor will prescribe the most appropriate pharmaceutical form of Desitrend according to weight and dose.

Dose in infants (1 month to 23 months) and children (2 to 11 years) weighing less than 50 kg

Your doctor will prescribe the most appropriate pharmaceutical form of Desitrend according to the age, weight and dose.
Levetiracetam oral solution is a presentation more appropriate to infants and children under the age of 6 years and to children and adolescents (from 6 to 17 years) weighing less than 50 kg and when sachets don't allow accurate dosage.

Method of administration



1. Hold sachet above arrow and shake content downwards.
2. Tear off at incision (arrowhead) or cut off at dotted line.
3. Pour content directly into the mouth and swallow the granules immediately with a sufficient quantity of liquid (e.g. a glass of water). Do not chew the coated granules, as they may be of bitter taste. You may take Desitrend with or without food.

The coated granules may also be suspended by shaking for a minimum of 2 minutes in at least 10 ml of water and administered via a feeding tube that should be rinsed twice with 10 ml of water each immediately after administration. If this method of administration is used, the suspension should be prepared immediately before administration.

Each sachet is for single use only.

Duration of treatment
- Desitrend is used as 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 sachets 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
- suicide attempt and suicidal ideation.

The most frequently reported side effects are 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 in 10 people
- nasopharyngitis (with e.g. runny or stuffy nose, sore or scratchy throat);
- somnolence (sleepiness), headache.

Common: may affect up to 1 in 10 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 up to 1 in 100 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 up to 1 in 1,000 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);
- delirium (acute confusional state);
- encephalopathy (brain disease, see sub-section "Tell your doctor immediately" for a detailed description of symptoms);
- seizures may become worse or happen more often;
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity);
- change of the heart rhythm (Electrocardiogram);
- pancreatitis (inflammation of the pancreas);
- liver failure, hepatitis (with e.g. flu-like symptoms, pain in the right upper waist, yellow skin and eyes);
- 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.
- limp or difficulty walking.

Evidence also suggests a possible predisposition of the Japanese population to neuroleptic malignant syndrome (NMS).

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 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 carton box and sachet after EXP:. The expiry date refers to the last day of the month.
- This medicine does not require any special storage conditions.
- If the contents of the sachets become discoloured or show signs of any deterioration you should seek the advice of your pharmacist.
- Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information
The active substance is levetiracetam.
Each sachet contains 250 mg of levetiracetam.
The other ingredients are: Povidone K30, Cellulose microcrystalline Silica colloidal anhydrous, Magnesium stearate, Polyvinyl alcohol, Titanium dioxide, Macrogol 3350 and Talc.

What Desitrend looks like and contents of the pack
Coated granules in sachets; the coated granules are white or almost white and round (diameter approx. 2 mm).
Desitrend coated granules are available in pack sizes of 30, 50 and 60 sachets.
Not all pack sizes may be marketed.

Manufacturer and product licence holder
Manufactured by Desitin Arzneimittel GmbH Weg beim Jaeger 214, Hamburg, D-22335 Germany.
Procured from the EU by product licence holder: Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

POM PL 20636/3174

Leaflet revision and issue date ref: 09.11.23[10]

Blind or partially sighted?
Is this leaflet hard to see or read?
Call 020 8423 2111 to obtain the leaflet in a format suitable for you.

PATIENT INFORMATION LEAFLET

3174
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Levetiracetam Star 250 mg coated granules in sachet

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.

Your medicine is available using the above name but will be referred to as Levetiracetam throughout this leaflet. Levetiracetam is available in other strengths.

What is in this leaflet

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

1. What Levetiracetam is and what it is used for

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

Do not take Levetiracetam
- 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 Levetiracetam
- 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 antiepileptics such as levetiracetam have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.
- If you have a family or medical history of irregular heart rhythm (visible on an electrocardiogram), or if you have a disease and/or take a treatment that make(s) you prone to heartbeat irregularities or salt imbalances.

Tell your doctor or pharmacist if any of the following side effects gets serious or last longer than a few days:
- Abnormal thoughts, feeling irritable or reacting more aggressively than usually, or if you or your family and friends notice important changes in mood or behaviour.
- Aggravation of epilepsy
  Your seizures may rarely become worse or happen more often, mainly during the first month after the start of treatment or increase of the dose. If you experience any of these new symptoms while taking Levetiracetam, see a doctor as soon as possible.

Children and adolescents

Levetiracetam coated granules are not indicated in children and adolescents below 16 years on its own (monotherapy), and are not recommended in
children under the age of 6 years as well as in the initial treatment of children weighing less than 25 kg.

Other medicines and Levetiracetam

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 loss of its effect.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Levetiracetam can be used during pregnancy, only if after careful assessment it is considered necessary by your doctor.

You should not stop your treatment without discussing this with your doctor. A risk of birth defects for your unborn child cannot be completely excluded.

Breast-feeding is not recommended during treatment.

Driving and using machines

Levetiracetam 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.

3. How to take Levetiracetam

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Take the number of sachets following your doctor's instructions.
Levetiracetam must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

Adjunctive therapy and monotherapy (from 16 years of age)

Adults (≥18 years) and adolescents (12 to 17 years) weighing 50 kg or more:
- Recommended dose: between 1,000 mg and 3,000 mg each day.

When you will first start taking Levetiracetam, your doctor will prescribe you a lower dose (500 mg each day) during 2 weeks before giving you the lowest daily dose of 1,000 mg.
Example: if your daily dose is intended to be 1,000 mg, your reduced starting dose is 1 sachet of 250 mg in the morning and 1 sachet of 250 mg in the evening, and the dose will be gradually incremented to reach 1,000 mg daily after 2 weeks.

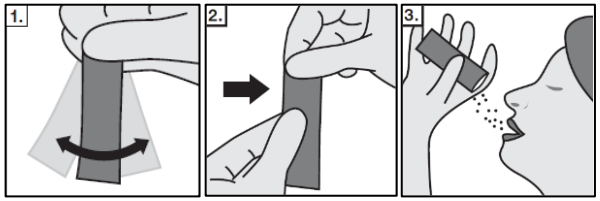
Adolescents (12 to 17 years) weighing 50 kg or less

Your doctor will prescribe the most appropriate pharmaceutical form of Levetiracetam according to weight and dose.

Dose in infants (1 month to 23 months) and children (2 to 11 years) weighing less than 50 kg

Your doctor will prescribe the most appropriate pharmaceutical form of Levetiracetam according to the age, weight and dose.
Levetiracetam oral solution is a presentation more appropriate to infants and children under the age of 6 years and to children and adolescents (from 6 to 17 years) weighing less than 50 kg and when sachets don't allow accurate dosage.

Method of administration



1. Hold sachet above arrow and shake content downwards.
2. Tear off at incision (arrowhead) or cut off at dotted line.
3. Pour content directly into the mouth and swallow the granules immediately with a sufficient quantity of liquid (e.g. a glass of water). Do not chew the coated granules, as they may be of bitter taste. You may take Levetiracetam with or without food.

The coated granules may also be suspended by shaking for a minimum of 2 minutes in at least 10 ml of water and administered via a feeding tube that should be rinsed twice with 10 ml of water each immediately after administration. If this method of administration is used, the suspension should be prepared immediately before administration.

Each sachet is for single use only.

Duration of treatment
- Levetiracetam is used as chronic treatment. You should continue Levetiracetam 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 Levetiracetam than you should
The possible side effects of an overdose of Levetiracetam are sleepiness, agitation, aggression, decrease of alertness, inhibition of breathing and coma. Contact your doctor if you took more sachets than you should. Your doctor will establish the best possible treatment of overdose.

If you forget to take Levetiracetam
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 Levetiracetam
If stopping treatment, Levetiracetam should be discontinued gradually to avoid an increase of seizures. Should your doctor decide to stop your Levetiracetam treatment, he/she will instruct you about the gradual withdrawal of Levetiracetam.
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
- suicide attempt and suicidal ideation.

The most frequently reported side effects are 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 in 10 people
- nasopharyngitis (with e.g. runny or stuffy nose, sore or scratchy throat);
- somnolence (sleepiness), headache.

Common: may affect up to 1 in 10 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 up to 1 in 100 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 up to 1 in 1,000 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);
- delirium (acute confusional state);
- encephalopathy (brain disease, see sub-section "Tell your doctor immediately" for a detailed description of symptoms);
- seizures may become worse or happen more often;
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity);
- change of the heart rhythm (Electrocardiogram);
- pancreatitis (inflammation of the pancreas);
- liver failure, hepatitis (with e.g. flu-like symptoms, pain in the right upper waist, yellow skin and eyes);
- 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.
- limp or difficulty walking.

Evidence also suggests a possible predisposition of the Japanese population to neuroleptic malignant syndrome (NMS).

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 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 Levetiracetam
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date stated on the carton box and sachet after EXP:. The expiry date refers to the last day of the month.
- This medicine does not require any special storage conditions.
- If the contents of the sachets become discoloured or show signs of any deterioration you should seek the advice of your pharmacist.
- Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information
The active substance is levetiracetam.
Each sachet contains 250 mg of levetiracetam.
The other ingredients are: Povidone K30, Cellulose microcrystalline Silica colloidal anhydrous, Magnesium stearate, Polyvinyl alcohol, Titanium dioxide, Macrogol 3350 and Talc.

What Levetiracetam looks like and contents of the pack
Coated granules in sachets; the coated granules are white or almost white and round (diameter approx. 2 mm).
Levetiracetam coated granules are available in pack sizes of 30, 50 and 60 sachets.
Not all pack sizes may be marketed.

Manufacturer and product licence holder
Manufactured by Desitin Arzneimittel GmbH Weg beim Jaeger 214, Hamburg, D-22335 Germany.
Procured from the EU by product licence holder: Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

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