PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Levetiracetam Sciecure 250 mg film-coated tablets
Levetiracetam Sciecure 500 mg film-coated tablets
Levetiracetam Sciecure 750 mg film-coated tablets
Levetiracetam Sciecure 1000 mg film-coated tablets

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 Levetiracetam Sciecure is and what it is used for

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

Levetiracetam Sciecure 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 Levetiracetam Sciecure

Do not take Levetiracetam Sciecure
- 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 Sciecure
- 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 levetiracetam 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
- Levetiracetam Sciecure is not indicated in children and adolescents below 16 years on its own (monotherapy).

Other medicines and Levetiracetam Sciecure
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 results in a loss 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.
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 Sciecure 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.

Levetiracetam Sciecure 250 mg, 750 mg tablets contain Sunset Yellow FCF (E110).
Sunset Yellow FCF (E110) colouring agent may cause allergic reactions.
The other strengths of Levetiracetam tablets do not contain this ingredient.

Levetiracetam Sciecure 1000 mg tablets contain lactose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product
The other strengths of Levetiracetam tablets do not contain this ingredient.

3. How to take Levetiracetam Sciecure

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 tablets following your doctor's instructions.
Levetiracetam Sciecure must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

Monotherapy
- **Dose in adults and adolescents (from 16 years of age):**
  General dose: between 1000 mg and 3,000 mg each day.
  When you will first start taking Levetiracetam, your doctor will prescribe you a lower dose during 2 weeks before giving you the lowest general dose.
  Example: if your daily dose is 1000 mg, your reduced starting dose is 2 tablets of 250 mg in the morning and 2 tablets of 250 mg in the evening.

Add-on therapy
- **Dose in adults and adolescents (12 to 17 years) weighing 50 kg or more:**
  General dose: between 1,000 mg and 3,000 mg each day.
  Example: if your daily dose is 1,000 mg, you might take 2 tablets of 250 mg in the morning and 2 tablets of 250 mg in the evening.
- **Dose in infants (1 month to 23 months), children (2 to 11 years) and adolescents (12 to 17 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 100 mg/ml oral solution is a formulation 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 tablets don't allow accurate dosage.

Method of administration
Swallow Levetiracetam tablets with a sufficient quantity of liquid (e.g. a glass of water). You may take Levetiracetam with or without food. After oral administration the bitter taste of levetiracetam may be experienced.
Duration of treatment
- Levetiracetam is used as a 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 Sciecure 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 tablets than you should. Your doctor will establish the best possible treatment of overdose.

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

If you stop taking Levetiracetam Sciecure
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.

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;
- 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);
- 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.
- limp 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 at: 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 Sciecure

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton box and blister after EXP:. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Levetiracetam Sciecure contains
The active substance is called levetiracetam.
One tablet of Levetiracetam Sciecure 250 mg contains 250 mg of levetiracetam.
One tablet of Levetiracetam Sciecure 500 mg contains 500 mg of levetiracetam.
One tablet of Levetiracetam Sciecure 750 mg contains 750 mg of levetiracetam.
One tablet of Levetiracetam Sciecure 1000 mg contains 1000 mg of levetiracetam.

The other ingredients are:
Tablet core: calcium hydrogen phosphate dihydrate, cellulose microcrystalline, crospovidone type A, hydroxypropylcellulose (L).

250 mg:
Film-coating: hypromellose (E464), titanium dioxide (E171), talc, propylene glycol (E1520) colourants*.

500 mg:
Film-coating: hypromellose (E464), titanium dioxide (E171), hydroxypropyl cellulose (E463), propylene glycol (E1520), sorbic acid (E200), sorbitan monooleate (E494), vanillin, colourants*.

750 mg:
Film-coating: hypromellose (E464), iron oxide red (E172), macrogol/PEG 4000, titanium dioxide (E171), colourants*.

1000 mg:
Film-coating: hypromellose (E464), lactose monohydrate,macrogol/PEG 4000, titanium dioxide (E171).

* The colourants are:
250 mg tablet: indigo carmine aluminium lake (E132), sunset yellow FCF aluminium lake (E110), quinoline yellow aluminium lake (E104)
500 mg tablet: quinoline yellow aluminium lake (E104)
750 mg tablet: indigo carmine aluminium lake (E132), sunset yellow FCF aluminium lake (E110)
1000 mg tablet: (no additional colourant).

What Levetiracetam Sciecure looks like and contents of the pack
Levetiracetam Sciecure 250 mg: The film-coated tablets are blue, oblong, biconvex film- coated tablets with "BS12" debossed on one side and "250" on the other side, 13.7±0.1 mm in length, 6.7±0.1 mm in width and 4.0±0.2 mm in thickness.
Levetiracetam Sciecure 500 mg: The film-coated tablets are yellow, oblong, biconvex film-coated tablets with "BS12" debossed on one side and "500" on the other side, 19.4±0.1 mm in length, 7.8±0.1 mm in width and 5.1±0.2 mm in thickness.
Levetiracetam Sciecure 750 mg: The film-coated tablets are pink, oblong, biconvex film-coated tablets with "BS12" debossed on one side and "750" on the other side, 22.8±0.1 mm in length, 10.9±0.1 mm in width and 5.4±0.2 mm in thickness.
Levetiracetam Sciecure 1000 mg: The film-coated tablets are white, oblong, biconvex film-coated tablets with "BS12" debossed on one side and "1000" on the other side, 22.8±0.1 mm in length, 10.9±0.1 mm in width and 6.7±0.2 mm in thickness.

White opaque PVC/PE/PVDC-Aluminium foil blister in cardboard boxes.

Levetiracetam Sciecure tablets are packaged in blister packs supplied in cardboard boxes containing:
- 250 mg: 60 film-coated tablets.
- 500 mg: 60 film-coated tablets.
- 750 mg: 60 film-coated tablets.
- 1000 mg: 60 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

Sciecure Pharma Ltd
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