Levetiracetam contains methyl paraben, propylene glycol and maltitol Levetiracetam oral solution includes methyl parahydroxybenzoate (E218) which may cause allergic reactions in people who are sensitive to it.

Levetiracetam oral solution also contains maltitol liquid (E965). If you have been told by your doctor that you have an allergy to some sugars, please talk to your doctor before taking this medicinal product.

2. 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.

Levetiracetam must be taken twice a day, once in the morning and once in the evening, at 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 10ml syringe included in the package for patients 4 years and above. General dose: Levetiracetam is taken twice daily, in two equally divided doses, each individual dose being measured between 5ml (500mg) and 15ml (1500mg). 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.

Add-on therapy

Dose in adults and adolescents (12 to 17 years) weighing 30 kg or more:

Measure the appropriate dosage using the 10ml syringe included in the package for patients of 4 years and above. General dose: Levetiracetam is taken twice daily, in two equally divided doses, each individual dose being measured between 5ml (500mg) and 15ml (1500mg). Dose in children 6 months and older Your doctor will prescribe the most appropriate form of Levetiracetam according to your age, weight and dose. For children 6 months to 4 years, measure the appropriate dosage using the 3ml syringe included in the package. For children above 4 years, measure the appropriate dosage using the 10ml syringe included in the package. General dose: Levetiracetam is taken twice daily in two equally divided doses, each individual dose being measured between 0.1ml (10mg) and 0.3ml (30mg), per kg bodyweight of the child. (see table below for dose examples).

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 1ml syringe included in the package. General dose: Levetiracetam is taken twice daily in two equally divided doses, each individual dose being measured between 0.07ml (7mg) and 0.23ml (21mg), per kg bodyweight of the infant. (see table below for dose examples).

Method of Administration:

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

Instructions for use:

Open the bottle press the cap and turn it up to 90 degrees (figure 2). Separate the adaptor from the syringe (figure 2) Insert the adaptor into the bottle neck. 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 pushing the piston down (figure 4 a), then push the piston upward in order to remove any possible bubble (figure 4 b). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 4 c).

Durations 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 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 than you should.
• Your doctor will establish the best possible treatment of withdrawal of Levetiracetam.
• If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Possible side effects

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

The most frequently reported adverse reactions were: nausea, vomiting, 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

• nausea/pharyngitis;

Common: may affect 1 to 10 users in 100 people

• somnolence (sleepiness), headache;
• anorexia (loss of appetite);
• depression; hostility or aggression, anxiety, insomnia, nervousness or irritability;
• convulsion, balance disorder (equilibrium disorder), insomnia, nervousness or irritability;
• dizziness (sensorimotor unsteadiness), lethargy (lack of energy and enthusiasm), tremor (involuntary trembling); vertigo (sensation of rotation);
• abdominal pain, diarrhoea, diarrhoea of gestation), vomiting, nausea;
• rash;
• asthenia/lack of energy (tiredness).

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

• decreased number of white blood platelets, decreased number of white blood cells;
• weight decrease, weight increase;
• suicidal and isolated 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), loss of balance in attention (loss of concentration);
• diplopia (double vision), vision blurred;
• electroencephalogram values in a liver function test;
• hair loss, eczema, pruritis;
• muscle weakness, myalgia (muscle pain);
• impotence.

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, tarsos and limbs, difficult in controlling movements, hypokinesia (hypermotility);
• pancreatitis;
• liver failure, hepatitis;
• 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, generally 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 (tissue damage of the skin as well as deep ulceration of the skin).

Contact your doctor if you took more than you should.

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. Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at: www.mhra.gov.uk/yellowcard. Alternatively you can call Freephone 0808 100 3352 (available from 10 a.m. to 2 p.m. Monday to Friday) or fill in a paper form available from your local pharmacy.

5. How to store Levetiracetam

• Keep this medicine out of sight and reach of children.
• Do not use this medicine after the expiry date stated on the carton box and bottle after EXP:
• The expiry date refers to the last day of the month.
• Do not use after 4 months of first opening the bottle.
• Store in the original bottle in order to protect from light.
• 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

Levetiracetam contains:
The active substance is called Levetiracetam. Each ml contains 100 mg of Levetiracetam.

The other ingredients are: Sodium citrate (for pH adjustment), Citric acid monohydrate (for pH adjustment), Methyl parahydroxybenzoate (E218), Glyceral (E422), Acass🎢le potassium (E950), Maltitol liquid (E965), Raspberry liquid and Purified water.

Levetiracetam looks like and the contents of the package

Levetiracetam 100mg/ml oral solution is a clear liquid. The 300 ml glass bottle of Levetiracetam (for children aged 4 years and above, adolescents and adults) is packed in a cardboard box containing a 15 ml oral syringe (graduated every 0.25 ml) and an adaptor for the syringe.

The 150 ml glass bottle of Levetiracetam (for infants and young children aged from 6 months to less than 4 years) is packed in a cardboard box containing a 3ml oral syringe (graduated every 0.1 ml) and an adaptor for the syringe.

The 150 ml glass bottle of Levetiracetam (for infants and young children aged from 6 months to less than 4 years) is packed in a cardboard box containing a 3ml oral syringe (graduated every 0.05 ml) and an adaptor for the syringe.

All not pack sizes may be available from your local pharmacist.

Marketing Authorization Holder and Manufacturer

This leaflet was last revised in December 2016

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