

Quetra 100mg/ml oral solution

Levetiracetam 100mg/mL

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What Quetra is used for

Quetra 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 seizures with or without secondary generalization). 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:
 - a). partial onset seizures with or without generalization in adults, adolescents children and children from 4 years of age with epilepsy.
 - b). 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.
 - c). primary generalized tonic-clonic seizures (major fits, including loss of consciousness) in adults and adolescents from 12 years of age with idiopathic generalized epilepsy (the type of epilepsy that is thought to have a genetic cause).

How Quetra works

Quetra contains the active substance Levetiracetam. Levetiracetam is an

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

Before you use Quetra

- When you must not use it

If you are allergic to levetiracetam, pyrrolidone derivatives or any of the other ingredients of this medicine.

Children and adolescents

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

- Before you start to use it

- 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 slowdown 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 Quetra have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.

Quetra oral solution contains methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).

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

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 or pharmacist for advice before taking this medicine. Quetra 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.

- Taking other medicines

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.

How to use Quetra

- How much to use

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 oral solution following your doctor's instructions.

Quetra 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: Quetra is taken twice daily, in two equally divided doses, each individual dose being measured between 5 ml (500 mg) and 15 ml (1500 mg).

Measure the appropriate dosage using syringe included in the package for patients 4 years and above.

When you will first start taking Quetra, 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):

General dose: Quetra is taken twice daily, in two equally divided doses, each individual dose being measured between 5 ml (500 mg) and 15 ml (1500 mg).

Measure the appropriate dosage using the syringe included in the package for patients of 4 years and above.

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

For children above 4 to 11 years and adolescents (12-17 years) weighing less than 50kg:

Your doctor will prescribe the most appropriate pharmaceutical form of Quetra according to the age, weight and dose. The exact quantity of oral solution formulation should be delivered using the syringe provided in the cardboard box.

Dose in children 4 years old and older

Weight	Starting dose: 0.1ml/kg twice daily	Maximum dose: 0.3 ml/kg twice daily
10 kg	1 ml twice daily	3 ml twice daily
15 kg	1.5 mg twice daily	4.5 ml twice daily
20 kg	2 ml twice daily	6 ml twice daily
25 kg	2.5 ml twice daily	7.5 ml twice daily
From 50 kg	5 ml twice daily	15 ml twice daily

Method of administration:

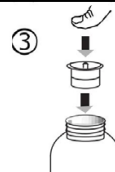
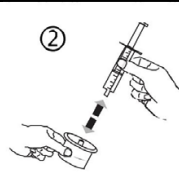
After measuring the correct dose with an appropriate syringe, Quetra oral solution may be diluted in a glass of water. You may take Quetra with or without food. After oral administration the bitter taste of levetiracetam may be experienced.

Instructions for use:

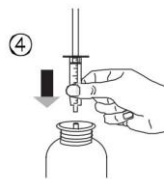
1. Open the bottle: press the cap and turn it anticlockwise (figure 1).



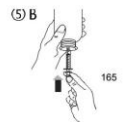
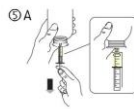
2. Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is well fixed.



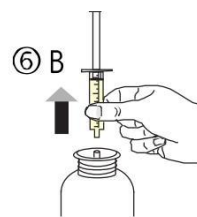
3. Take the syringe and put it in the adaptor opening (figure 4). Turn the bottle upside down (figure 5).



4. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upward in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 5C).



5. Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



6. Empty the contents of the syringe in a glass of by pushing the piston to the bottom of the syringe (figure 7).



7. Drink the whole contents of the glass.
8. Close the bottle with the plastic screw cap.

9. Wash the syringe with water (figure 8).



- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Quetra is used as a chronic treatment. You should continue Quetra 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 forget to use it

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 use too much (overdose)

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

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

While you are using it

- Things you must do

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

- Things you must not do

If stopping treatment, Quetra should be discontinued gradually to avoid an increase of seizures. Should your doctor decide to stop your Quetra treatment, he/she will instruct you about the gradual withdrawal of Quetra.

- Things to be careful of

Driving and using machines:

Quetra may impair your ability to drive or operate any tools or machinery, as levetiracetam 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.

Side effects

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

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 side effects

- nasopharyngitis;
- somnolence (sleepiness), headache.

Common side effects

- 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), nausea, vomiting;
- rash;
- asthenia/fatigue (tiredness).

Uncommon side effects

- decreased number of blood platelets, decreased number of white blood cells;
- weight increase, weight decrease;
- suicide attempt and suicidal ideation, mental disorder, abnormal behavior, 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 side effects

- infection;
- decreased number of all blood cell types;
- severe allergic reactions such as (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), anaphylactic reaction [severe allergic reaction including weakness, feel light-headed or dizzy or have difficulty breathing], 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;
- 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);
- limp or difficulty walking.

Tell your doctor immediately if you notice any of the following:

- Symptoms such as low urine volume, tiredness, nausea, vomiting, confusion and swelling in the leg,

ankles or feet, may be a sign of sudden decrease of kidney function.

- Signs or symptoms including muscleache, feeling of weakness and dark urine may indicate the side effect of rhabdomyolysis (breakdown of muscle tissue).
- 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.

- You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring. by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Quetra

- Storage

Keep out of the reach and sight of children.

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

Store below 30 °C, in the original container in order to protect from light.

- Disposal

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 to protect the environment.

Product Description

- What it looks like

Quetra oral solution is a clear, colourless liquid with sweet fruity odour and bitter raspberry flavour.

- Ingredients

- Active ingredient:
Levetiracetam.

- Inactive ingredients:

Sodium citrate
Citric acid
Methyl parahydroxybenzoate
Glycerol
Acesulfame potassium
Maltitol liquid
Raspberry liquid
Water purified

- MAL number:

MAL22016018AZ

Manufacturer

Remedica Ltd,
Aharnon Str.,
Limassol Industrial Estate,
3056 Limassol, Cyprus

Product Registration Holder

Eucogen Sdn. Bhd.,
No. 6A, Jalan Sungai Burung U 32/U,
Bukit Rimau, Seksyen 32, 40460
Shah Alam.

Date of revision

23/11/2022

Serial Number

NPRA (R2) 21/044