

Package leaflet: Information for the patient

Brivaracetam 10mg/ml solution for injection/infusion brivaracetam

The full name of your medicine is Brivaracetam 10mg/ml solution for injection/infusion. It is referred to as Brivaracetam injection/ infusion throughout this leaflet.

Read all of this leaflet carefully before you start using 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

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2. What you need to know before you use Brivaracetam injection/infusion
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1. What Brivaracetam injection/infusion is and what it is used for

What Brivaracetam injection/infusion is

Brivaracetam injection/infusion contains the active substance brivaracetam. It belongs to a group of medicines called 'anti-epileptics'. These medicines are used to treat epilepsy.

What Brivaracetam injection/infusion is used for

- Brivaracetam injection/infusion is used in adults, adolescents and children from 2 years of age.
- It is used to treat a type of epilepsy that has partial seizures with or without a secondary generalisation.
- Partial seizures are fits that start by only affecting one side of the brain. These partial seizures can spread and extend to larger areas on both sides of the brain – this is called a 'secondary generalisation'.
- You have been given this medicine to lower the number of fits (seizures) you have.
- Brivaracetam injection/infusion is used together with other medicines for epilepsy.

2. What you need to know before you take Brivaracetam injection/infusion

Do not use Brivaracetam injection/infusion if:

- you are allergic to brivaracetam, other similar chemical compounds as levetiracetam or piracetam or any of the other ingredients of this medicine (listed in section 6). If you are not sure, talk to your doctor or pharmacist before taking Brivaracetam injection/infusion.
- you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Brivaracetam injection/infusion.
- Serious skin reactions including Stevens-Johnson syndrome have been reported in association with Brivaracetam injection/infusion treatment. Stop using Brivaracetam injection/infusion and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Warnings and precautions

Talk to your doctor or pharmacist before using Brivaracetam injection/infusion if:

- You have thoughts of harming or killing yourself. A small number of people being treated with anti-epileptic medicines such as brivaracetam have had thoughts of harming or killing themselves. If you have any of these thoughts at any time, contact your doctor immediately.
- You have liver problems - your doctor may need to adjust your dose.

Children

Brivaracetam injection/infusion is not recommended for use in children under 2 years of age.

Other medicines and Brivaracetam injection/infusion

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

In particular, tell your doctor if you are taking any of the following medicines – this is because your doctor may need to adjust your Brivaracetam injection/infusion dose:

- Rifampicin - a medicine used to treat bacterial infections.
- St John's wort (also known as *Hypericum perforatum*) - a herbal medicine used to treat depression and anxiety as well as other conditions.

Brivaracetam injection/infusion with alcohol

- Combining this medicine with alcohol is not recommended.
- If you drink alcohol while taking brivaracetam the negative effects of alcohol may be increased.

Pregnancy and breast-feeding

Fertile women should discuss the use of contraceptives with the doctor.

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

It is not recommended to take Brivaracetam injection/infusion if you are pregnant, as the effects of brivaracetam on pregnancy and the unborn baby are not known.

It is not recommended to breast-feed your baby while taking Brivaracetam injection/infusion, as brivaracetam passes into breast milk.

Do not stop treatment without talking to your doctor first. Stopping treatment could increase your seizures and harm your baby.

Driving and using machines

- You may feel sleepy, dizzy or tired while using brivaracetam.
- These effects are more likely at the start of the treatment or after a dose increase.
- Do not drive, cycle or use any tools or machines until you know how the medicine affects you.

Brivaracetam injection/infusion contains sodium

This medicine contains 19.1 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 1 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Brivaracetam injection/infusion

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

You will use brivaracetam together with other medicines for epilepsy.

- When you start taking this medicine you will take brivaracetam orally (as tablets or an oral solution) or be given it as an injection or infusion.

- Brivaracetam injection/infusion is used for a short amount of time when you cannot take brivaracetam orally.
- You can switch between taking brivaracetam orally to the solution for injection/infusion, and the other way around.

How much you will be given

Your doctor will work out the right daily dose for you. Take the daily dose in two equal divided doses, approximately 12 hours apart.

Adolescents and children weighing 50 kg or more, and adults

- The recommended dose is from 25 mg to 100 mg taken twice a day. Your doctor may then decide to adjust your dose to find the best dose for you.

Adolescents and children weighing from 20 kg to less than 50 kg

- Your doctor may prescribe the injection only for a few days if you cannot take your medicine by mouth.
- The recommended dose is from 0.5 mg to 2 mg for each kg of bodyweight, taken twice a day. Your doctor may then decide to adjust your dose to find the best dose for you.

Children weighing from 10 kg to less than 20 kg

- Your child's doctor may prescribe the injection only for a few days if your child cannot take the medicine by mouth.
- The recommended dose is from 0.5 mg to 2.5 mg for each kg of bodyweight, taken twice a day. Your child's doctor may then decide to adjust your child's dose to find the best dose for your child.

People with liver problems

If you have problems with your liver:

- As an adolescent or child weighing 50 kg or more, or as an adult, the maximum dose you will take is 75 mg twice a day.
- As an adolescent or child weighing from 20 kg to less than 50 kg, the maximum dose you will take is 1.5 mg for each kg of bodyweight twice a day.
- As a child weighing from 10 kg to less than 20 kg, the maximum dose your child will take is 2 mg for each kg of bodyweight twice a day.

How Brivaracetam injection/infusion is given

Brivaracetam injection/infusion is administered as an injection or infusion into a vein by a doctor or a nurse. The medicine is injected slowly into your vein or given as an infusion (drip) over 15 minutes.

How long to use Brivaracetam injection/infusion for

- Your doctor will decide for how many days you will be given the injections or infusion.
- For the long term treatment with brivaracetam, your doctor will ask you to take brivaracetam tablets or oral solution.

If you have more Brivaracetam injection/infusion than you should

If you think you have been given too much brivaracetam, tell your doctor straight away.

If you stop using Brivaracetam injection/infusion

- Do not stop taking this medicine unless your doctor tells you to. This is because stopping treatment could increase the number of fits you have.
- If your doctor asks you to stop taking this medicine they will lower your dose gradually. This helps to stop your fits coming back or getting worse.

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.

Very common: may affect more than 1 in 10 people

- feeling sleepy or dizzy

Common: may affect up to 1 in 10 people

- flu
- feeling very tired (fatigue)
- convulsion, a feeling of 'spinning' (vertigo)
- feeling and being sick, constipation
- pain or discomfort at the injection or infusion site
- depression, anxiety, not being able to sleep (insomnia), irritability
- infections of the nose and throat (such as the 'common cold'), cough
- decrease appetite

Uncommon: may affect up to 1 in 100 people

- allergic reactions
- abnormal thinking and/or loss of touch with reality (psychotic disorder), being aggressive, nervous excitement (agitation)
- thoughts or attempts of harming or killing yourself: tell your doctor straight away
- a decrease in white blood cells (called 'neutropenia') - shown in blood tests

Not known: frequency cannot be estimated from the available data

- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome)

Additional side effects in children

Common: may affect up to 1 in 10 people

- restlessness and hyperactivity (psychomotor hyperactivity)

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 Brivaracetam injection/infusion

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 and vial after EXP. The expiry date refers to the last day of that month.

Brivaracetam injection/ infusion may be diluted before it is injected by your doctor or nurse. In such cases, it should be used straight after dilution.

This medicine does not require any special storage conditions.

Each vial of Brivaracetam injection/ infusion must be used only once (single use). Any unused solution should be discarded.

Only clear solution free from particles and discolouration should be used.

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 Brivaracetam injection/infusion contains

The active substance is brivaracetam.

- Each ml contains 10 mg brivaracetam
- Each 5 ml vial contains 50 mg brivaracetam

The other ingredients are: Sodium chloride, sodium acetate trihydrate, glacial acetic acid and water for injections.

What Brivaracetam injection/infusion looks like and contents of the pack

Brivaracetam injection/infusion is a clear, colourless solution free from visible particles.

Brivaracetam injection/infusion 5 ml vial is packed in a carton box of 10 vials.

Marketing Authorisation Holder and Manufacturer

Amarox Limited
Congress House, 14 Lyon Road
Harrow, HA1 2EN
United Kingdom

This leaflet was last revised in 12/2025.

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The following information is intended for medical or healthcare professionals only

Brivaracetam injection/infusion can be administered as a bolus injection or as an infusion:

- Intravenous bolus: may be administered directly without dilution
- Intravenous infusion: may be administered over 15 minutes in a compatible diluent

Brivaracetam injection/infusion may be diluted with the following solutions: sodium chloride 9 mg/ml (0.9 %), glucose 50 mg/ml (5 %) solution for injection or lactated Ringer's solution.

Each vial of Brivaracetam injection/infusion must be used only once (single use). Any unused solution should be discarded (see section 3).

After dilution

Chemical and physical in-use stability has been demonstrated for 72 hours at 25 °C, when the product is diluted to a concentration of 0.1 mg/ml or 1.5 mg/ml with the diluents listed in section 6.6 and stored in PVC or polyolefin bags.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are responsibility of the user.