

Package leaflet: Information for the patient

Briviact 10mg/ml solution for injection/infusion brivaracetam

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

1. What Briviact is and what it is used for
2. What you need to know before you use Briviact
3. How to use Briviact
4. Possible side effects
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1. What Briviact is and what it is used for

What Briviact is

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

What Briviact is used for

- Briviact 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.
- Briviact is used together with other medicines for epilepsy.

2. What you need to know before you take Briviact

Do not use Briviact 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 Briviact.

Warnings and precautions

Talk to your doctor or pharmacist before using Briviact if:

- You have thoughts of harming or killing yourself. A small number of people being treated with anti-epileptic medicines such as Briviact 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

Briviact is not recommended for use in children under 2 years of age.

Other medicines and Briviact

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 Briviact 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.

Briviact with alcohol

- Combining this medicine with alcohol is not recommended.
- If you drink alcohol while taking Briviact 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 Briviact if you are pregnant, as the effects of Briviact on pregnancy and the unborn baby are not known.

It is not recommended to breast-feed your baby while taking Briviact, as Briviact 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 Briviact.
- 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.

Briviact 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 Briviact

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 Briviact together with other medicines for epilepsy.

- When you start taking this medicine you will take Briviact orally (as tablets or an oral solution) or be given it as an injection or infusion.
- Briviact solution for injection/infusion is used for a short amount of time when you cannot take Briviact orally.
- You can switch between taking Briviact 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 Briviact is given

Briviact 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 Briviact for

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

If you have more Briviact than you should

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

If you stop using Briviact

- 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

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 or pharmacist. 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 Briviact

- 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.
- Briviact may be diluted before it is injected by your doctor or nurse. In such cases, it should be used straight after dilution.
- This medicinal product does not require any special storage conditions.
- Each vial of Briviact solution for injection/infusion must be used only once (single use). Any unused solution should be discarded.
- Only clear solution free from particles and discoloration 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 Briviact 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 acetate (trihydrate), glacial acetic acid, sodium chloride, water for injections.

What Briviact looks like and contents of the pack

Briviact 10 mg/ml solution for injection/infusion is a clear, colourless, sterile solution.

Briviact 10 mg/ml solution for injection/infusion 5 ml vial is packed in a carton box of 10 vials.

Marketing Authorisation Holder

UCB Pharma Limited, 208 Bath Road, Slough, Berkshire, SL1 3WE, United Kingdom.

Manufacturer

UCB Pharma S.A., Chemin du Foriest, B-1420 Braine-l'Alleud, Belgium.

This leaflet was last revised in February 2023.

The following information is intended for medical or healthcare professionals only

Briviact solution for 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

Briviact 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 Briviact solution for injection/infusion must be used only once (single use). Any unused solution should be discarded (see section 3).