

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations)- 1986

This medicine is to be supplied upon a physician's prescription only

Briviact Oral Solution

Active ingredient:

Briviact Oral Solution contains 10 mg brivaracetam per 1 ml of solution.

For the list of excipients and allergens in the medicine, please see chapter 2 section: "Important information regarding some of the ingredients of the medicine" and chapter 6: "Additional information".

Read the entire leaflet carefully before you start using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, contact the physician or the pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

This medicine is intended for adults, adolescents and children from 4 years of age.

1. What is the medicine intended for?

Briviact is indicated as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy.

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 prescribed this medicine to lower the number of seizures you have. Briviact is used together with other medicines to treat epilepsy.

Therapeutic group: anti-epileptics.

2. Before using this medicine

Do not take Briviact if:

- You are hypersensitive (allergic) to the active ingredient brivaracetam, other similar chemical compounds as levetiracetam or piracetam or any of the other ingredients of this medicine (listed in chapter 6). If you are not sure, talk to your physician or pharmacist before taking Briviact.

Special warnings regarding the use of this medicine

Talk to your physician or pharmacist before taking 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 physician immediately.
- You have liver problems. Your physician may need to adjust your dose.

Children and adolescents

Briviact is not recommended for use in children under 4 years of age.

Other medicines and Briviact

Tell your physician or pharmacist if you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements. In particular, your physician may need to adjust your Briviact dose if you take the following medicines:

- Rifampicin (used to treat bacterial infections).
- St John's wort, [(Hypericum perforatum) an herbal medicine used to treat depression, anxiety and other conditions].

Taking this medicine with food

The medicine may be taken with or without food.

Using the medicine 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, breast-feeding and fertility

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, consult with your physician or pharmacist before using medicines.

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 physician first. Stopping treatment could increase your seizures and harm your baby.

Driving and using machines

- You may feel sleepy, dizzy or tired while taking 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. Children should be warned about riding bicycles or playing close to the road and the like.

Important information regarding some of the ingredients of the medicine

Briviact oral solution contains:

- Methyl parahydroxybenzoate (E218) - this may cause allergic reactions (possibly delayed).
- Sodium: This medicine contains less than 1 mmol sodium (23mg) per millilitre, that is to say essentially "sodium free".
- Sorbitol (E420) (a type of sugar): This medicine contains 168 mg sorbitol in each ml. Sorbitol is a source of fructose. If your physician has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your physician before you (or your child) take or receive this medicine.

- Propylene glycol (E1520): This medicine contains maximum 5.5 mg propylene glycol in each milliliter.

3. How to use the medicine?

Always take this medicine exactly as your physician has told you. Check with your physician or pharmacist if you are not sure about the dosage or method of administration of the medicine.

You will take Briviact together with other medicines for epilepsy.

The dosage and manner of treatment will be determined only by the physician. Your physician will work out the right dose for you.

Take this medicine in two equal doses - one in the morning and one in the evening at about the same time each day.

Adults, adolescents and children who weigh 50 kg or more

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

Children and adolescents who weigh less than 50 kg

The recommended dose is from 0.5 mg to 2 mg for each kg of body weight, taken twice a day. Your physician may then decide to adjust your dose to find the best dose for you.

The table below only shows examples of doses to take. Your physician will work out the right dose for you, depending on your weight.

	Dose taken twice daily for children aged 4 years and up and weighing less than 50 kg			
Weight	0.5 mg/kg = 0.05 ml/kg	1 mg/kg=0.1 ml/kg	1.5 mg/kg = 0.15 ml/kg	2 mg/kg = 0.2 ml/kg
10 kg	0.5 ml	1 ml	1.5 ml	2 ml
15 kg	0.75 ml	1.5 ml	2.25 ml	3 ml
20 kg	1 ml	2 ml	3 ml	4 ml
25 kg	1.25 ml	2.5 ml	3.75 ml	5 ml
30 kg	1.5 ml	3 ml	4.5 ml	6 ml
35 kg	1.75 ml	3.5 ml	5.25 ml	7 ml
40 kg	2 ml	4 ml	6 ml	8 ml
45 kg	2.25 ml	4.5 ml	6.75 ml	9 ml
50 kg	2.5 ml	5 ml	7.5 ml	10 ml

Patients with liver problems

If you have problem with your liver:

- As an adult, adolescent or child weighing 50 kg or more, the maximum dose you will take is 75 mg twice a day.
- As a child or adolescent weighing less than 50 kg, the maximum dose you will take is 1.5 mg for each kg of body weight twice a day.

Do not exceed the recommended dose.

Briviact oral solution can be swallowed undiluted or diluted (mixed) in water or juice shortly before swallowing.

Instructions for use for patients/carers:

Two oral syringes are provided in the carton. Check with your physician which one you should use.

- If you weigh less than 20 kg, it is recommended to use the 5 ml oral syringe provided in the carton to ensure accurate dosing.
- If you weigh 20 kg or more, your physician will recommend the use of the 5 ml oral syringe or the 10 ml oral syringe provided in the carton to ensure accurate dosing.

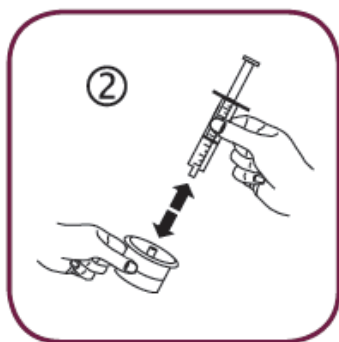
5 ml oral dosing syringe	10 ml oral dosing syringe
The 5 ml oral syringe has two overlapping graduations: in steps of 0.25 ml and in steps of 0.1 ml.	The 10 ml oral syringe has one graduation in steps of 0.25 ml.

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



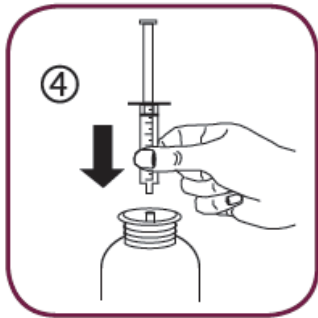
Follow these steps the **first time** you take Briviact:

- Take off the adaptor from the oral syringe (figure 2).
- Put the adaptor into the top of the bottle (figure 3). Make sure it is fixed well in place. You do not need to remove the adaptor after use.

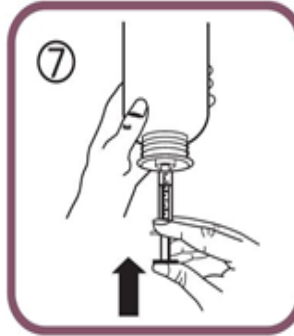
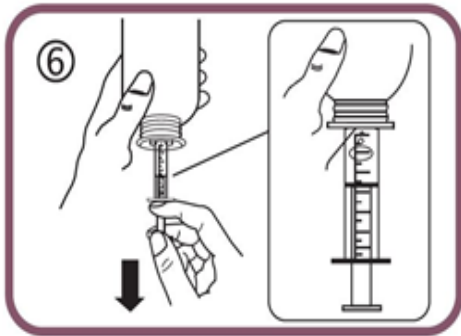


Follow these steps **each time** you take Briviact:

- Attach the oral syringe to the adaptor opening (figure 4).
- Turn the bottle upside down (figure 5).



- Hold the bottle upside down in one hand and use the other hand to fill the oral syringe.
- To fill the oral syringe with a small amount of solution, pull the plunger down (figure 6).
- Then push the plunger up to remove any possible air bubbles (figure 7).
- Pull the plunger down to the dose marker on the oral syringe that matches the dose in milliliters prescribed by your physician (figure 8).



- Turn the bottle the right way up (figure 9).
- Take the oral syringe out of the adaptor (figure 10).



There are two ways in which you can choose to drink the medicine:

- empty the contents of the syringe into water (or juice) by pushing the plunger to the bottom of the syringe (figure 11) – you will then need to drink all of the water (add just enough to make it easy to drink) **or**

- drink the solution directly from the oral syringe without water – drink the whole contents of the syringe (figure 12).



- Close the bottle with the plastic screw cap (you do not need to remove the adaptor).
- Wash the oral syringe with water only (figure 13)
- Keep the bottle, the oral syringe, and the leaflet in the carton.



Duration of use

Briviact is a long term treatment. Keep taking Briviact until your physician tells you to stop.

If you have accidentally taken a higher dosage

If you have taken more Briviact than you should, consult your physician. You may feel dizzy and sleepy.

You may also have any of the following symptoms: feeling sick, a feeling of 'spinning', problems of keeping your balance, anxiety, feeling very tired, irritability, being aggressive, not being able to sleep, depression, thoughts or attempts of harming or killing yourself.

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a physician or a hospital emergency room and bring the package of the medicine with you.

If you forget to take Briviact

- If you miss a dose take it as soon as you remember.
- Then take your next dose at the time you would normally take it.
- Do not take a double dose to make up for a forgotten dose.
- If you are not sure what to do, ask your physician or pharmacist.

Continue with the treatment as recommended by the physician.
Even if there is an improvement in your health condition, do not stop taking this medicine without consulting the physician.

If you stop taking Briviact

- Do not stop taking this medicine unless your physician tells you to. This is because stopping treatment could increase the number of seizures you have.
- If your physician asks you to stop taking this medicine, the dose will be lowered gradually. This helps to prevent seizures coming back or getting worse.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions on the use of this medicine, ask your physician or pharmacist.

4. Side effects

Like all medicines, Briviact can cause side effects in some users. Do not be alarmed by reading the list of side effects, you may not experience any of them.

Contact your physician immediately if you have thoughts or attempts of harming or killing yourself.

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)
- nausea and vomiting, constipation
- depression, anxiety, unable to sleep (insomnia), irritability
- infections of the nose and throat (e.g. 'common cold'), cough
- decreased appetite

Uncommon (may affect up to 1 in 100 people):

- allergic reactions
- abnormal thinking and/or loss of touch with reality (psychotic disorder), aggressiveness, agitation
- thoughts or attempts of harming or killing yourself; tell your physician immediately
- a decrease in white blood cells (neutropenia) which is shown in blood tests

Additional side effects in children

Common side effects (may affect up to 1 in 10 people)

- restlessness and hyperactivity (psychomotor hyperactivity)

If a side effect appears, if any side effect gets worse or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” that appears on the homepage of the Ministry of Health’s website (www.health.gov.il) which links to an online form for reporting side effects, or by the following link: <https://sideeffects.health.gov.il/>
In addition, you can report by emailing the Registration Holder’s Patient Safety Unit at: drugsafety@neopharmgroup.com

5. How to store the medicine

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without specific instruction from the physician.
- Do not use the medicine after the expiration date (exp. date) appearing on the cardboard box and bottle. The expiration date refers to the last day of that month.

Storage conditions

- No special storage conditions. It is recommended to keep at room temperature.
- After first opening of the bottle, **use within 5 months**, with no special storage conditions. It is recommended to keep at room temperature.

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. Additional information

- **In addition to the active ingredient, the medicine also contains:**

Sorbitol liquid, glycerol, sucralose, raspberry flavor 7557-A, carmellose sodium, sodium citrate, methyl parahydroxybenzoate, anhydrous citric acid, purified water.

- **What Briviact looks like and contents of the pack**

The solution is slightly viscous, clear, colourless to yellowish liquid.

The 300 ml glass bottle of Briviact is packed in a cardboard box containing two oral syringes, a 10 ml syringe and a 5 ml syringe, and an adaptor for the syringe.

Registration holder: Neopharm Ltd., 6 Hashiloach St., P.O.B. 7063, Petach Tikva 4917001.

Manufacturer: UCB Pharma S.A., Bruxelles, Belgium.

Drug registration number at the national medicines registry of the Ministry of Health:
159 93 35246

Revised in May 2023 according to MOHs guidelines.

Briviact OS PIL vs 01A