Package leaflet: Information for the users

Brivaracetam Syri Pharma 10 mg/ml, drank
brivaracetam

Read all of this leaflet carefully before you start taking 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.

The name of your medicine is Brivaracetam Syri Pharma 10 mg/ml, drank but it will be referred to as 'Brivaracetam' throughout this leaflet.

What is in this leaflet

1. What Brivaracetam is and what it is used for
2. What you need to know before you take Brivaracetam
3. How to take Brivaracetam
4. Possible side effects
5. How to store Brivaracetam
6. Contents of the pack and other information

1. What Brivaracetam is and what it is used for

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

What Brivaracetam is used for
- Brivaracetam 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 is used together with other medicines for epilepsy.

2. What you need to know before you take Brivaracetam

Do not take Brivaracetam 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.

Warnings and precautions
Talk to your doctor or pharmacist before taking brivaracetam 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 is not recommended for use in children under 2 years of age.

Other medicines and brivaracetam
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 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 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 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, 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 taking 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 oral solution contains
Methyl parahydroxybenzoate (E218): May cause allergic reactions (possibly delayed).
Sodium: This medicine contains less than 1 mmol sodium (23 mg) per millilitre i.e. 1.8294 mg, that is to say essentially 'sodium free
Sorbitol (E420) (a type of sugar): This medicine contains 167.86 mg sorbitol in each ml. Sorbitol is a source of fructose. If your doctor 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 doctor before you (or your child) take or receive this medicine.
Propylene glycol (E1520): This medicine contains maximum 4.936 mg propylene glycol in each millilitre.

3. How to take brivaracetam
Always take this medicine exactly as your doctor has told you. You will take brivaracetam together with other medicines for epilepsy.

How much to take
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.

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

Dose in ml to be taken twice daily and which syringe to use - for adolescents and children weighing 50 kg or more, and adults:

Weight	Dose in ml (corresponding to 25 mg)	Dose in ml (corresponding to 50 mg)	Dose in ml (corresponding to 75 mg)	Dose in ml (corresponding to 100 mg)
50 kg or more	2.5 ml	5 ml	7.5 ml	10 ml
	Use the 5 ml syringe		**Use the 10 ml syringe**	

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

- 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.

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

Dose in ml to be taken twice daily and which syringe to use - for adolescents and children weighing from 20 kg to less than 50 kg:

Weight	Dose in ml (corresponding to 0.5 mg/kg = 0.05 ml/kg)	Dose in ml (corresponding to 1 mg/kg = 0.1 ml/kg)	Dose in ml (corresponding to 1.5 mg/kg = 0.15 ml/kg)	Dose in ml (corresponding to 2 mg/kg = 0.2 ml/kg)
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*
	Use the 5 ml syringe		**For volume between 0.5 ml and 5 ml, use the 5 ml oral syringe** *** For volume above 5 ml and up to 10 ml, use the 10 ml oral syringe**	

Children weighing from 10 kg to less than 20 kg

- 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.

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

Dose in ml to be taken twice daily and which syringe to use - for children weighing from 10 kg to less than 20 kg:

Weight	Dose in ml (corresponding to 0.5 mg/kg = 0.05 ml/kg)	Dose in ml (corresponding to 1.25 mg/kg = 0.125 ml/kg)	Dose in ml (corresponding to 1.5 mg/kg = 0.15 ml/kg)	Dose in ml (corresponding to 2 mg/kg = 0.2 ml/kg)	Dose in ml (corresponding to 2.5 mg/kg = 0.25 ml/kg)
10 kg	0.5 ml	1.25 ml	1.5 ml	2 ml	2.5 ml
12 kg	0.6 ml	1.5 ml	1.8 ml	2.4 ml	3.0 ml
14 kg	0.7 ml	1.75 ml	2.1 ml	2.8 ml	3.5 ml
15 kg	0.75 ml	1.9 ml	2.25 ml	3 ml	3.75 ml
Use the 5 ml syringe					

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 to take Brivaracetam oral solution
- You can take Brivaracetam oral solution on its own, or dilute it in water, orange juice, lemon juice or soda lime juice shortly before swallowing.
- The medicine may be taken with or without food.
- An enteral feeding tube made of silicone (8FR, 10FR), Polyurethane (8FR, 18 FR), or PVC (8FR, 12FR, 18FR) may be used when administering Brivaracetam Syri Pharma 10mg/ml Oral solution. Feeding tube to be flushed with at least 15 mL of water following administration of the dose.

Instructions for use for patients or carers:
Two oral syringes will be provided in the carton. Check with your doctor which one you should use.
- For volume between 0.5 ml and 5 ml, you should use the 5 ml oral syringe provided in the carton to ensure accurate dosing.
- For volume above 5 ml and up to 10 ml, you should use the 10 ml oral syringe provided in the carton to ensure accurate dosing.

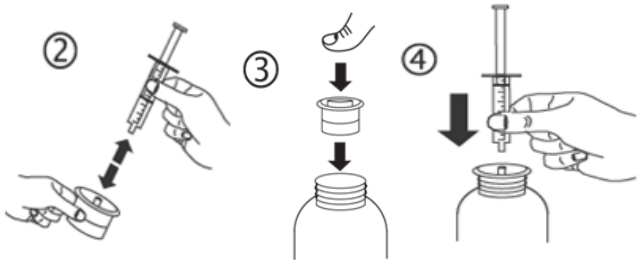
5 ml oral dosing syringe	10 ml oral dosing syringe
The 5 ml oral syringe has graduation marks at every 0.5 ml and intermediate graduation at every 0.1 ml and 0.25 ml.	The 10 ml oral syringe has graduation marks of 1ml and intermediate graduation of 0.25 ml.

Instructions for the use of syringe:

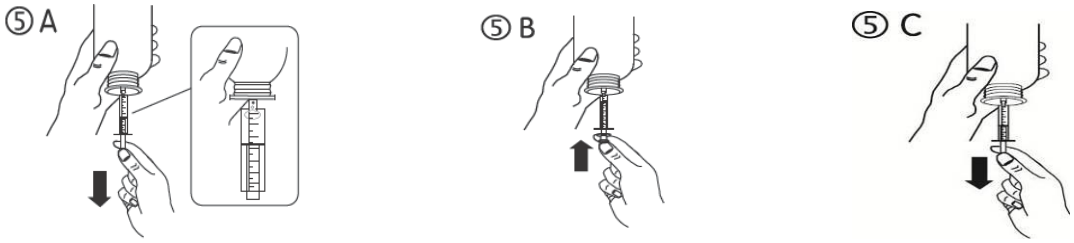
a) Open the bottle: press the cap and turn it anticlockwise (figure 1).



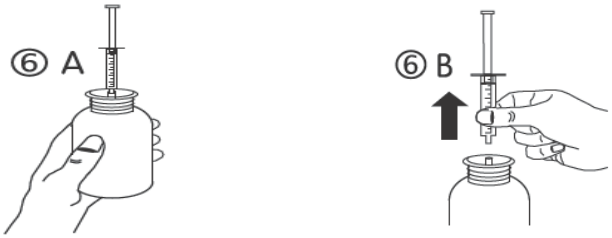
b) Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).

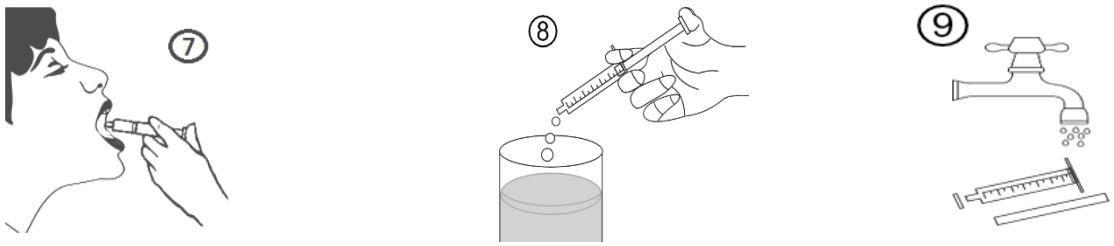


c) Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed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



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





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

1. Drink the solution directly from the oral syringe without water – drink the whole contents of the syringe (figure 7). Empty the contents of the syringe into the patient's mouth by pushing the piston to the bottom of the syringe (figure 7). The contents of the syringe should be emptied into the side cheek of the patient's mouth to avoid a choking hazard

OR

2. Empty the contents of the syringe into water, orange juice, lemon juice or soda lime juice by pushing the plunger to the bottom of the oral syringe (figure 8) – you will then need to drink all of the liquid (add just enough to make it easy to drink).

f) Close the bottle with the plastic cap. Wash the syringe with water (figure 9).

How long to take Brivaracetam for
Brivaracetam is a long-term treatment – keep taking Brivaracetam until your doctor tells you to stop.
If you take more Brivaracetam than you should
If you have taken more brivaracetam than you should, talk to your doctor. 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 forget to take Brivaracetam
- 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 doctor or pharmacist.

If you stop taking Brivaracetam
- 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
- depression, anxiety, not being able to sleep (insomnia), irritability
- infections of the nose and throat (such as the '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), 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Netherlands

Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store brivaracetam

- 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 on the bottle after 'EXP'. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Discard 100 days after first opening.
- Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist
- 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 contains

The active substance is brivaracetam.
Each ml oral solution contains 10 mg of brivaracetam.

The other ingredients are methyl parahydroxybenzoate (E218), carmellose sodium (E466), sorbitol liquid (containing sorbitol, E420(i)), glycerol (E422), sucralose (E955), citric acid anhydrous (E330), sodium citrate dihydrate (E331), raspberry flavour (contains propylene glycol (E1520)) and purified water.

What Brivaracetam looks like and contents of the pack

Brivaracetam is slightly viscous, clear, colourless to pale yellow colour solution supplied in 300 ml amber glass bottle with tamper-evident child-resistant white (polyethylene/polypropylene) plastic cap with EPE liner.

The pack also contains a 10 ml oral syringe with 1 ml graduation and 0.25 ml intermediate graduation marks and 5 ml oral syringe with 0.5 ml graduation and 0.1 ml and 0.25 ml intermediate graduation marks with an adaptor.

Marketing Authorisation Holder and Manufacturer:
Marketing Authorisation Holder:
Syri Pharma Limited
1 Windmill Lane
Dublin 2, D02 F206
Ierland.

Manufacturer:
Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park,
Paola PLA 3000, Malta.

In het register ingeschreven onder: RVG 134172

This medicine is authorised in the Member States of the European Economic Area under the following name:
NL: Brivaracetam Syri Pharma 10 mg/ml, drank
MT: Brivaracetam Syri Pharma 10 mg/ml Oral Solution

If this leaflet is hard to see or read, please call +353 1437 0882 for help.

Deze bijsluiter is voor het laatst goedgekeurd in september 2026.