PACKAGE LEAFLET

Package leaflet: Information for the patient

Brivaracetam STADA 10 mg, filmomhulde tabletten
Brivaracetam STADA 25 mg, filmomhulde tabletten
Brivaracetam STADA 50 mg, filmomhulde tabletten
Brivaracetam STADA 75 mg, filmomhulde tabletten
Brivaracetam STADA 100 mg, filmomhulde tabletten

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.

What is in this leaflet

1. What <Product name> is and what it is used for

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

What <Product name> is used for
- <Product name> 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.
- <Product name> is used together with other medicines for epilepsy.

2. What you need to know before you take <Product name>

Do not take <Product name>:
- 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 <Product name>.
- you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking brivaracetam. Serious skin reactions including Stevens-Johnson syndrome have been reported in association with brivaracetam treatment. Stop using <Product name> 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 taking <Product name>:

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

Children
<Product name> is not recommended for use in children under 2 years of age.

Other medicines and <Product name>
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 <Product name> 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.

<Product name> with alcohol
- Combining this medicine with alcohol is not recommended.
- If you drink alcohol while taking <Product name> 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 are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is not recommended to take <Product name> 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 <Product name>, 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 <Product name>.
- 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.

<Product name> contains lactose and sodium
- lactose (a type of sugar)- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- sodium- This medicine contains less than 1 mmol sodium (23mg) per tablet dose, that is to say essentially 'sodium free'.

3. How to take <Product name>

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Other form(s) of this medicine may be more suitable for certain patients e.g. children (if tablets cannot be swallowed in whole, for example); ask your doctor or pharmacist.

You will take <Product name> 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.
For 10mg only: The tablet can be divided into equal doses.

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
- 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
- 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 to take <Product name> tablets
- Swallow the tablets whole with a glass of liquid.
- The medicine may be taken with or without food.

How long to take <Product name> for
<Product name> is a long term treatment – keep taking <Product name> until your doctor tells you to stop.

If you take more <Product name> than you should
If you have taken more <Product name> 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 <Product name>
- 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 <Product name>
- 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

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Product name>

- 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, bottle label and blister after EXP. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- 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 <Product name> contains

The active substance is brivaracetam.
Each <Product name> 10 mg film-coated tablets contains 10 mg brivaracetam.
Each <Product name> 25 mg film-coated tablets contains 25 mg brivaracetam.
Each <Product name> 50 mg film-coated tablets contains 50 mg brivaracetam.
Each <Product name> 75 mg film-coated tablets contains 75 mg brivaracetam.
Each <Product name> 100 mg film-coated tablets contains 100 mg brivaracetam.

The other ingredients are:

- Tablet core: lactose monohydrate, cellulose, microcrystalline (type 102) (E460), hypromellose 2910 (5 mPa·s) (E464), croscarmellose sodium, silica, colloidal anhydrous (E551), magnesium stearate (E470b)
- Tablet coating: poly(vinyl alcohol) (E1203), calcium carbonate (E170), macrogol 4000 (E1521), talc (E553b)

<Product name> 25 mg film-coated tablets also contains: Iron oxide black (E172), Iron oxide yellow (E172)
<Product name> 50 mg film-coated tablets also contains: Iron oxide yellow (E172)
<Product name> 75 mg film-coated tablets also contains: Iron oxide black (E172), Iron oxide red (E172)
<Product name> 100 mg film-coated tablets also contains: Iron oxide yellow (E172), Iron oxide black (E172)

What <Product name> looks like and contents of the pack
<Product name> 10 mg film-coated tablets are white to off-white, round biconvex tablets, debossed with '10' on one side and breakline on the other.
<Product name> 25 mg film-coated tablets are grey, oblong biconvex tablets, debossed with '25' on one side and plain on the other.
<Product name> 50 mg film-coated tablets are yellow, oblong biconvex tablets, debossed with '50' on one side and plain on the other.
<Product name> 75 mg film-coated tablets are purple, oblong biconvex tablets, debossed with '75' on one side and plain on the other.
<Product name> 100 mg film-coated tablets are green, oblong biconvex tablets, debossed with '100' on one side and plain on the other.

<Product name> is available in Aluminium-OPA/Alu/PVC blisters containing 14, 56 or 100 film-coated tablets or multipacks containing 168 (3 packs of 56) film-coated tablets or perforated unit-dose blisters containing 14 x 1, 56 x 1 or 100 x 1 film-coated tablets or multipacks containing 168 (3 packs of 56 x 1) film-coated tablets.

<Product name> is also available in High-Density Polyethylene (HDPE) bottles, closed with a polypropylene (PP) child resistant cap containing 60 film-coated tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:
STADA Arzneimittel AG
Stadastrasse 2-18
61118 Bad Vilbel
Duitsland

Fabrikant:
PharOS MT Ltd.
HF62X, Hal Far Industrial Estate
BBG 3000 Birzebbugia
Malta

PharOS Pharmaceutical Oriented Services Ltd.
Lesvou Street End, Thesi Loggos Industrial Zone
144 52 Metamorfossi
Griekenland

STADA Arzneimittel AG

Stadastrasse 2-18
61118 Bad Vilbel
Duitsland

Centrafarm Services B.V.
Van de Reijtstraat 31-E
4814 NE Breda
Nederland

Clonmel Healthcare Ltd
Waterford Road,
E91 D768 Tipperary
Clonmel, Co.
Ierland

Stada M&D S.R.L.
Strada Trascaului Nr 10
401135 Turda
Roemenië

Laboratori Fundació Dau
C/C, 12-14 Pol. Ind. Zona Franca
08040 Barcelona
Spanje

In het register ingeschreven onder

Brivaracetam STADA 10 mg, filmomhulde tabletten	RVG 132915
Brivaracetam STADA 25 mg, filmomhulde tabletten	RVG 132916
Brivaracetam STADA 50 mg, filmomhulde tabletten	RVG 132917
Brivaracetam STADA 75 mg, filmomhulde tabletten	RVG 132918
Brivaracetam STADA 100 mg, filmomhulde tabletten	RVG 132919

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Denemarken, Duitsland, Finland, Hongarije, IJsland, Nederland, Noorwegen, Spanje, Tsjechië, Zweden	Brivaracetam STADA
Ierland, Malta	Brivaracetam Clonmel

Deze bijsluiter is voor het laatst goedgekeurd in maart 2025.