Patient leaflet in accordance with the Pharmacists' Regulations (Preparations)- 1986
This medicine is to be supplied upon a physician's prescription only

Briviact® 10 mg film-coated tablets
Briviact® 25 mg film-coated tablets
Briviact® 50 mg film-coated tablets
Briviact® 75 mg film-coated tablets
Briviact® 100 mg film-coated tablets

Active ingredient:
Briviact 10 mg film-coated tablets contain brivaracetam 10 mg
Briviact 25 mg film-coated tablets contain brivaracetam 25 mg
Briviact 50 mg film-coated tablets contain brivaracetam 50 mg
Briviact 75 mg film-coated tablets contain brivaracetam 75 mg
Briviact 100 mg film-coated tablets contain brivaracetam 100 mg

For the list of excipients and allergens of the medicine, please see section 2: “Important information regarding some of the ingredients of the medicine” and section 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 used in adults, adolescents and children from 4 years of age to treat a type of epilepsy characterized by the occurrence of partial seizures with or without 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 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 section 6). If you are not sure, talk to your physician or pharmacist before taking Briviact.
- You have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Briviact.
  Serious skin reactions including Stevens-Johnson syndrome have been reported in association with Briviact treatment. Stop using Briviact and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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 (a medicine used to treat bacterial infections).
- St John's wort [(Hypericum perforatum) a herbal medicine used to treat depression and 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 film-coated tablets contain:
- Lactose (a type of sugar) - If you have been told by your physician that you have an intolerance to some sugars, contact your physician before taking this medicine.
- Sodium - This medecine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium free'.

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 this medicine. Briviact is taken 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. The recommended dose for adults, adolescents, and children who weigh 50 kg or more is usually between 25 mg and 100 mg twice a day
Your physician may decide to adjust your dose to find the best dose for you.

The recommended dose for children and adolescents who weigh less than 50 kg is usually between 0.5 mg to 2 mg for each kg of body weight twice a day.
Your physician may decide to adjust your dose to find the best dose for you.

Patients with liver problems
If you have a 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.

Swallow the tablets whole with a glass of liquid.
There is no information regarding crushing, dividing and chewing the tablet. If you are not able to swallow the tablets, you may be recommended using Briviact oral solution. May be taken with or without food

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 with 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 from coming back or getting worse.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> 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. <u>Side effects</u>
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

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 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 carton and blister. 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.

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:**

Lactose monohydrate, lactose anhydrous, croscarmellose sodium, betadex, magnesium stearate.
Coating
10 mg film-coated tablets: polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc.
25 mg film-coated tablets: polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc, iron oxide black (E172), iron oxide yellow (E172).
50 mg film-coated tablets: polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc, iron oxide yellow (E172), iron oxide red (E172).

75 mg film-coated tablets: polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc, iron oxide red (E172), iron oxide black (E172), iron oxide yellow (E172).
100 mg film-coated tablets: polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc, iron oxide yellow (E172), iron oxide black (E172).

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

Briviact 10 mg are white to off-white, round, film-coated tablets of 6.5 mm in diameter and debossed with ‘u10’ on one side.
Briviact 25 mg are grey, oval, film-coated tablets of 8.9 mm x 5.0 mm and debossed with ‘u25’ on one side.
Briviact 50 mg are yellow, oval, film-coated tablets of 11.7 mm x 6.6 mm and debossed with ‘u50’ on one side.
Briviact 75 mg are purple, oval, film-coated tablets of 13.0 mm x 7.3 mm and debossed with ‘u75’ on one side.
Briviact 100 mg are green-grey, oval, film-coated tablets of 14.5 mm x 8.1 mm and debossed with ‘u100’ on one side.

Briviact tablets are packaged in blister packs supplied in cardboard boxes containing either 14, 56 or 100 film-coated tablets or in multipacks containing 168 (3 packs of 56) film-coated tablets.
All packs are available in PVC/PCTFE - Aluminium blisters.

Not all pack sizes may be marketed.

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

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

Drug registration numbers at the national medicinal products registry of the Ministry of Health:
Briviact 10 mg film-coated tablets: 159-88-35241
Briviact 25 mg film-coated tablets: 159-89-35242
Briviact 50 mg film-coated tablets: 159-90-35243
Briviact 75 mg film-coated tablets: 159-91-35244
Briviact 100 mg film-coated tablets: 159-92-35245

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