IN **Package leaflet: Information for the patient**

℞ BRIVARACETAM

BRIVIACT®

film-coated tablets

50 mg, 75 mg, 100 mg

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.

NAME OF THE MEDICINAL PRODUCT

Briviact 50 mg film-coated tablets
Briviact 75 mg film-coated tablets
Briviact 100 mg film-coated tablets

INDICATION

Briviact is indicated as adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy.

SPECIAL WARNING AND PRECAUTION FOR USE

Talk to your doctor 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 doctor immediately.
- You have liver problems your doctor may need to adjust your dose.

Children and young people

Briviact is not recommended for use in children and young people under 16 years of age.

INTERACTION WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, your doctor 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, (also known as Hypericum perforatum) a herbal medicine used to treat depression and anxiety and 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, BREAST-FEEDING AND FERTILITY

It is not recommended to take Briviact if you are pregnant or breast-feeding, as the effects of Briviact on pregnancy and the unborn baby or the new-born child are not known. Seek advice immediately from your doctor if you are pregnant or are planning to become pregnant.

No human data on the effect of brivaracetam on fertility are available.

Do not stop treatment without talking to your doctor first as this could increase your seizures and a worsening of your disease can harm your baby.

EFFECTS ON ABILITY TO DRIVE AND USE 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.

Briviact contains lactose

Briviact film-coated tablets contain 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.

POSOLOGY AND METHOD OF ADMINISTRATION

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You will take Briviact together with other medicines for epilepsy.

How much to take
- The recommended dose is between 50 mg and 200 mg each day, your doctor may decide to adjust your optimal dose within the dose range.
- Take the medicine in two equally divided doses - once in the morning and once in the evening at about the same time each day.

People with liver problems

If you have problem with your liver, the maximum dose you will take is 150 mg each day.

Method of administration
- Swallow the tablets whole with a glass of liquid.
- The medicine may be taken with or without food.

How long to take Briviact for

Briviact is a long term treatment – keep taking Briviact until your doctor tells you to stop.

OVERDOSE

If you have taken more Briviact than you should, talk to your doctor. You may feel dizzy and sleepy.

Antidote for overdosing

There is no specific antidote for overdose with brivaracetam. Treatment of an overdose should include general supportive measures. Since less than 10% of brivaracetam is excreted in urine, haemodialysis is not expected to significantly enhance brivaracetam clearance

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 doctor or pharmacist

If you stop taking 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.

CONTRAINDICATIONS

Do not use Briviact if you are allergic to brivaracetam, other pyrrolidone derivatives or any of the other ingredients of this medicine (See section-List of excipients). If you are not sure, talk to your doctor or pharmacist before taking Briviact.

UNDESIRABLE EFFECTS/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, unable 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
- psychotic disorder, being aggressive, thoughts or attempts of harming or killing yourself, nervous excitement (agitation)
- a decrease in white blood cells (called 'neutropenia') - shown in blood tests

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.

INCOMPATIBILITIES- Not Applicable

SPECIAL PRECAUTIONS FOR STORAGE
- 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 blister after EXP. The expiry date refers to the last day of that month.
- **Store below 30° C.**
- 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.

SHELF LIFE - 4 Years

WHAT BRIVIACT CONTAINS

The active substance is brivaracetam.

Each film-coated tablet contains 50mg, 75 mg, or 100 mg brivaracetam.

LIST OF EXCIPIENTS:

Brivaracetam film-coated tablet 50mg: Lactose monohydrate, Anhydrous lactose, Opadry II 85F38197 Yellow, Magnesium stearate. Betadex, Croscarmellose sodium.

Brivaracetam film-coated tablet 75mg: Opadry II 85F200021 Purple, Lactose monohydrate, Magnesium stearate, Croscarmellose sodium, Betadex, Anhydrous lactose.

Brivaracetam film-coated tablet 100mg: Croscarmellose sodium, Lactose monohydrate, Betadex, Anhydrous lactose, Magnesium stearate, Opadry II 85F270000, Tan.

WHAT BRIVIACT LOOKS LIKE AND CONTENTS OF THE PACK

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.

NATURE AND CONTENTS OF CONTAINER

Briviact tablets are packaged in blister packs supplied in cardboard boxes containing 14 film-coated tablets.

All packs are available in PVC/PCTFE - Aluminium blisters.

SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

MANUFACTURER

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