



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Briviact®

solution for injection

(pronounced "BREE-vee-act")

Contains the active ingredient brivaracetam (pronounced "BREE-va-RA-se-tam")

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Briviact.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Briviact against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Briviact is used for

Briviact solution for injection is used in combination with other medicines to control epilepsy. Epilepsy is a condition where you have repeated seizures. There are many different types of seizures, ranging from mild to severe.

This medicine belongs to a group of medicines called antiepileptics. These medicines are thought to work by controlling brain chemicals

which send signals to nerves so that seizures do not happen.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

There is no evidence that Briviact is addictive.

This medicine is available only with a doctor's prescription.

Briviact is not recommended for use in children under the age of 4 years as its safety and effectiveness has not been established in this age group.

Before you take Briviact

When you must not take it

Do not take Briviact if you have an allergy to:

- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

If you are not sure whether any of the above conditions apply to you, ask your doctor.

Do not take this medicine after the expiry date printed on the pack.

Do not take this medicine if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines, especially barbiturates (such as phenobarbitone) or any other antiepileptic medicines (such as carbamazepine, lamotrigine or levetiracetam)
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- kidney problems
- liver problems.

Tell your doctor if you are pregnant or intend to become pregnant.

Briviact may affect your developing baby if you take it during

pregnancy. However, it is very important to control your seizures while you are pregnant. Your doctor will outline and weigh up all the risks and benefits of taking Briviact during pregnancy to help decide whether or not you should take it.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Your doctor will discuss the risks and benefits of using Briviact if you are breastfeeding.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Briviact.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Briviact may interfere with each other. These include:

- rifampicin, a medicine used to treat tuberculosis

Briviact does not interact with the oral contraceptive pill.

However, you may be given Briviact together with other antiepileptic medicines that do interact and may affect the effectiveness of your contraceptive. Your doctor may advise you to use an additional method of contraception if you take Briviact with other antiepileptic medicines.

How to take Briviact

How much to take

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor will tell you how much Briviact you will need to take each day. This may depend on your

condition and whether or not you are taking any other medicines.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How to take it

Briviact therapy can be initiated with either tablets, oral solution or by injection. The solution for injection is an alternative form of treatment for a short time, when Briviact can't be taken by mouth. It will be administered into a vein by a healthcare professional. It is possible to switch directly from oral administration to injection and the other way around.

When to take it

Take Briviact twice a day, once in the morning and once at night. Take it at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

If you forget to take it

Contact your doctor if you have missed one or more doses.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

How long to take it

Most antiepileptic medicines take time to work, so do not be discouraged if you do not feel better straight away.

Continue taking your medicine for as long as your doctor tells you to.

This medicine helps control your condition, but does not cure it. Therefore you must take your medicine every day, even if you feel well.

Do not stop taking Briviact, or change the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

Stopping Briviact suddenly may cause unwanted side effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone in Australia 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Briviact. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdose may include feeling dizzy or drowsy.

While you are using Briviact

Things you must do

Tell your doctor immediately if you notice an increase in seizures or a change in the type of seizures you usually have.

Tell your doctor immediately if you have symptoms of depression or thoughts of harming yourself.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking this medicine.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Briviact.

Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking Briviact.

Tell your doctor if you feel Briviact is not helping your condition.

Your doctor may need to change your medicine.

Tell your doctor if, for any reason, you have not taken this medicine exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily.

If you become pregnant while taking this medicine, tell your doctor.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some tests from time to time. This helps to prevent unwanted side effects.

Things you must not do

Do not give Briviact to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.

Do not take Briviact to treat any other complaints unless your doctor tells you to.

Do not stop taking Briviact or change the dosage unless your doctor tells you to.

Stopping Briviact suddenly may cause unwanted side effects or make your condition worse.

Things to be careful of

Be careful driving or operating machinery until you know how Briviact affects you.

As with other antiepileptic medicines Briviact may cause dizziness or drowsiness.

If you are feeling dizzy or drowsy, do not drive a car, operate machinery, or do anything else that could be dangerous.

Combining this medicine with alcohol is not recommended. If you drink alcohol while taking Briviact the negative effects of alcohol may be increased.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Briviact.

This medicine helps most people with epilepsy but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

If you get any side effects, do not stop taking Briviact without first talking to your doctor or pharmacist.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- flu and upper respiratory tract infections
- cough
- dizziness
- nausea (feeling sick) or vomiting
- constipation
- feeling tired, drowsy or sleepy

The above list includes the more common side effects of your medicine. They are mostly mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- feelings of depression, anxiety or nervousness
- feeling aggressive

- spinning sensations
- recurrent infections

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- thoughts of harming yourself
- more frequent or more severe seizures
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

The above list includes more serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

After using Briviact

Storage

The vial will be kept in the pack until it is time to administer the medicine. The medicine will not keep well if the vial is taken out of the pack.

The vial will be kept in a cool dry place where the temperature stays below 30°C, and where children cannot reach it.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

BRIVIACT solution for injection is a clear, colourless solution packaged in clear, colourless glass vials with grey rubber stoppers and sealed with aluminium caps fitted with white tear-off seals. Each single use vial contains 5 mL of solution for injection.

Ingredients

Each 5 mL vial contains 50 mg of brivaracetam as the active ingredient.

Other ingredients in Briviact solution for injection include:

- sodium acetate trihydrate
- glacial acetic acid
- sodium chloride
- water for injections

Briviact solution for injection does not contain sucrose, gluten, lactose, tartrazine or any other azo dyes.

Australian Sponsor:

UCB Pharma
A division of UCB Australia Pty
Ltd
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Malvern Vic 3144
Australia

Briviact 50 mg/5 mL solution for injection

- AUST R 243795

Date of preparation:

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SPRL*