

Material # / Product: **LF BRIVANEL 10mg 25mg 50mg 75mg 100mg OLS UK**

Version: **03** Date: **05.01.2026** Substitutes mat. #: - Mockup #: -

Folded dimensions:
1 fold in horizontal to 140 x 270 mm

Pantones:
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Package leaflet: Information for the patient

Brivanel 10 mg film-coated tablets
Brivanel 25 mg film-coated tablets
Brivanel 50 mg film-coated tablets
Brivanel 75 mg film-coated tablets
Brivanel 100 mg film-coated tablets

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

1. What Brivanel is and what it is used for

What Brivanel is

Brivanel film-coated tablets (referred to as Brivanel) contains the active substance brivaracetam. It belongs to a group of medicines called 'anti-epileptics'. These medicines are used to treat epilepsy.

What Brivanel is used for

- Brivanel 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.
- Brivanel is used together with other medicines for epilepsy.

2. What you need to know before you take Brivanel

Do not take Brivanel if

- you are allergic to brivaracetam, other similar chemical compounds as levitracetam 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 Brivanel.
- you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Brivanel.

Serious skin reactions including Stevens-Johnson syndrome have been reported in association with brivaracetam treatment. Stop using Brivanel 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 Brivanel if:
 - you have thoughts of harming or killing yourself. A small number of people being treated with anti-epileptic medicines such as Brivanel 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

Brivanel is not recommended for use in children under 2 years of age.

Other medicines and Brivanel

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 Brivanel 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.

Brivanel with alcohol

- Combining this medicine with alcohol is not recommended.
- If you drink alcohol while taking Brivanel 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.

2. How to take Brivanel

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 can not be swallowed in whole, for example); ask your doctor or pharmacist. You will take Brivanel 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.

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 Brivanel

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

How long to take Brivanel for

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

If you take more Brivanel than you should

If you have taken more Brivanel 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 Brivanel

- 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 Brivanel

- 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.

3. How to take Brivanel

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 can not be swallowed in whole, for example); ask your doctor or pharmacist. You will take Brivanel 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.

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 Brivanel

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

How long to take Brivanel for

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

If you take more Brivanel than you should

If you have taken more Brivanel 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 Brivanel

- 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 Brivanel

- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, [Website: www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard), or **search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.**

5. How to store Brivanel

- 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.
- This medicine 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 Brivanel contains

- The active substance is brivaracetam.
- Each film-coated tablet contains 10 mg brivaracetam.
- Each film-coated tablet contains 25 mg brivaracetam.
- Each film-coated tablet contains 50 mg brivaracetam.
- Each film-coated tablet contains 75 mg brivaracetam.
- Each film-coated tablet contains 100 mg brivaracetam.

The other ingredients are:
Core
Lactose monohydrate, croscarmellose sodium, lactose (anhydrous) and magnesium stearate.

Coating
Poly(vinyl alcohol) (E1203), titanium dioxide (E171), macrogol 4000 (E1521) and talc (E553b).

Poly(vinyl alcohol) (E1203), titanium dioxide (E171), macrogol 4000 (E1521), talc (E553b), iron oxide black (E172), iron oxide yellow (E172).

Poly(vinyl alcohol) (E1203), titanium dioxide (E171), macrogol 4000 (E1521), talc (E553b), iron oxide yellow (E172), iron oxide red (E172).

Poly(vinyl alcohol) (E1203), titanium dioxide (E171), macrogol 4000 (E1521), iron oxide red (E172), iron oxide black (E172), iron oxide yellow (E172).

Poly(vinyl alcohol) (E1203), titanium dioxide (E171), macrogol 4000 (E1521), talc (E553b), iron oxide yellow (E172), iron oxide black (E172).

What Brivanel looks like and contents of the pack

Film-coated tablets are white, round (dimension 5.5 mm) biconvex film coated tablets, debossed with "10" on one side and plain on the other side.

Film-coated tablets are grey, oval (dimension 8.9 mm X 5.0 mm) biconvex film coated tablets, debossed with "25" on one side and plain on the other side.

Film-coated tablets are yellow, oval (dimension 11.7 mm X 6.5 mm) biconvex film coated tablets, debossed with "50" on one side and plain on the other side.

Film-coated tablets are purple, oval (dimension 13.0 mm X 7.3 mm) biconvex film coated tablets, debossed with "75" on one side and plain on the other side.

Film-coated tablets are green-grey, oval (dimension 14.5 mm X 8.1 mm) biconvex film coated tablets, debossed with "100" on one side and plain on the other side.

Brivanel 10 mg film-coated tablets are packaged in

- Blisters composed by PVC/PCTFE (Aclar) Clear - Aluminium or PVC/PE/PVDC Clear - Aluminium containing 14, 28, 56 and 84 film-coated tablets
- HDPE bottle with silica gel desiccant contained in the polypropylene cap containing 56, 60, 100 and 168 film-coated tablets

Brivanel 25 mg film-coated tablets are packaged in

- Blisters composed by PVC/PCTFE (Aclar) Clear - Aluminium or PVC/PE/PVDC Clear - Aluminium containing 14, 28, 56 and 84 film-coated tablets
- HDPE bottle with silica gel desiccant contained in the polypropylene cap containing 56, 60, 100 and 168 film-coated tablets

Brivanel 50 mg film-coated tablets are packaged in

- Blisters composed by PVC/PCTFE (Aclar) Clear - Aluminium or PVC/PE/PVDC Clear - Aluminium containing 14, 28, 56 and 84 film-coated tablets
- HDPE bottle with silica gel desiccant contained in the polypropylene cap containing 56, 60, 100 and 168 film-coated tablets

Brivanel 75 mg film-coated tablets are packaged in

- Blisters composed by PVC/PCTFE (Aclar) Clear - Aluminium or PVC/PE/PVDC Clear - Aluminium containing 14, 28, 56 and 84 film-coated tablets
- HDPE bottle with silica gel desiccant contained in the polypropylene cap containing 168 film-coated tablets

Brivanel 100 mg film-coated tablets are packaged in

- Blisters composed by PVC/PCTFE (Aclar) Clear - Aluminium or PVC/PE/PVDC Clear - Aluminium containing 14, 28, 56 and 84 film-coated tablets
- HDPE bottle with silica gel desiccant contained in the polypropylene cap containing 56, 60, 100 and 168 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Laboratorios Liconsa S.A
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Brivanel is distributed by **Exeltis UK Limited**, Two Snowhill, 7th Floor, Birmingham, B4 6GA, UK.

This leaflet was last revised in January 2026.

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