

Provecta 10 mg, 25 mg, 50 mg, 75 mg and 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 5.

The product is known by the name above but will be referred to as Provecta throughout the rest of this leaflet.

In this leaflet:

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

1. Serious side effects

Like other antiepileptic drugs, brivaracetam may cause suicidal thoughts or actions in a very small number of people, about 1 in 500 people taking it.

Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- Thoughts about suicide or dying
- New or worse depression
- Feeling agitated or restless
- Trouble sleeping (insomnia)
- Acting aggressive, feeling angry, or being violent
- An extreme increase in activity and talking (mania)
- Attempts to commit suicide
- New or worse anxiety
- Panic attacks
- New or worse irritability
- Acting on dangerous impulses
- Other unusual changes in behavior or mood

Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
 - Keep all follow-up visits with your healthcare provider as scheduled.
 - Call your healthcare provider between visits as needed, especially if you are worried about symptoms.
- Do not stop Provecta without first talking to a healthcare provider.**
- Stopping Provecta suddenly can cause serious problems.
 - Stopping a seizure medicine suddenly can cause seizures that will not stop (status epilepticus).

2. What Provecta is and what it is used for

Provecta is a prescription medicine used to treat partial-onset seizures.

3. What you need to know before you take Provecta

Do not take Provecta

Do not take Provecta if you are allergic to brivaracetam or any of the ingredients in Provecta. See section 7 of this leaflet for a complete list of ingredients in Provecta.

Warnings and precautions

Before taking Provecta, tell your healthcare provider about all of your medical conditions, including if you:

- Have or had depression, mood problems, or suicidal thoughts or behavior.
- Have liver problems.
- Have abused or been dependent on prescription medicines, street drugs, or alcohol.
- Are pregnant or plan to become pregnant. It is not known if brivaracetam will harm your unborn baby.
- Tell your healthcare provider right away if you become pregnant while taking brivaracetam. You and your healthcare provider will have to decide if you should take brivaracetam while you are pregnant.
- Are breastfeeding or plan to breastfeed. It is not known if brivaracetam passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take brivaracetam.

Other medicines and Provecta

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Provecta may affect the way other medicines work, and other medicines may affect how Provecta works. Do not start a new medicine without first talking with your healthcare provider. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine.

Pregnancy and breast-feeding

Before taking Provecta, tell your healthcare provider if you:

- Are pregnant or plan to become pregnant. It is not known if brivaracetam will harm your unborn baby.
- Tell your healthcare provider right away if you become pregnant while taking brivaracetam. You and your healthcare provider will have to decide if you should take brivaracetam while you are pregnant.
- Are breastfeeding or plan to breastfeed. It is not known if brivaracetam passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take brivaracetam.

Driving and using machines

Do not drive or operate machinery until you know how brivaracetam affects you. Brivaracetam may cause drowsiness, tiredness, dizziness, and problems with your balance and coordination.

Provecta contains sodium and lactose

Provecta contains sodium. Each film-coated Tablet of Provecta 10 mg, 25 mg, 50 mg, 75 mg and 100 mg Film-coated Tablets contains 0.21 mg, 0.525 mg, 1.05 mg, 1.575 mg or 2.1 mg sodium, respectively. This medicine contains less than 1 mmol sodium (23 mg) per film-coated Tablet, that is to say essentially "sodium-free". Provecta contains lactose. Each film-coated Tablet of Provecta 10 mg, 25 mg, 50 mg, 75 mg and 100 mg Film-coated Tablets contains 37.7 mg, 94.25 mg, 188.5 mg, 288.7 mg or 377 mg lactose, respectively. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

4. How to take Provecta

Take Provecta exactly as your healthcare provider tells you.

Your healthcare provider will tell you how much Provecta to take and when to take it.

Your healthcare provider may change your dose if needed. Do not change your dose without talking to your healthcare provider.

Take Provecta with or without food.

Swallow Provecta tablets whole with a liquid. Do not chew or crush Provecta tablets before swallowing.

Monotherapy or Adjunctive Therapy

The recommended dosage for patients is included in Table 1. In pediatric patients weighing less than 50 kg, the recommended dosing regimen is dependent upon body weight. When initiating treatment, gradual dose escalation is not required. Dosage should be adjusted based on clinical response and tolerability.

Table 1: Recommended Dosage for Patients

Age and Body Weight	Initial Dosage	Minimum and Maximum Maintenance Dosage
Adults (16 years and older)	50 mg twice daily (100 mg per day)	25 mg to 100 mg twice daily (50 mg to 200 mg per day)
Pediatric patients weighing 50 kg or more who are able to swallow the tablets	25 mg to 50 mg twice daily (50 mg to 100 mg per day)	25 mg to 100 mg twice daily (50 mg to 200 mg per day)
Pediatric patients weighing 20 kg to less than 50 kg who are able to swallow the tablets	0.5 mg/kg to 1 mg/kg twice daily (1 mg/kg to 2 mg/kg per day)	0.5 mg/kg to 2 mg/kg twice daily (1 mg/kg to 4 mg/kg per day)

Patients with Hepatic Impairment

The recommended dosage for patients with hepatic impairment is included in Table 2.

Table 2: Recommended Dosage for Patients with Hepatic Impairment

Age and Body Weight	Initial Dosage	Maximum Maintenance Dosage
Adults (16 years and older)	25 mg twice daily (50 mg per day)	75 mg twice daily (150 mg per day)
Pediatric patients weighing 50 kg or more who are able to swallow the tablets	0.5 mg/kg twice daily (1 mg/kg per day)	1.5 mg/kg twice daily (3 mg/kg per day)
Pediatric patients weighing 20 kg to less than 50 kg who are able to swallow the tablets	0.5 mg/kg twice daily (1 mg/kg per day)	1.5 mg/kg twice daily (3 mg/kg per day)

If you take more Provecta than you should

If you take too much Provecta, call your doctor or go to the nearest emergency room right away.

If you stop taking Provecta

Do not stop Provecta without first talking to a healthcare provider.

- Stopping Provecta suddenly can cause serious problems.
- Stopping a seizure medicine suddenly can cause seizures that will not stop (status epilepticus).

5. Possible side effects

Brivaracetam may cause serious side effects, including:

- See "Serious side effects"
- Nervous system problems. Drowsiness, tiredness, and dizziness are common with brivaracetam, but can be severe. See "Driving and using machines" brivaracetam can also cause problems with balance and coordination.
- Mental (psychiatric) symptoms. Brivaracetam can cause mood and behavior changes such as aggression, agitation, anger, anxiety, apathy, mood swings, depression, hostility, and irritability. Irritability and anxiety are common with brivaracetam, and can be severe. People who take brivaracetam can also get psychotic symptoms such as hallucinations (seeing or hearing things that are really not there), delusions (false or strange thoughts or beliefs), and unusual behavior.

The most common side effects of brivaracetam in adults include:

- Sleepiness
- Dizziness
- Feeling tired
- Nausea and vomiting

Side effects of brivaracetam in the intended pediatric patients are similar to those seen in adults.

These are not all the possible side effects of brivaracetam. For more information, ask your healthcare provider or pharmacist. Tell your healthcare provider about any side effect that bothers you or that does not go away. Call your doctor for medical advice about side effects.

6. How to store Provecta

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Store in the original package.

Do not use this medicine after the expiry date which is stated on the package after "EXP". The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration.

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.

7. Contents of the pack and other information

What Provecta contains

The active substance is brivaracetam.

Each film-coated tablet of Provecta 10 mg, 25 mg, 50 mg, 75 mg and 100 mg Film-coated Tablets contains 10 mg, 25 mg, 50 mg, 75 mg or 100 mg brivaracetam, respectively.

The other ingredients are betadex, croscarmellose sodium, lactose, magnesium stearate and Opadry white.

What Provecta looks like and contents of the pack

Provecta 10 mg Film-coated Tablets are white to off-white round-shaped film-coated tablets debossed with "10" on one side and plain on the other side in aluminum lidding foil clear PVC/Aclar blisters.

Pack size: 14 Film-coated Tablets

Provecta 25 mg Film-coated Tablets are white to off-white oval-shaped film-coated tablets debossed with "25" on one side and plain on the other side in aluminum lidding foil clear PVC/Aclar blisters.

Pack size: 60 Film-coated Tablets

Provecta 50 mg Film-coated Tablets are white to off-white oval-shaped film-coated tablets debossed with "50" on one side and plain on the other side in aluminum lidding foil clear PVC/Aclar blisters.

Pack size: 60 Film-coated Tablets

Provecta 75 mg Film-coated Tablets are white to off-white oval-shaped film-coated tablets debossed with "75" on one side and plain on the other side in aluminum lidding foil clear PVC/Aclar blisters.

Pack size: 60 Film-coated Tablets

Provecta 100 mg Film-coated Tablets are white to off-white oval-shaped film-coated tablets debossed with "100" on one side and plain on the other side in aluminum lidding foil clear PVC/Aclar blisters.

Pack size: 60 Film-coated Tablets

Marketing Authorization Holder and Batch releaser

Arkema Pharmaceuticals LLC

Bayader Wadi El Seer

Industrial Area

P.O. Box 182400

Amman 1118, Jordan

Tel: + (962-6) 5802900

Fax: + (962-6) 581702

Website: www.hikma.com

Bulk manufacturer

Jazeera Pharmaceutical Industries

Al-Kharj Road

P.O. Box 106229

Riyadh 11666, Saudi Arabia

Tel: + (966-11) 8107023, + (966-11) 2142472

Fax: + (966-11) 2078170

e-mail: SAVP@hikma.com

This leaflet was last revised in 01/2024; version number Un4.0.

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 (see details below). By reporting side effects, you can also help provide more information on the safety of this medicine.

• Jordan

Jordan Food and Drug Administration- Rational Drug Use and Pharmacovigilance Department

e-mail: jpc@fda.jo

Website: https://primaryreporting.who-umc.org/JO

Tel: + (962-6) 5632000

QR Code:



• United Arab of Emirates

Pharmacovigilance & Medical Device Section

P.O. Box: 1853

Tel: 80011111

Email: pv@moah.gov.ae

Drug Department

Ministry of Health & Prevention

Dubai

• Saudi Arabia

The National Pharmacovigilance Centre (NPC)

SFDA Call Center: 19999

E-mail: npc.drug@sfd.gov.sa

Website: https://ade.sfd.gov.sa

• Other GCC States

Please contact the relevant competent authority.

Council of Arab Health Ministers, Union of Arab Pharmacists

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Size:
170*250
Pantone.
2766