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IMPORTANT INFORMATION

1. Site items and Pharmacodes: Site item code and pharmacode will be provided by Adalvo to client, and client needs to add this information in the artwork before a technical approval is granted.

ARTWORK CONTACT

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ADALVO

FRONT

150 mm

20 mm

PHARMACODE

530 mm

Package leaflet: Information for the patient

Brivaracetam Altair 10 mg film-coated tablets
Brivaracetam Altair 25 mg film-coated tablets
Brivaracetam Altair 50 mg film-coated tablets
Brivaracetam Altair 75 mg film-coated tablets
Brivaracetam Altair100 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 brivaracetam tablet is and what it is used for
2. What you need to know before you take brivaracetam tablet
3. How to take
4. Possible side effects
5. How to store brivaracetam tablet
6. Contents of the pack and other information

The name of your medicine is "Brivaracetam Altair 10 mg, 25 mg, 50 mg, 75 mg and 100 mg film-coated tablet" but will be referred to as "Brivaracetam tablets" in this leaflet.

1. What brivaracetam tablet is and what it is used for

What brivaracetam tablet is
Brivaracetam tablet contains the active substance brivaracetam. It belongs to a group of medicines called 'anti-epileptics'. These medicines are used to treat epilepsy.

What brivaracetam tablet is used for
- Brivaracetam tablet 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.
- Brivaracetam tablet is used together with other medicines for epilepsy.

2. What you need to know before you take brivaracetam tablet

Do not take brivaracetam tablet if
- You are allergic to 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 doctor or pharmacist before taking brivaracetam tablet.
- You have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking this medicine.

Serious skin reactions including Stevens-Johnson syndrome have been reported in association with brivaracetam treatment. Stop using this medicine 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 brivaracetam tablet if:
- You have thoughts of harming or killing yourself. A small number of people being treated with anti-epileptic medicines such as brivaracetam tablet 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
Brivaracetam tablet is not recommended for use in children under 2 years of age.

Other medicines and brivaracetam tablet
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 brivaracetam tablet 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.

Brivaracetam tablet with alcohol
- Combining this medicine with alcohol is not recommended.
- If you drink alcohol while taking brivaracetam tablet 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 planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is not recommended to take brivaracetam tablet if you are pregnant, as the effects of brivaracetam tablet on pregnancy and the unborn baby are not known.

It is not recommended to breast-feed your baby while taking brivaracetam tablet, as brivaracetam tablet passes into breast milk.

Do not stop treatment without talking to your doctor first. Stopping treatment could increase your seizures and harm your baby.

Driving and using machines
- You may feel sleepy, dizzy or tired while taking brivaracetam tablet.
- 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.

Brivaracetam tablet contains lactose and sodium
Brivaracetam tablet 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.
- sodium – This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. How to take

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

PHARMACODE

20 mm

BACK

150 mm

70 mm

PHARMACODE

530 mm

How long to take brivaracetam tablet for
Brivaracetam tablet is a long term treatment – keep taking brivaracetam tablet until your doctor tells you to stop.
If you take more brivaracetam tablet than you should
If you have taken more brivaracetam tablet 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 brivaracetam tablet
- 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 brivaracetam tablet
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store brivaracetam tablet

- 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, bottle and blister after EXP. The expiry date refers to the last day of that month.
- This medicinal product 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 brivaracetam tablet contains
The active substance is brivaracetam.
Each film-coated tablet contains 10 mg, 25 mg, 50 mg, 75 mg, or 100 mg brivaracetam.

The other ingredients are:

Core
Croscarmellose sodium (E468), lactose monohydrate, lactose anhydrous, magnesium stearate (E470b)

Coating
- 10 mg film-coated tablets: polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 3350, talc(E553b).
- 25 mg film-coated tablets: polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 3350, talc (E553b), iron oxide yellow (E172), iron oxide black (E172).
- 50 mg film-coated tablets: polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 3350, talc (E553b), iron oxide yellow (E172), iron oxide red (E172).
- 75 mg film-coated tablets: polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 3350, talc (E553b), iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172).
- 100 mg film-coated tablets: polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 3350, talc (E553b), iron oxide yellow (E172), iron oxide black (E172).

What brivaracetam tablet looks like and contents of the pack

Brivaracetam tablet 10 mg are white to off-white, round film coated tablets of 5.1 mm diameter and debossed with '10' on one side.

Brivaracetam tablet 25 mg are grey, oval film-coated tablets with dimensions of 9.1 mm x 5.1 mm and debossed with '25' on one side.

Brivaracetam tablet 50 mg are yellow, oval film-coated tablets with dimensions of 11.8 mm x 6.7 mm and debossed with '50' on one side.

Brivaracetam tablet 75 mg are purple, oval film-coated tablets with dimensions of 13.1 mm x 7.4 mm and debossed with '75' on one side.

Brivaracetam tablet 100 mg are greenish-grey, oval film-coated tablets with dimensions of 14.7 mm x 8.3 mm and debossed with '100' on one side.

Brivaracetam tablet tablets are packaged in:
- White HDPE bottles with PP screw caps (with liner) and silica gel desiccant cannister
- PVC/PCTFE-Aluminium blisters

Pack sizes:
14, 56 film-coated tablets (blisters)
multipack of 168 (3 packs of 56) film-coated tablets.
60 film-coated tablets (bottle)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Altair Science Limited
78 Wembley Park Drive Wembley, HA9 8HB
United Kingdom

Manufacturer
Misom Labs Limited
Malta Life Sciences Park,
Ls2.01.06 Industrial Estate
San Gwann, SGN 3000, Malta

Adalvo Limited
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San Gwann, SGN 3000, Malta

This leaflet was last revised in September 2025.

Please contact the MA Holder listed above to request a copy of this leaflet in Braille, large print or CD.

Humanis Item Code:

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Colors	BLACK	**Font Size**	9 pt
Track Date	190925	**Fonts used:**	Times new roman