Package leaflet: Information for the patient

Lacosamide Aristo 50 mg film-coated tablets
Lacosamide Aristo 100 mg film-coated tablets
Lacosamide Aristo 150 mg film-coated tablets
Lacosamide Aristo 200 mg film-coated tablets
lacosamide

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 Lacosamide Aristo is and what it is used for
2. What you need to know before you take Lacosamide Aristo
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1. What Lacosamide Aristo is and what it is used for

What Lacosamide Aristo is
Lacosamide Aristo contains lacosamide. This belongs to a group of medicines called "antiepileptic medicines". These medicines are used to treat epilepsy.
You have been given this medicine to lower the number of fits (seizures) you have.

What Lacosamide Aristo is used for
Lacosamide Aristo is used in adults, adolescents and children aged 4 years and older.
It is used:
- on its own or in association with other antiepileptic medicines to treat a certain type of epilepsy characterised by the occurrence of partial-onset seizure with or without secondary generalisation. In this type of epilepsy, fits first affect only one side of your brain. However, these may then spread to larger areas on both sides of your brain.
- in association with other antiepileptic medicines to treat primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in patients with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

2. What you need to know before you take Lacosamide Aristo

Do not take Lacosamide Aristo
- if you are allergic to lacosamide, or any of the other ingredients of this medicine (listed in section 6). If you are not sure whether you are allergic, please discuss with your doctor.
- if you have a certain type of heart beat problem called second- or third-degree AV block.

Do not take Lacosamide Aristo if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions
Talk to your doctor before taking Lacosamide Aristo if:
- you have thoughts of harming or killing yourself. A small number of people being treated with antiepileptic medicinal products such as lacosamide have had thoughts of harming or killing themselves. If you have any of these thoughts at any time, tell your doctor straight away.
- you have a heart problem that affects the beat of your heart and you often have a particularly slow, fast or irregular heart beat (such as AV block, atrial fibrillation and atrial flutter);
- you have severe heart disease such as heart failure or have had a heart attack;
- you are often dizzy or fall over. Lacosamide Aristo may make you dizzy - this could increase the risk of accidental injury or a fall. This means that you should take care until you are used to the effects of this medicine.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Lacosamide Aristo.

If you are taking Lacosamide Aristo, talk to your doctor if you are experiencing a new type of seizure or worsening of existing seizures.

If you are taking Lacosamide Aristo and you are experiencing symptoms of abnormal heartbeat (such as slow, rapid or irregular heartbeat, palpitations, shortness of breath, feeling lightheaded, fainting), seek medical advice immediately (see section 4).

Children under 4 years
Lacosamide Aristo is not recommended for children aged under 4 years. This is because we do not yet know whether it will work and whether it is safe for children in this age group.

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines that affect your heart - this is because Lacosamide Aristo can also affect your heart:
- medicines to treat heart problems
- medicines which can increase the "PR interval" on a scan of the heart (ECG or electrocardiogram) such as medicines for epilepsy or pain called carbamazepine, lamotrigine or pregabalin
- medicines used to treat certain types of irregular heart beat or heart failure

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Lacosamide Aristo.

Also tell your doctor or pharmacist if you are taking any of the following medicines - this is because they may increase or decrease the effect of Lacosamide Aristo on your body:
- medicines for fungal infections called fluconazole, itraconazole or ketoconazole
- a medicine for HIV called ritonavir
- medicines used to treat bacterial infections called clarithromycin or rifampicin
- a herbal medicine used to treat mild anxiety and depression called St. John's Wort

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Lacosamide Aristo.

Lacosamide Aristo with alcohol
As a safety precaution, do not take Lacosamide Aristo with alcohol.

Pregnancy and breast-feeding
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 Lacosamide Aristo if you are pregnant as the effects of Lacosamide Aristo on pregnancy and the unborn baby are not known.
It is not recommended to breast-feed your baby while taking Lacosamide Aristo as lacosamide passes into breast milk. Seek advice immediately from your doctor if you get pregnant or are planning to become pregnant. They will help you decide if you should take Lacosamide Aristo or not.

Do not stop treatment without talking to your doctor first as this could increase your fits (seizures). A worsening of your disease can also harm your baby.

Driving and using machines
Do not drive, cycle or use any tools or machines until you know how this medicine affects you. This is because Lacosamide Aristo may make you feel dizzy or cause blurred vision.

3. How to take Lacosamide Aristo

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

Taking Lacosamide Aristo
- Take Lacosamide Aristo twice each day - once in the morning and once in the evening.
- Try to take it at about the same time each day.
- Swallow the tablet with a glass of water.
- You may take Lacosamide Aristo with or without food.
- The 100 mg, 150 mg and 200 mg tablets can be divided into equal doses.

You will usually start by taking a low dose each day and your doctor will slowly increase this over a number of weeks. When you reach the dose that works for you, this is called the "maintenance dose", you then take the same amount each day. Lacosamide Aristo is used as a long term treatment. You should continue to take Lacosamide Aristo until your doctor tells you to stop.

How much to take
Listed below are the normal recommended doses of Lacosamide Aristo for different age groups and weights.
Your doctor may prescribe a different dose if you have problems with your kidneys or with your liver.

Adolescents and children weighing 50 kg or more and adults
<u>When you take Lacosamide Aristo on its own</u>
- The usual starting dose is 50 mg twice a day.
  Your doctor may also prescribe a starting dose of 100 mg of Lacosamide Aristo twice a day.
- Your doctor may increase your twice daily dose every week by 50 mg. This will be until you reach a maintenance dose between 100 mg and 300 mg twice a day.

<u>When you take Lacosamide Aristo with other antiepileptic medicines</u>
- The usual starting dose is 50 mg twice a day.
- Your doctor may increase your twice daily dose every week by 50 mg. This will be until you reach a maintenance dose between 100 mg and 200 mg twice a day.
- If you weigh 50 kg or more, your doctor may decide to start Lacosamide Aristo treatment with a single "loading" dose of 200 mg. You would then start your ongoing maintenance dose 12 hours later.

Children and adolescent weighing less than 50 kg

The dose depends on their body weight. They usually start treatment with the syrup and only change to tablets if they are able to take tablets and get the correct dose with the different tablet strengths. The doctor will prescribe the formulation that is best suited to them.

If you take more Lacosamide Aristo than you should
If you have taken more Lacosamide Aristo than you should, contact your doctor immediately. Do not try to drive. You may experience:
- dizziness
- feeling sick (nausea) or being sick (vomiting)
- fits (seizures), heart beat problems such a slow, fast or irregular heartbeat, coma or a fall in blood pressure with rapid heartbeat and sweating

If you forget to take Lacosamide Aristo
- If you have missed a dose within the first 6 hours of the scheduled dose, take it as soon as you remember.
- If you have missed a dose beyond the first 6 hours of the scheduled dose, do not take the missed tablet anymore. Instead, take Lacosamide Aristo at the next time that you would normally take it.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Lacosamide Aristo
- Do not stop taking Lacosamide Aristo without talking to your doctor, as your epilepsy may come back again or become worse.
- If your doctor decides to stop your treatment with Lacosamide Aristo, they will tell you how to decrease the dose step by step.

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.

Nervous system side effects such as dizziness may be higher after a single “loading” dose.

Talk to your doctor or pharmacist if you get any of the following:

Very common (may affect more than 1 in 10 people):
- Headache
- Feeling dizzy or sick (nausea)
- Double vision (diplopia)

Common (may affect up to 1 in 10 people):
- Short jerks of a muscle or group of muscles (myoclonic seizures)
- Difficulties in coordinating your movements or walking
- Problems in keeping your balance, shaking (tremor), tingling (paraesthesia) or muscle spasms, falling easily and getting bruises
- Troubles with your memory, thinking or finding words, confusion
- Rapid and uncontrollable movements of the eyes (nystagmus), blurred vision
- A spinning sensation (vertigo), feeling drunk
- Being sick (vomiting), dry mouth, constipation, indigestion, excessive gas in the stomach or bowel, diarrhoea
- Decreased feeling or sensitivity, difficulty in articulating words, disturbance in attention
- Noise in the ear such as buzzing, ringing or whistling

- Irritability, trouble sleeping, depression
- Sleepiness, tiredness or weakness (asthenia)
- Itching, rash

Uncommon (may affect up to 1 in 100 people):
- Slow heart rate, palpitations, irregular pulse or other changes in the electrical activity of your heart (conduction disorder)
- Exaggerated feeling of wellbeing, seeing and/or hearing things which are not there
- Allergic reaction to medicine intake, hives
- Blood tests may show abnormal liver function, liver injury
- Thoughts of harming or killing yourself or attempting suicide: tell your doctor straight away
- Feeling angry or agitated
- Abnormal thinking or losing touch with reality
- Serious allergic reaction which causes swelling of the face, throat, hands, feet, ankles, or lower legs
- Fainting
- Difficulties in coordinating your movements or walking

Not known (frequency cannot be estimated from available data):
- Abnormal rapid heartbeat (ventricular tachyarrhythmia)
- A sore throat, high temperature and getting more infections than usual. Blood tests may show a severe decrease in a specific class of white blood cells (agranulocytosis)
- A serious skin reaction which may include a high temperature and other flu-like symptoms, a rash on the face, extended rash, swollen glands (enlarged lymph nodes). Blood tests may show increased levels of liver enzymes and a type of white blood cell (eosinophilia)
- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens–Johnson syndrome), and a more severe form causing skin peeling in more than 30 % of the body surface (toxic epidermal necrolysis)
- Convulsion

Additional side effects in children

Common (may affect up to 1 in 10 children):
- Runny nose (nasopharyngitis)
- Fever (pyrexia)
- Sore throat (pharyngitis)
- Eating less than usual

Uncommon (may affect up to 1 in 100 children):
- Feeling sleepy or lacking in energy (lethargy)

Not known (frequency cannot be estimated from available data)
- Changes in behaviour, not acting like themselves

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 the Yellow Card Scheme at: 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 Lacosamide Aristo

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 Lacosamide Aristo contains
The active substance is lacosamide.
One tablet of Lacosamide Aristo 50 mg contains 50 mg lacosamide.
One tablet of Lacosamide Aristo 100 mg contains 100 mg lacosamide.
One tablet of Lacosamide Aristo 150 mg contains 150 mg lacosamide.
One tablet of Lacosamide Aristo 200 mg contains 200 mg lacosamide.

The other ingredients are:
Tablet core: microcrystalline cellulose, hydroxypropylcellulose, hydroxypropylcellulose (low substituted), colloidal anhydrous silica, crospovidone, magnesium stearate.
Film-coat: polyvinyl alcohol, macrogol 3350, talc, titanium dioxide (E171),
50 mg tablet: red iron oxide (E172), black iron oxide (E172), indigo carmine aluminium lake (E132).
100 mg tablet: yellow iron oxide (E172).
150 mg tablet: yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172).
200 mg tablet: indigo carmine aluminium lake (E132).

What Lacosamide Aristo looks like and contents of the pack
Lacosamide Aristo 50 mg are light pink coloured, round, biconvex, film-coated tablets with an approximate diameter of 7 mm.
Lacosamide Aristo 100 mg are yellow coloured, oval, biconvex, film-coated tablets with a break mark on one side and approximate dimensions of 13 mm x 6 mm.
Lacosamide Aristo 150 mg are dark beige coloured, oval, biconvex, film-coated tablets with a break mark on one side and approximate dimensions of 15 mm x 7 mm.
Lacosamide Aristo 200 mg are dark blue coloured, oval, biconvex, film-coated tablets with a break mark on one side and approximate dimensions of 16 mm x 7.8 mm.

Lacosamide Aristo is available in packs of 14, 20, 30, 56, 60 and 168 film-coated tablets in PVC/aluminium blister.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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