Package leaflet: Information for the user

Arupsan 200 mg tablets
Arupsan 800mg tablets

eslicarbazepine acetate

Read all of this leaflet carefully before you or your child 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 <Invented Name> is and what it is used for

<Invented Name> contains the active substance eslicarbazepine acetate.
<Invented Name> belongs to a group of medicines called antiepileptics used to treat epilepsy, a condition where someone has repeated seizures or fits.

<Invented Name> is used:
- on its own (monotherapy) in adult patients with newly diagnosed epilepsy

- with other antiepileptic medicines (adjunctive therapy), in adult, adolescents and children patients above 6 years of age, who are experiencing seizures that affect one part of the brain (partial seizure). These seizures may or may not be followed by a seizure affecting all of the brain (secondary generalisation).

<Invented Name> has been given to you by your doctor to reduce your number of seizures.

2. What you need to know before you take <Invented Name>

Do not take <Invented Name>:
- if you are allergic to eslicarbazepine acetate, to other carboxamide derivatives (e.g. carbamazepine or oxcarbazepine, medicines used to treat epilepsy) or to any of the other ingredients of this medicine (listed in section 6);
- if you suffer from a certain type of heart rhythm disorder (second or third degree atrioventricular (AV) block).

Warnings and precautions
Talk to your doctor or pharmacist before taking <Invented Name>.

Contact your doctor immediately:

- if you have blistering or peeling of the skin and/or mucous membranes, rash, swallowing or breathing problems, swelling of your lips, face, eyelids, throat or tongue. These could be signs of an allergic reaction.

- if you suffer from confusion, worsening of seizures or decreased consciousness which can be signs of low blood salt levels.

Please tell your doctor:

- if you have kidney problems. Your doctor may need to adjust the dose. <Invented Name> is not recommended in patients with severe renal disease.
- if you have liver problems. <Invented Name> is not recommended in patients with severe liver problems.
- if you are taking any medicine which can cause an abnormality on the ECG (electrocardiogram) called increased PR interval. If you are not sure if the medicines you are taking could have this effect, discuss with your doctor.
- if you suffer from a heart disease such as heart failure or heart attack, or have any heart rhytm disorder.
- if you suffer from seizures that begin with a widespread electric discharge that involves both sides of the brain.

A small number of people being treated with antiepileptics have had thoughts of harming or killing themselves. If at any time you have these thoughts, when taking <Invented Name>, contact your doctor immediately.

<Invented Name> may make you feel dizzy and/or drowsy, particularly at the beginning of treatment. Take special care when taking <Invented Name> to avoid accidental injury, such as fall.

Take special care with <Invented Name>:
Serious and potentially life-threatening skin reactions including Stevens-Johnson syndrome/toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in post-marketing experience in patients treated with <Invented Name>.
If you develop a serious rash or another skin symptoms (see section 4), stop taking <Invented Name> and contact your doctor or seek medical attention immediately.

In patients of Han Chinese or Thai origin the risk of serious skin reactions associated with carbamazepine or chemically-related compounds may be predicted by testing a blood sample of these patients. Your doctor should be able to advise if a blood test is necessary before taking <Invented Name>.

Children
<Invented Name> is not to be given to children aged 6 years and below.

Other medicines and <Invented Name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is just in case any of them interfere with how <Invented Name> works or how <Invented Name> interferes with their effect.
Tell your doctor if you are taking:

- phenytoin (a medicine used to treat epilepsy) since your dose may need to be adjusted;
- carbamazepine (a medicine used to treat epilepsy) since your dose may have to be adjusted and the following side effects of <Invented Name> may occur in higher frequency: seeing double, abnormal coordination and dizziness;

- hormonal contraceptives (such as the contraceptive pill) since <Invented Name> may make these less effective;
- simvastatin (a medicine used to lower cholesterol levels) since your dose may have to be adjusted;
- rosuvastatin, a medicine used to lower cholesterol level;
- the blood thinner - warfarin;
- tricyclic antidepressants e.g. amitriptyline;
- do not take oxcarbazepine (a medicine used to treat epilepsy) with <Invented Name>, as it is not known whether it is safe to take these medicines together.

See 'Pregnancy and breast-feeding' section for advice about contraception.

Pregnancy and breast-feeding

It is not recommended to take <Invented name> if you are pregnant, as the effects of <Invented name> on pregnancy and the unborn baby are not known.

If you are planning a pregnancy, talk to your doctor before you stop contraception and before you become pregnant. Your doctor may decide to change your treatment.

There are limited data from the use of eslicarbazepine acetate in pregnant women. Research has shown an increased risk of birth defects and problems with neurodevelopment (development of the brain) in children of women taking antiepileptic medicines particularly when more than one antiepileptic medicine is taken at the same time.

If you are or think you might be pregnant, tell your doctor straight away. You should not stop taking your medicine until you have discussed this with your doctor. Stopping your medication without consulting your doctor could cause seizures, which could be dangerous to you and your unborn child. Your doctor may decide to change your treatment.

If you are a woman of childbearing age and are not planning a pregnancy; you should use effective contraception during treatment with <Invented name>. <Invented name> may affect how hormonal contraceptives, such as the contraceptive (birth control) pill, work and make them less effective at preventing pregnancy. Therefore, it is recommended that you use other forms of safe and effective contraception, when taking <Invented name>. Talk to your doctor, who will discuss with you the most suitable type of contraception to use while you are taking <Invented name>. If treatment with <Invented name> is discontinued you should continue using effective contraception up to the end of the current menstrual cycle.

If you take <Invented name> during pregnancy, your baby is also at risk for bleeding problems right after birth. Your doctor may give you and your baby a medicine to prevent this.

Do not breast-feed while you are taking <Invented name>. It is not known whether it passes into breast milk.

Driving and using machines

<Invented Name> may make you feel dizzy, drowsy and affect your vision, particularly at the beginning of treatment. If this happens to you, do not drive or use any tools or machines

<Invented name> contains

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

3. How to take <Invented Name>

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

Adults

Dose when you start treatment
400 mg once daily for one or two weeks, before increasing to the maintenance dose. Your doctor will decide whether you will be given this dose for one or two weeks.

Maintenance dose
The usual maintenance dose is 800 mg once daily.
Depending on how you respond to <Invented Name>, your dose may be increased to 1,200 mg once daily. If you are taking <Invented Name> on its own your doctor may consider you can benefit of a dose of 1,600 mg once daily.

Patients with kidney problems
If you have kidney problems you will usually be given a lower dose of <Invented Name>. Your doctor will work out the correct dose for you. <Invented Name> is not recommended if you have severe kidney problems.

Elderly (over 65 years of age)
If you are elderly and taking <Invented Name> on its own the dose of 1,600 mg is not a suitable dose for you.

Children above 6 years of age

Dose when you start treatment
The starting dose is 10 mg per kg body weight taken once a day for one or two weeks, before increasing to the maintenance dose.

Maintenance dose
Depending on the response to <Invented Name>, the dose may be increased by 10 mg per kg body weight, at intervals of one or two weeks, up to 30 mg per kg body weight. The maximum dose is 1,200 mg once daily.

Children ≥60 kg
Children with 60 kg or more body weight should take the same dose as adults.

Other form of this medicine, like oral suspension, maybe more suitable for children. Ask your doctor or pharmacist.

Method and route of administration
<Invented Name> is for oral use. Swallow the tablet with a glass of water.
<Invented Name> tablets may be taken with or without food.

The tablet can be divided into equal doses.

If you take more <Invented Name> than you should
If you accidently take more <Invented name> than you should, you are potentially at risk of having more seizures; or you may feel like your heart beat is irregular or faster. Contact a doctor or go to a

hospital immediately if you experience any of the above symptoms. Take the medicine pack with you. This is so the doctor knows what you have taken.

If you forget to take <Invented Name>

If you forget to take a tablet, take it as soon as you remember and carry on as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking <Invented Name>

Do not stop taking your tablets suddenly. If you do, you are at risk of having more seizures. Your doctor will decide how long you should take <Invented Name>. Should your doctor decide to stop your treatment with <Invented Name> your dose will usually be reduced gradually. It is important that your treatment is completed as advised by your doctor or your symptoms may get 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.

The following side effects can be very serious. If they happen to you stop taking <Invented Name> and tell a doctor or go to a hospital immediately, as you may need urgent medical treatment:

- blistering or peeling of the skin and/or mucous membranes, rash, swallowing or breathing problems, swelling of your lips, face, eyelids, throat or tongue. These could be signs of an allergic reaction.

Very common (may affect more than 1 in 10 people) side effects are:

- Feeling dizzy or sleepy.

Common (may affect up to 1 in 10 people) side effects are:

- Feeling unsteady or having a sensation of spinning or floating;
- Feeling sick or vomiting;
- Headache;
- Diarrhoea;
- Seeing double or blurred vision;
- Difficulty in concentration;
- Feeling low in energy or tired;
- Shaking;
- Skin rash;
- Blood tests showing that you have low levels of sodium in your blood;
- Decrease of appetite;
- Difficulty in sleeping;
- Difficulty in coordinating movements (ataxia).
- Weight increase

Uncommon (may affect up to 1 in 100 people) side effects are:

- Clumsiness;
- Allergy;
- Constipation;
- Seizures;
- Underactive thyroid gland. Symptoms include decreased level of thyroid hormone levels (seen in blood tests), cold intolerance, large tongue, thin and brittle fingernails or hair and low body temperature;
- Liver problems (such as increased liver enzymes);

- High blood pressure or severe increase in blood pressure;
- Low blood pressure or a fall in blood pressure on standing up;
- Blood tests showing that you have low levels of salts (including chloride) in your blood or a reduction in red blood cells;
- Dehydration;
- Eye movement changes, fuzzy vision or red eye;
- Having falls;
- Thermal burn;
- Poor memory or forgetfulness;
- Crying, feeling depressed, nervous or confused, lack of interest or emotion;
- Inability to speak or write or understand spoken or written language;
- Agitation;
- Attention deficit/ hyperactivity disorder;
- Irritability;
- Mood changes or hallucinations;
- Difficulty in speaking;
- Nosebleed;
- Chest pain;
- Tingling and/or feeling numb in any part of your body;
- Migraine;
- Burning sensation;
- Abnormal sense of touch;
- Disturbances in the sense of smell;
- Ringing in the ears;
- Hearing difficulty;
- Swelling in your legs and arms;
- Heart burn, stomach upset, abdominal pain, abdominal bloating and discomfort or dry mouth;
- Charcoal (dark) stool;
- Inflamed gums or toothache;
- Sweating or having dry skin;
- Itching;
- Skin changes (e.g. red skin);
- Hair loss;
- Urinary tract infection;
- Feeling generally weak, unwell or having chills;
- Weight loss;
- Muscle pain, pain in limbs, muscular weakness;
- Bone metabolism disorder;
- Increased bone proteins;
- Flushing, cold limbs;
- Slower or irregular heart beat;
- Feeling extremely sleepy;
- Sedation;
- Neurological movement disorder where your muscles contract causing twisting and repetitive movements or abnormal postures. Symptoms include tremors, pain, cramping;
- Medicine toxicity;
- Anxiety.

Not known (frequency cannot be estimated from available data) side effects are:
- Reduction in blood platelets which increases risk of bleeding or bruising;
- Severe pain in the back and stomach (caused by inflamation of the pancreas);
- Reduction in white blood cells which makes infections more likely;

- Reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, red and swollen eyes and can be preceded by fever and/or flu-like symptoms (Stevens-Johnson syndrome/toxic epidermal necrolysis);
- Initially flu-like symptoms, rash on the face then widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome);
- Serious allergic reaction which causes swelling of the face, throat, hand, feet, ankles, or lower legs;
- Urticaria (skin rash with itching).
- Lethargy, confusion, muscle twitching or significant worsening of convulsions (possible symptoms of low sodium levels in the blood due to inappropriate ADH secretion)

The use of <Invented Name> is associated with an abnormality in ECG (electrocardiogram) called increase in PR interval. Side effects associated with this ECG abnormality (e.g. fainting and slowing of heart beat) may occur.

There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures with structurally related antiepileptics medicines like carbamazepine and oxcarbazepine. Check with your doctor or pharmacist, if you are on long-term antiepileptic treatment, have a history of osteoporosis, or take steroids.

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented Name>

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 blister and the carton 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 to protect the environment.

6. Contents of the pack and other information

What <Invented Name> contains
- The active substances is eslicarbazepine acetate.
  - Each tablet contains 200 mg of eslicarbazepine acetate.
  - Each tablet contains 800 mg of eslicarbazepine acetate.
- The other ingredients are croscarmellose sodium(E468), magnesium stearate(E572), povidone (E1201), cellulose microcrystalline (E460) and colloidal silica anhydrous (E551).

What <Invented Name> looks like and contents of the pack

200 mg: White to off-white, oblong, uncoated tablets debossed with “V1” on one side and break line on other side. The size of the tablet is approximately 11.00 x 5.70 mm.

The tablet can be divided into equal doses.
800 mg: White to off-white, oblong, uncoated tablets, debossed with “V7” on one side and break line on other side. The size of the tablet is approximately 19.00 x 9.80 mm.
The tablet can be divided into equal doses.

200mg:
The tablets are packaged in blisters in cardboard boxes containing 20, 30 or 60 tablets, and in HDPE bottles with child resistant closure in cardboard boxes containing 60 tablets.
Not all pack sizes may be marketed.

800mg:
The tablets are packaged in blisters in cardboard boxes containing 20, 30 or 60 tablets, and in HDPE bottles with child resistant closure in cardboard boxes containing 30 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

< To be completed nationally>

Manufacturer

Laboratori Fundacio Dau
C/c 12-14 Poligon Industrial Zona Franca
Barcelona
08040
Spain

Pharmadox Healthcare Limited
KW20A Kordin Industrial Park
Paola
PLA 3000
Malta

Accord Healthcare Polska Sp. z.o.o.
Ul.Lutomierska 50, 95-200, Pabianice
Pabianice
95-200
Poland

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