

Episenta® 500mg prolonged-release granules
Episenta® 1000mg prolonged-release granules
 (sodium valproate)

(Referred to in this leaflet as Episenta granules)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet in case you need to refer to it again.
- If you want to know more about your medicine or have any questions, you should ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What Episenta Granules are and what they are used for
2. Before you take Episenta Granules
3. How to take Episenta Granules
4. Possible side effects
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1. WHAT EPISENTA GRANULES ARE AND WHAT THEY ARE USED FOR

Episenta granules contain the active ingredient sodium valproate, which belongs to a group of medicines called antiepileptics, which are used to control epileptic seizures.

Episenta granules are used to treat various types of epilepsy (seizures).

2. BEFORE YOU TAKE EPISENTA GRANULES

Do NOT take Episenta granules if:

- you are allergic (hypersensitive) to sodium valproate or any of the other ingredients of the granules (listed in Section 6 Further Information)
- you, or a member of your family, have or have had severe liver problems
- you suffer from a disease called porphyria (a rare condition that affects the breakdown of components of red blood cells).

Before you take Episenta granules tell your doctor if:

- you have systemic lupus erythematosus (an allergic condition which causes joint pain, skin rashes and fever)
- you have any metabolic disorders, particularly inherited enzyme deficiency disorders such as urea cycle disorder because of a risk of an increased ammonia level in your blood
- you have reduced kidney function. Your doctor may want to monitor the levels of sodium valproate in your blood and change your dose as necessary
- you are pregnant, think you might be, or are planning to become pregnant
- you are a woman of childbearing age. You should be informed of the risks and benefits of treatment with Episenta in pregnancy
- you are breast feeding
- you are being tested for diabetes, as Episenta may affect the results of urine tests.

Taking/using other medicines

Tell your doctor if you are taking or have recently taken any of the following medicines as they may affect the way Episenta granules work or they may be affected by Episenta:

- colestyramine - used to reduce the level of blood lipids (fats)
- other antiepileptic medicines e.g. phenytoin, primidone, carbamazepine, phenobarbital, lamotrigine
- mefloquine and chloroquine – used to prevent and treat malaria
- cimetidine – used to treat ulcers
- antipsychotics – used to treat psychological disorders e.g. olanzapine
- antidepressants – used to treat depression, including monoamine oxidase inhibitors
- anticoagulation therapy– used to thin the blood e.g. warfarin
- salicylates e.g. aspirin
- antibiotics e.g. erythromycin, imipenem, meropenem
- benzodiazepines – used as sleeping tablets and to treat anxiety
- zidovudine – used to treat HIV and AIDS.

It may still be possible for you to be take Episenta granules; your doctor will advise you on what is suitable for you.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Take special care with Episenta Granules

A small number of people being treated with antiepileptics such as sodium valproate have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Pregnancy:

- It is very important that you tell your doctor before you take Episenta if you are pregnant or are planning to become pregnant.
- Tell your doctor immediately if you become pregnant whilst taking Episenta. Your doctor should discuss with you the problems that may arise if Episenta is used in pregnancy because of the potential risk to the foetus.

Women who are receiving treatment for epilepsy are 2 to 3 times more likely to have babies with deformities than in the general population. The deformities most frequently seen are cleft palate and heart or blood vessel defects. Developmental delay has also been reported in children born to mothers with epilepsy.

Women who take sodium valproate during the first months of pregnancy to control their epilepsy have a small risk (1 to 2%) of having a baby with spina bifida, an abnormality of the spinal cord. Taking folic acid 5 mg daily as soon as you stop contraception may lower the risk of having a baby with spina bifida. There is also an increased risk of other deformities in your baby. These can usually be detected in the first part of pregnancy by the routine antenatal screening tests. Some babies may develop less quickly than normal and rarely, some may have clotting problems if the mother has taken sodium valproate during pregnancy.

If treatment with Episenta granules is considered necessary, the lowest effective dose will be used, which may be given in several small doses during the day. During pregnancy, specialised prenatal monitoring should be given to detect any deformities.

It is important, however, not to stop taking Episenta granules suddenly as this may result in seizures, which may harm you or your unborn baby.

Driving and using machines:

You may experience drowsiness when you first start taking Episenta granules, or if you are taking it with other medicines, such as other antiepileptic drugs or benzodiazepines. If affected you should not drive or operate machinery.

3. HOW TO TAKE EPISENTA GRANULES

Always take Episenta granules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will decide the number of sachets you should take. This will depend on your age and weight and will be adjusted to achieve adequate control of your seizures.

The daily dosage may be taken as one single or two divided doses (half in the morning and half in the evening) before, with, or after meals.

Continued overleaf.....

Dose for adults including the elderly:
The usual starting dose is 600mg daily increasing by 150 – 300mg every three days until the seizures are controlled.

This dose is usually within the range of 1000mg to 2000 mg daily, but can be increased to a maximum of 2500mg daily if necessary.

Your doctor may alter your dose if you are taking other antiepileptic drugs, have poor kidney function or you are an elderly patient.

Dose for children:

The dose for children will depend on their weight.

For children over 20kg the usual starting dose is 300mg daily. This can be increased up to a maximum of 35mg for each kg of bodyweight to control the seizures.

For children under 20kg the usual dose is 20mg for each kg of bodyweight, which can be increased up to a maximum of 40mg for each kg of bodyweight daily.

Do not stop taking Episenta granules without consulting your doctor. You should continue to take Episenta granules for as long as your doctor tells you to.

How to take Episenta:

Episenta granules should be swallowed, without chewing, with plenty of liquid, e.g. a full glass of water.

- Tear open the sachet and sprinkle or stir the contents into soft food or a drink and swallow immediately without chewing or crushing the granules.
- The food or drink should be cold or at room temperature.
- Do not store a mixture of the granules with liquid or soft food for future use.
- If the granules are taken in a drink, some may stick to the glass after the drink has been finished, you should be rinse the glass with a small amount of water and drink this as well.
- The granules should not be given in babies' bottles as they can block the teat.

If you take more Episenta granules than you should or if someone else accidentally takes your medicine, contact your nearest casualty department or tell your doctor or pharmacist immediately. Remember to take the pack, this leaflet and any remaining sachets with you.

If you forget to take a dose of Episenta granules:

Take it as soon as you remember. If your next dose is due within 2 hours, take a single dose now and do not take the next dose. Never double up the next dose to make up for the one missed.

4. POSSIBLE SIDE EFFECTS

Like all medicines Episenta granules can cause side effects although not everyone will get them.

Tell your doctor **IMMEDIATELY** if you notice any of the following serious side effects. You may require urgent medical attention.

- You suddenly feel ill, particularly in the first 6 months of treatment, which may include:
 - repeated vomiting, stomach pain, nausea, dislike of usual food, loss of appetite
 - extreme tiredness, drowsiness, weakness
 - jaundice (yellowing of the skin or whites of the eyes)
 - swelling of the feet, legs or eyelids, bruising, nosebleed
 - worsening of your epilepsy.

These symptoms may indicate a serious effect on your liver. Your blood may be taken before or during treatment to check for any effects on the liver, particularly in very young children and those at risk

- Severe pain in the abdomen and back, nausea and vomiting. You may have a serious, rare problem with you pancreas
- Blistering of the skin, mouth, eyes and genitals

If you experience any of the side effects below tell your doctor if they become troublesome or you are worried:

- nausea, mild stomach ache or diarrhoea, especially when starting the treatment
- weight gain as your appetite may be increased
- shakiness (tremor), drowsiness, unsteadiness when walking
- tiredness and confusion which may rarely progress to hallucinations and loss of consciousness
- headache, convulsions, delirium and coma have been reported rarely
- increased alertness, and occasionally aggression, hyperactivity and worsening behaviour
- loss of co-ordination, vomiting and reduced levels of consciousness may indicate changes in the amount of ammonia in the blood
- allergic reactions
- skin reactions such as acne or rashes
- kidney problems which will be detected by testing your urine, bedwetting or an increased need to pass urine
- change in women's periods
- increased hair growth in women
- temporary hair loss, which may be more curly on re-growth
- breast enlargement in men
- loss of hearing
- immune disorders e.g. vasculitis (inflammation of the blood vessels often with skin rash)
- see your doctor if you develop bruising or bleeding

Many of these effects normally reverse when you stop taking Episenta granules.

The white shells of the granules may be seen in the stools of the patient. This is normal and should not be of any concern.

If you, or your carer, notice any side effects not listed in this leaflet, please inform your doctor or pharmacist

5. HOW TO STORE EPISENTA GRANULES

Keep out of reach and sight of children. Store the sachets in their original packaging below 30°C. Keep the container tightly closed. Do not use after the expiry date printed on the sachet and carton.

6. FURTHER INFORMATION

What Episenta granules contain:

- The active substance is sodium valproate
- The other ingredients are calcium stearate, silicon dioxide (methylated) ammonio methacrylate copolymer type B, sodium lauryl sulphate, polysorbate 80, ethylcellulose, dibutylsebacate and oleic acid.

What Episenta granules look like and the contents of the pack:

Episenta prolonged-release granules are white to off-white granules packed in sachets. The sachets are available in packs of 50, 100 and 200 for both the 500mg and the 1000mg strengths. Not all pack sizes may be marketed.

Marketing Authorisation Holder:
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