Package leaflet: Information for the user

[QR code to be included:]
https://www.medicines.org.uk/emc/product/293/rmms

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Episenta solution for injection
(Sodium Valproate 100 mg/ml)

WARNING

Episenta Injection, sodium valproate 100 mg/ml, can seriously harm an unborn child when taken during pregnancy. If you are a female able to have a baby you must use effective method of birth control (contraception) without interruptions during your entire treatment with Episenta Injection. Your doctor will discuss this with you but you must also follow the advice in section 2 of this leaflet.

Schedule an urgent appointment with your doctor if you want to become pregnant or if you think you are pregnant.

Do not stop taking Episenta Injection unless your specialist tells you to as your condition may become worse.

If you are a parent or caregiver of a female child treated with Episenta Injection, you must also read section 2 of this leaflet carefully and contact your child's doctor once they experience their first period.

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.
- 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 Episenta Injection is and what it is used for
2. What you need to know before you use Episenta Injection
3. How to use Episenta Injection
4. Possible side effects
5. How to store Episenta Injection
6. Contents of the pack and other information

1. What Episenta Injection is and what it is used for

Episenta Injection contains sodium valproate, which belongs to a group of medicines called antiepileptics. These are used to control epileptic seizures.

Episenta solution for injection is used to treat various types of epileptic seizures (fits) when it is not possible to take sodium valproate tablets.

2. What you need to know before you take Episenta Injection

Do not use Episenta Injection

- if you are allergic to sodium valproate or any of the other ingredients of this medicine (listed in section 6).
  Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- if you have liver problems, or yu or your family have a history of liver problems, especially if caused by taking a medicine.
- if you have a rare illness called porphyria which affectsyour metabolism.
- if you have a known metabolic disorder, i.e. urea cycle disorder.
- if you have a genetic problem caused by a mitochondrial disorder (e.g. Alpers-Huttenlocher syndrome).
- if you have a deficiency in carnitine (a very rare metabolic disease) that is untreated.
- if you are pregnant, unless nothing else works for you (see 'Pregnancy, breast-feeding and fertility – Important advice for women' below).

If you are a woman able to have a baby, you must not take Episenta Injection unless you use effective method of birth control (contraception) at all times during your entire treatment with Episenta Injection. Do not stop taking Episenta Injection or your contraception, until you have discussed this with your specialist. Your specialist will advise you further (see below under 'Pregnancy, breast-feeding and fertility – Important advice for women').

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before having Episenta Injection.

Warnings and precautions

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), erythema multiforme and angioedema have been reported in association with valproate treatment. Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

The risk of liver damage is increased if Episenta is taken by children under 3 years of age, in people taking other antiepileptic medicine at the same time or having other neurological or metabolic disease and severe forms of epilepsy.
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.

As with other antiepileptic drugs, convulsions may become worse or happen more frequently whilst taking this medicine. If this happens contact your doctor immediately.

If you or your child taking Episenta develops problems with balance and co-ordination, feeling lethargic or less alert, vomiting, tell your doctor immediately. This may be due to increased amount of ammonia in the blood.

Talk to your doctor, nurse or pharmacist before taking Episenta Injection if:

- you have a brain disease or a metabolic condition affecting your brain.
- you have problems with your pancreas.

- you have diabetes or are being tested for diabetes. This medicine may affect the results of urine tests.
- you know or your doctor suspects that there is a genetic problem caused by a mitochondrial disorder in your family, because of a risk of damage to your liver.
- you are suspected to suffer from any metabolic disorders, particularly hereditary enzyme deficiency disorders such as “urea cycle disorder” because of a risk of increased ammonia level in the blood.
- you have a rare disorder named 'carnitine palmitoyltransferase type II deficiency’, because you are at an increased risk of muscle disorders.
- you have impaired dietary intake in carnitine, found in meat and dairy products, especially in children less than 10 years old.
- you have a deficiency in carnitine and are taking carnitine.
- you have kidney problems. Your doctor may monitor your valproate level or adjust your dose.
- you have an illness called ‘systemic lupus erythematosus (SLE)’ – a rare disease of the immune system which affects skin, bones, joints and internal organs.
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking valproate.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before having Episenta Injection.

Weight gain
Having Episenta Injection may make you put on weight. Talk to your doctor about how this will affect you.

Blood tests
Your doctor may do blood tests and liver function tests before and during your treatment with this medicine. Episenta Injection can change the levels of liver enzymes shown in blood tests. This can mean that your or your child’s liver is not working properly.

Other medicines and Episenta Injection
Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Episenta Injection can affect the way some other medicines work. Also some medicines can affect the way Episenta Injection works.

<u>The following medicines can increase the chance of you getting side effects, when taken with Episenta Injection:</u>
- some medicines used for pain and inflammation (salicylates) such as aspirin
- some other medicines used to treat fits (epilepsy) – see section 3, ‘Patients taking other medicines for fits’. This includes medicines such as phenobarbital, primidone, phenytoin, carbamazepine, rufinamide, topiramate, lamotrigine and felbamate.
- Cannabidiol (used to treat epilepsy and other conditions)
- acetazolamide used to treat glaucoma, edema or fits
- some anti-infectives that contain pivalate (e.g. pivampicillin, adefovir dipivoxil).
- clozapine (to treat mental health conditions)

<u>Episenta Injection may increase the effect of the following medicines:</u>
- medicines used for thinning the blood (such as warfarin)
- zidovudine used to treat HIV infection
- temozolomide used to treat cancer
- medicines for depression
- monoamine oxidase inhibitors (MAOI) such as moclobemide, selegiline, linezolid

- medicines used to calm emotional and mental health problems (including schizophrenia, bipolar disorder and depression) such as quetiapine, diazepam and olanzapine
- nimodipine
- propofol – used for anaesthesia

The following medicines can affect the way Episenta Injection works:
- oestrogen-containing products (including some birth control pills)
- some medicines used for the prevention and treatment of malaria such as mefloquine and chloroquine
- cimetidine used for stomach ulcers
- protease inhibitors such as lopinavir and ritonavir – used for HIV infection and AIDS
- antibiotics e.g. erythromycin, carbapenem agents (antibiotics used to treat bacterial infections). The combination of valproic acid and carbapenems should be avoided because it may decrease the effect of sodium valproate.
- rifampicin used to treat tuberculosis and other infections
- cholestyramine used to lower blood fat (cholesterol) levels
- metamizole – used to treat pain and fever
- methotrexate – used to treat cancer and inflammatory diseases.

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

Taking Episenta Injection with food and drink
Alcohol intake is not recommended during treatment.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Important advice for women
- You must not use Episenta Injection if you are pregnant, unless your specialist has determined that no alternative treatment works for you.
- If you are a woman able to have a baby, you must not take Episenta Injection unless you use an effective method of birth control (contraception) at all times during your entire treatment with Episenta Injection.
- Do not stop taking Episenta Injection or your birth control (contraception), until you have discussed this with your specialist. Your specialist will advise you further.

The risks of valproate when taken during pregnancy
- Talk to your doctor immediately if you are planning to have a baby or are pregnant.
- Valproate carries a risk if taken during pregnancy. The higher the dose, the higher the risks but all doses carry a risk, including when valproate is used in combination with other medicines to treat epilepsy.
- It can cause serious birth defects and can affect the physical and mental development of the child as it grows after birth. If you take valproate during pregnancy, you have a higher risk than other women of having a child with birth defects that require medical treatment. Because valproate has been used for many years, we know that in women who take valproate around 11 babies in every 100 will have birth defects. This compares to 2–3 babies in every 100 born to women from the general population.
- The most frequently reported birth defects include *spina bifida* (where the bones of the spine are not properly developed); facial and skull malformations; heart, kidney, urinary tract and sexual organ malformations; limb defects and multiple associated malformations affecting several organs and parts of the body. Birth defects may result in disabilities which may be severe and/or permanent.

    - Hearing problems or deafness have been reported in children exposed to valproate during pregnancy.
- Eye malformations have been reported in children exposed to valproate during pregnancy in association with other congenital malformations. These eye malformations may affect vision.
- It is estimated that up to 30–40% of children whose mothers took valproate during pregnancy may have problems with early childhood development. Children affected can be slow to walk and talk, intellectually less able than other children, and have difficulty with language and memory.
    - Autism and related disorders are more often diagnosed in children exposed to valproate during pregnancy, and there is some evidence that children exposed to valproate during pregnancy are at increased risk of developing Attention Deficit Hyperactivity Disorder (ADHD).
- If you take valproate during pregnancy, your baby may have a lower weight than expected for their age at birth.
- Before prescribing this medicine to you, your specialist will have explained what might happen to your baby if you become pregnant whilst taking valproate. If you decide later you want to have a baby you must not stop taking your medicine or your method of birth control (contraception) until you have discussed this with your specialist.
- If you are a parent or a caregiver of a female child treated with valproate, you must contact their doctor once your child using valproate experiences their first period (menarche).
- Some birth control pills (oestrogen-containing birth control pills) may lower valproate levels in your blood. Make sure you talk to your doctor about the method of birth control (contraception) that is the most appropriate for you.
- Ask your doctor or nurse about taking folic acid when planning to have a baby. Folic acid can lower the general risk of *spina bifida* and early miscarriage that exists with all pregnancies. However, it is unlikely that it will reduce the risk of birth defects associated with valproate use.

Please choose and read the situations which apply to you from the situations described below:

0 I AM STARTING TREATMENT WITH EPISENTA INJECTION

0 I AM TAKING EPISENTA INJECTION AND NOT PLANNING TO HAVE A BABY

0 I AM TAKING EPISENTA INJECTION AND PLANNING TO HAVE A BABY

0 I AM PREGNANT AND I AM TAKING EPISENTA INJECTION

I AM STARTING TREATMENT WITH EPISENTA INJECTION

If this is the first time you have been prescribed Episenta Injection your specialist will have explained the risks to an unborn child if you become pregnant. Once you are able to have a baby, you must use an effective method of birth control (contraception) at all times during your entire treatment with Episenta Injection. Talk to your doctor or family planning clinic if you need advice on birth control (contraception).

Key messages:

- Pregnancy must be excluded before start of treatment with Episenta Injection with the result of a pregnancy test, confirmed by your specialist.
- You must use an effective method of birth control (contraception) during your entire treatment with Episenta Injection.
- You must discuss the appropriate methods of birth control (contraception) with your doctor. Your doctor will give you information on preventing pregnancy, and may refer you to a specialist for advice on birth control.
- You must get regular (at least annual) appointments with a specialist experienced in the management of epilepsy. During this visit your specialist will make sure you are well aware of and have understood all the risks and advices related to the use of valproate during pregnancy.
- Tell your doctor if you want to have a baby.
- Tell your doctor **immediately** if you are pregnant or think you might be pregnant.

I AM HAVING EPISENTA INJECTION AND NOT PLANNING TO HAVE A BABY

If you are continuing treatment with Episenta Injection but you are not planning to have a baby, you must use an effective method of birth control (contraception) at all times during your entire treatment with Episenta Injection. Talk to your doctor or family planning clinic if you need advice on birth control (contraception).

Key messages:

- You must use an effective method of birth control (contraception) at all times during your entire treatment with Episenta Injection.
- You must discuss appropriate and effective methods of birth control (contraception) with your doctor. Your doctor will give you information on preventing pregnancy, and may refer you to a specialist for advice on birth control (contraception).
- You must get regular (at least annual) appointments with a specialist experienced in the management of epilepsy. During this visit your specialist will make sure you are well aware and have understood all the risks and advices related to the use of valproate during pregnancy.
- Tell your doctor if you want to have a baby.
- Tell your doctor **immediately** if you are pregnant or think you might be pregnant.

I AM HAVING EPISENTA INJECTION AND PLANNING TO HAVE A BABY

If you are planning to have a baby, first schedule an appointment with your doctor.
Do not stop taking Episenta Injection or your birth control (contraception), until you have discussed this with your specialist. Your specialist will advise you further.
Babies born to mothers who have been on valproate are at serious risk of birth defects and problems with development which can be seriously debilitating. Your doctor will refer you to a specialist experienced in the management of epilepsy, so that alternative treatment options are evaluated early on. Your specialist can put several actions in place so that your pregnancy goes as smoothly as possible and any risks to you and your unborn child are reduced as much as possible.
Your specialist may decide to change the dose of Episenta Injection or switch you to another medicine, or stop treatment with Episenta Injection, a long time before you become pregnant – this is to make sure your illness is stable.

Ask your doctor or nurse about taking folic acid when planning to have a baby. Folic acid can lower the general risk of *spina bifida* and early miscarriage that exists with all pregnancies. However, it is unlikely that it will reduce the risk of birth defects associated with valproate use.

Key messages:

- Do not stop taking Episenta Injection unless your specialist tells you to.
- Do not stop using your methods of birth control (contraception) before you have talked to your specialist and worked together on a plan to ensure your condition is controlled and the risks to your baby are reduced.
- First schedule an appointment with your specialist. During this visit your specialist will make sure you are well aware and have understood all the risks and advices related to the use of valproate during pregnancy.
- Your specialist will try to switch you to another medicine, or stop treatment with Episenta Injection a long time before you become pregnant.
- Schedule an urgent appointment with your doctor if you are pregnant or think you might be pregnant.

I AM PREGNANT AND I AM USING EPISENTA INJECTION

Do not stop taking Episenta Injection, unless your specialist tells you to as your condition may become worse. Schedule an urgent appointment with your doctor if you are pregnant or think you might be pregnant. Your doctor will advise you further.

Babies born to mothers who have been on valproate are at serious risk of birth defects and problems with development which can be seriously debilitating.
You will be referred to a specialist experienced in the management of epilepsy, so that alternative treatment options can be evaluated.
In the exceptional circumstances when Episenta Injection is the only available treatment option during pregnancy, you will be monitored very closely both for the management of your underlying condition and to check how your unborn child is developing. You and your partner could receive counselling and support regarding the valproate exposed pregnancy.

Ask your doctor or nurse about taking folic acid. Folic acid can lower the general risk of *spina bifida* and early miscarriage that exists with all pregnancies. However, it is unlikely that it will reduce the risk of birth defects associated with valproate use.

Key messages:
- Schedule an urgent appointment with your doctor if you are pregnant or think you might be pregnant.
- Do not stop taking Episenta Injection unless your specialist tells you to.
- Make sure you are referred to a specialist experienced in the treatment of epilepsy to evaluate the need for alternative treatment options.
- You must get thorough counselling on the risks of Episenta Injection during pregnancy, including malformations and physical and mental development disorders in children.
- Make sure you are referred to a specialist for prenatal monitoring in order to detect possible occurrences of malformations.

Make sure you read the Patient Guide that you will receive from your doctor, nurse or pharmacist. Your specialist will discuss the Annual Risk Acknowledgement Form and will ask you to sign it and keep it. You will also receive a Patient Card from your doctor, nurse or pharmacist to remind you of valproate risks in pregnancy.

Newborn babies of mothers who took valproate during pregnancy may have:
- Blood clotting problems (such as blood not clotting very well). This may appear as bruising or bleeding which takes a long time to stop.
- Hypoglycaemia (low blood sugar).
- Hypothyroidism (underactive thyroid gland, which can cause tiredness or weight gain).
- Withdrawal syndrome (including agitation, irritability, hyperexcitability, jitteriness, hyperkinesia, muscle problems, tremor, convulsions and feeding problems). In particular, this may occur in newborns whose mothers have taken valproate during the last trimester of their pregnancy.

Breast-feeding
A small amount of sodium valproate, the active substance of Episenta Injection, gets into the breast milk. Talk to your doctor about whether you should breast-feed your baby. Ask your doctor, nurse or pharmacist for advice before taking any medicine.

Important advice for male patients

Potential risks related to taking valproate in the 3 months before conception of a child

A study suggests a possible risk of mental and movement related developmental disorders (problems with early childhood development) in children born to fathers treated with valproate in the 3 months before conception. In this study, around 5 children in 100 had such disorders when born to fathers treated with valproate as compared to around 3 children in 100 when born to fathers treated with lamotrigine or levetiracetam (other medicines that can be used to treat your disease). The risk for children born to fathers who stopped valproate treatment 3 months (the time needed to form new sperm) or longer before

conception is not known. The study has limitations and therefore it is not clear if the increased risk for movement and mental developmental disorders suggested by this study is caused by valproate. The study was not large enough to show which particular type of movement and mental developmental disorder children may be at risk of developing.

As a precautionary measure, your GP or specialist will discuss with you:
- The potential risk in children born to fathers treated with valproate
- The need to use effective contraception (birth control) for you and your female partner during treatment and for 3 months after stopping treatment
- The need to consult your specialist when you are planning to conceive a child and before stopping contraception (birth control)
- The possibility of other treatments that can be used to treat your disease, depending on your individual situation

Do not donate sperm when taking valproate or for 3 months after stopping valproate.

Talk to your GP or specialist if you are thinking about having a baby.

If your female partner becomes pregnant while you used valproate in the 3 months period before conception and you have questions, contact your GP or specialist. Do not stop your treatment without talking to your GP or specialist. If you stop your treatment, your symptoms may become worse.

You should get regular appointments with your GP. During this visit your GP will discuss with you the precautions associated with valproate use. They will refer you to a specialist to discuss the possibility of other treatments that can be used to treat your disease, depending on your individual situation.

Driving and using machines
You may experience drowsiness when you are first given Episenta Injection, or if you are also taking other medicines, such as other antiepileptic drugs or benzodiazepines. If affected, you should not drive or operate machinery.

Episenta Injection contains sodium
This medicine contains 41.6 mg sodium (cooking/table salt) in each 3 ml ampoule. This is equivalent to 2 % of the recommended maximum daily dietary intake of sodium for an adult.
This medicine contains 138.8 mg sodium (cooking/table salt) in each 10 ml ampoule. This is equivalent to 7 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Episenta Injection

Episenta Injection treatment must be started and supervised by a doctor specialised in the treatment of epilepsy.

Dosage
Your doctor will decide on the amount of Episenta Injection you will be given. This will depend on your age and weight and will be adjusted to achieve adequate control of your seizures. If you have been taking sodium valproate by mouth, the dose given to you will be the same by injection. If you have been receiving other medicines for epilepsy the dose of Episenta Injection will be increased gradually over about 2 weeks. The total daily dose will normally be given by three or four slow injections, lasting 3-5 minutes, into your veins during the day, or by a continuous infusion (drip).

Adults, including the elderly

The recommended starting dose is 400–800 mg (4–8 ml) daily increasing by 150–300 mg (1.5–3.0 ml) every 3 days, until the seizures are controlled. The maximum daily dose you should receive is 2,500 mg (25 ml).
Your doctor may decrease your dose if you are taking other antiepileptic drugs, have poor kidney function or you are an elderly patient.

Children and adolescents
The dose for children will depend on their weight. This is usually 20–40 mg (0.2–0.4 ml) for each kg of body weight.

Your treatment with Episenta Injection will be changed to oral therapy (by mouth) as soon as possible.

Patients with kidney problems
Your doctor may decide to adjust your dose.

Patients taking other medicines for fits (epilepsy)
You or your child may be taking other medicines for epilepsy at the same time as Episenta Injection. If so, your doctor should gradually initiate treatment depending on your or your child's condition.
Your doctor may increase the dose of Episenta Injection by 5–10 mg for each kg of body weight each day depending on which other medicines you are taking.

If you think you have missed a dose or been given more Episenta Injection than you should
Episenta Injection will be given to you by a doctor, who will ensure that the correct dose is given for your condition. If you have any concerns tell your doctor or nurse.

If you stop using Episenta Injection
It is important for you to keep having your Episenta Injection treatment until your doctor decides to stop. If you stop, your seizures may return.

Tests
Make sure you or your child keep your regular appointments for a check up. They are very important as your or your child's dose may need to be changed. Episenta Injection can change the levels of liver enzymes shown up in blood tests. This can mean that your or your child's liver is not working properly. If you or your child go into hospital or visit another doctor or a dentist, tell them you are taking Episenta Injection.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines this medicine can cause side effects although not everybody gets them.

Tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- You have an **allergic reaction** which may manifest as:
  - Blisters with skin detachment (blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet) with or without rash), sometimes with flu-like symptoms such as fever, chills, or aching muscles. These may be signs of conditions named 'Toxic epidermal necrolysis' or 'Stevens-Johnson Syndrome'.
  - Skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These may be signs of a condition named 'erythema multiforme'.

- Allergy-triggered swelling with painful itchy welts (most often around the eyes, lips, throat and sometimes hands and feet) and swallowing or breathing problems. These may be signs of 'angioedema' or an anaphylactic reaction.
- Syndrome with skin rash, fever, lymph node enlargement and possible impairment of other organs. These may be signs of a condition named 'Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)'.

- Liver problems and problems of the pancreas may show as a sudden illness which may happen in the first six months of treatment. This happens in a very small number of people taking Episenta. It includes feeling sick (nausea) and being sick (vomiting) many times; extreme tiredness, drowsiness and weakness; stomach pain including severe upper stomach pain; yellowing of the skin or whites of the eyes (jaundice); loss of appetite; swelling of the legs and feet (may also include other parts of the body); worsening of your fits or a general feeling of being unwell. Your doctor may tell you to stop taking Episenta Injection immediately if you have these symptoms.
- Blood disorders that can be shown in blood tests. Signs may include:
  - Spontaneous bruising or bleeding due to blood clotting problems or decreased platelet count, or getting more infections than usual (thrombocytopenia).
  - Severe decrease of white blood cells or bone marrow failure, sometimes revealed by fever and breathing difficulty (agranulocytosis).
  - Decreased red blood cell count (anaemia) or abnormally increased red blood cell size (macrocytosis).
  - Bone marrow disorders that affect red blood cells, white blood cells and platelets (pancytopenia).
- Drowsiness, change in consciousness level (including coma), confusion, loss of memory, abnormal behaviour including changes in attention, concentration and mood. This could also be associated with hallucinations or more frequent or severe fits. This is more likely if other medicine to treat fits such as phenobarbital and topiramate are taken at the same time or if the Episenta starting dose is high or has been suddenly increased.
- Underactive thyroid gland, which may cause tiredness or weight gain (hypothyroidism).
- Difficulty breathing, pain or pressure in the chest chest (especially when breathing in), shortness of breath and dry cough due to buildup of fluid around the lungs (pleural effusion).
- An increase in the number and severity of convulsions.
- Muscle pain and weakness (rhabdomyolysis).
- Joint pain, fever, fatigue or rash. These may be signs of systemic lupus erythematosus (SLE).
- Problems with balance and co-ordination, feeling lethargic or less alert, associated with being sick (vomiting). This may be due to an increased amount of ammonia in your blood.
- Shakiness (tremor), jerky muscle movements, unsteadiness when walking (parkinsonism, extrapyramidal disorder, ataxia).
- Rapid, uncontrollable movement of the eyes.
- Kidney disease or kidney problems (renal failure, tubulointerstitial nephritis and Fanconi syndrome) which may manifest as reduced urinary output or blood in the urine.
- Confusion, that could be due to decreased levels of sodium in your blood, identified by a blood test, or to a condition named 'Syndrome of Inappropriate Antidiuretic Hormone (SIADH) secretion'.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet:

- Feeling sick (nausea), being sick (vomiting), stomach ache or diarrhoea, especially when starting treatment.
- Overgrowth of gums (gingival hypertrophia), swelling of gums, sore mouth, mouth ulcers and burning feeling of mouth (stomatitis)
- Feeling dizzy
- Headache
- Hearing loss, hearing problems or deafness

- Double vision
- Nail and nail bed disorders
- Skin problems such as rashes. These happen rarely, but more often in people also taking lamotrigine.
- Transient hair loss, abnormal hair growth, abnormal hair texture, changes in hair colour
- Increased levels of some hormones (androgens), which may lead to increased hair growth on the face, breasts or chest (particularly in women), acne or thinning hair.
- Skin rash caused by inflammation of small blood vessels (vasculitis)
- Irregularity or absence of women's period , pain during women's period, cysts in the ovaries (polycystic ovaries)
- Breast enlargement in men, male infertility (usually reversible after treatment discontinuation and may be reversible after dose reduction. Do not stop your treatment without speaking to your doctor first)
- Swelling of the feet and legs (oedema)
- Obesity, weight gain – as your appetite may be increased
- Bedwetting or increased need to pass urine, unintentional passing of urine (urinary incontinence)
- Passing a lot of urine and feeling thirsty (Fanconi syndrome)
- Decrease in carnitine levels (shown in blood or muscular tests)
- Seeing, feeling or hearing things that are not there (hallucinations)
- Aggression, agitation, disturbance in attention, abnormal behaviour, restlessness/hyperactivity, memory impairment, or cognitive or learning disorder
- Tingling or numbness in the hands and feet
- Lowering of normal body temperature
- Darker areas of skin and mucosae (hyperpigmentation)

Bone disorders
There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term antiepileptic medication, have a history of osteoporosis, or take steroids.

Tests
Episenta Injection can change levels of liver enzymes, blood clotting factors, salts or sugars shown up on blood and urine tests.

Additional side effects in children
Some side effects of valproate occur more frequently in children or are more severe compared to adults. These include liver damage, inflammation of the pancreas (pancreatitis), bedwetting (enuresis), renal dysfunction (Fanconi Syndrome), overgrowth of gum tissue, aggression, agitation, disturbance in attention, abnormal behavior, hyperactivity and learning disorder.

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search 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 Episenta Injection

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 label after “Exp.:”. The expiry date refers to the last day of that month.

Do not use this medicine if you notice signs of deterioration such as crystallisation or discolouring.

Do not freeze the medicine.

Episenta solution for injection may be diluted with 0.9 % saline or 5 % dextrose before infusion. Your hospital pharmacy will ensure that the solution for injection is diluted and stored in an appropriate manner.

6. Contents of the pack and other information

What Episenta Injection contains:
- The active substance is sodium valproate 100 mg per ml.
- The other ingredients are disodium edentate and water for injections.

What Episenta Injection looks like and contents of the pack
Episenta solution for injection is a clear colourless solution. It is available in glass (type I) ampoules with silicone coating on the inside containing either 3 ml or 10 ml of the solution for injection. Each pack contains 5 ampoules.

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