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Package leaflet: Information for the patient

Sodium Valproate Strandhaven 200 mg/5 ml Oral Solution

(Sodium Valproate)

▼ **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.

WARNING

Sodium Valproate can seriously harm an unborn baby when taken during pregnancy. If you are a female able to have a baby, you must use an effective method of birth control (contraception) at all times during your entire treatment with Sodium Valproate Oral Solution. Your specialist will discuss this with you, but you must also follow the advice in section 2 of this leaflet.

Schedule an urgent appointment with your general practitioner (GP) for a referral to a specialist if you want to become pregnant or if you think you are pregnant.

Do not stop taking Sodium Valproate Oral Solution 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 Sodium Valproate Oral Solution you must also read section 2 of this leaflet carefully and contact your child's GP once they experience their first period, the GP will refer your child to their specialist.

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, please ask your GP, specialist 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 GP, specialist or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sodium Valproate Oral Solution is and what it is used for
2. What you need to know before you take Sodium Valproate Oral Solution
3. How to take Sodium Valproate Oral Solution
4. Possible side effects
5. How to store Sodium Valproate Oral Solution
6. Contents of the pack and other information

1. What Sodium Valproate Oral Solution is and what it is used for

What Sodium Valproate Oral Solution is

The name of your medicine is Sodium Valproate Strandhaven 200 mg/5 ml Oral Solution (called Sodium Valproate Oral Solution in this leaflet).

What Sodium Valproate Oral Solution contains

Sodium Valproate Oral Solution contains a medicine called Sodium Valproate. It belongs to a group of medicines called anti-convulsants or anti-epileptic agents. It works by helping to calm the brain down.

What Sodium Valproate Oral Solution is used for

Sodium Valproate Oral Solution is used to treat epilepsy (fits) in adults and children.

For male patients aged under 55 years not having used valproate before and for female patients aged under 55 years: this medicine is only used when two specialists have agreed that your condition does not respond to other treatments.

2. What you need to know before you take Sodium Valproate Oral Solution

Do not take Sodium Valproate Oral Solution if you:

- are allergic (hypersensitive) to Sodium Valproate or any of the other ingredients of Sodium Valproate Oral Solution (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- have liver problems, or you or your family have a history of liver problems, especially if caused by taking a medicine.
- have a rare illness called porphyria which affects your metabolism.
- have a known metabolic disorder, i.e. a urea cycle disorder.
- have a genetic problem caused by a mitochondrial disorder (e.g. Alpers-Huttenlocher syndrome).
- have a deficiency in carnitine (a very rare metabolic disease) that is untreated.
- are pregnant, unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks (see "Pregnancy, breast-feeding and fertility – Important advice for women" below).
- If you are a woman aged under 55 years who is able to have a baby, you must not take Sodium Valproate Oral Solution unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks and you use effective method of birth control (contraception) at all times during your entire treatment with Sodium Valproate Oral Solution. Do not stop taking Sodium Valproate Oral Solution 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 GP, specialist or pharmacist before taking Sodium Valproate Oral Solution.

Warnings and precautions

- The risk of liver damage is increased if Sodium Valproate Oral Solution 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 anti-epileptics such as Sodium Valproate have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your GP or specialist.
- As with other anti-epileptic drugs, convulsions may become worse or happen more frequently whilst taking this medicine. If this happens contact your GP or specialist immediately.
- If you or your child taking Sodium Valproate Oral Solution develops problems with balance and co-ordination, feeling lethargic or less alert, vomiting, tell your GP immediately. This may be due to an increased amount of ammonia in the blood.
- 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.

Talk to your GP, specialist or pharmacist before taking Sodium Valproate Oral Solution if you:

- have a brain disease or a metabolic condition affecting your brain.
- have problems with your pancreas.
- have diabetes or are being tested for diabetes. This medicine may affect the results of urine tests.
- 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.
- 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
- have a rare disorder named 'carnitine palmitoyltransferase type II deficiency', because you are at an increased risk of muscle disorders.
- have impaired dietary intake in carnitine, found in meat and dairy products, especially in children less than 10 years old.
- have a deficiency in carnitine and are taking carnitine
- have kidney problems. Your specialist may monitor your valproate level or adjust your dose.
- have an illness called 'systemic lupus erythematosus (SLE)' – a rare disease of the immune system which affects skin, bones, joints and internal organs.
- 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 GP, specialist or pharmacist before taking Sodium Valproate Oral Solution.

Weight gain

Taking Sodium Valproate Oral Solution may make you put on weight. Talk to your GP, specialist or pharmacist about how this will affect you.

Blood tests

Your GP and/or specialist may request blood tests and liver function tests before and during your treatment with this medicine. Sodium Valproate Oral Solution 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 Sodium Valproate Oral Solution

Tell your GP, specialist 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 Sodium Valproate Oral Solution can affect the way some other medicines work. Also, some medicines can affect the way Sodium Valproate Oral Solution works.

In particular, check with your GP, specialist or pharmacist if you are taking any of the following:

- 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, rifinamide, topiramate, acetazolamide, lamotrigine and felbamate.
- Cannabidiol (used to treat epilepsy and other conditions).
- Medicines used to calm emotional and mental health disorders (including schizophrenia, bipolar disorder and depression) such as quetiapine, diazepam and olanzapine.
- Monoamine oxidase inhibitors (MAOIs) such as moclobemide (used to treat depression and anxiety), selegiline (used to treat Parkinson's disease), linezolid (used to treat infections).
- Anticoagulants such as warfarin – used to thin the blood and prevent clots. Your doctor may change your dose of the blood thinning medicine and monitor your treatment closely.
- Zidovudine and protease inhibitors such as lopinavir and ritonavir – used to treat HIV infection and AIDS.
- Carbapenem agents (antibiotics used to treat bacterial infections) such as panipenem, imipenem, meropenem, rifampicin and erythromycin. The combination of Sodium Valproate Oral Solution and carbapenems should be avoided because it may decrease the effect of your medicine.
- Some anti-infectives that contain pivalate (e.g., pivampicillin, aciclovir, dipivoxil).
- Some medicines used to treat or prevent malaria such as mefloquine and chloroquine.
- Temozolomide – used to treat cancer.
- Cimetidine – used to treat stomach ulcers.
- Cholestyramine – used to lower blood fat (cholesterol) levels.
- Nimodipine – used to treat bleeding in the brain (subarachnoid haemorrhage).
- Propofol – used for anaesthesia.
- Oestrogen-containing products (including some birth control pills).
- Metamizole – used to treat pain and fever.
- Methotrexate – used to treat cancer and inflammatory diseases.
- Clozapine (to treat mental health conditions)

Sodium Valproate Oral Solution with alcohol

Alcohol intake is not recommended during treatment.

Pregnancy, breast-feeding and fertility

Important advice for female patients aged under 55 years

- You must not use Sodium Valproate Oral Solution if you are pregnant, unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks.
- If you are a female patient aged under 55 years, you must not take Sodium Valproate Oral Solution unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks. If 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 Sodium Valproate Oral Solution.
- Do not stop taking Sodium Valproate Oral Solution 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

- Contact your GP immediately if you are planning to have a baby or are pregnant. Your GP will urgently refer you to your specialist.
- 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 and may lead to permanent disability. 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, two specialists will have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks, and your specialists will have explained what might happen to your baby if you become pregnant whilst taking valproate.
- If you decide later that 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 GP once your child using valproate experiences their first period (menarche). Their GP will refer your child to their specialist who will decide with another specialist whether valproate is the only possible treatment or whether another medicine should be prescribed.
- Some birth control pills (oestrogen-containing birth control pills) may lower valproate levels in your blood. Make sure you talk to your GP, specialist or sexual health and contraception clinic about the method of birth control (contraception) that is the most appropriate for you.
- Ask your specialist 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 the situations which apply to you and read the description below:

- **I AM STARTING TREATMENT WITH SODIUM VALPROATE ORAL SOLUTION**
- **I AM TAKING SODIUM VALPROATE ORAL SOLUTION AND NOT PLANNING TO HAVE A BABY**
- **I AM TAKING SODIUM VALPROATE ORAL SOLUTION AND PLANNING TO HAVE A BABY**
- **I AM PREGNANT AND I AM TAKING SODIUM VALPROATE ORAL SOLUTION**

I AM STARTING TREATMENT WITH SODIUM VALPROATE ORAL SOLUTION

If you are a female patient aged under 55 years who is able to have a baby, this medicine can only be prescribed for you if two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks. If this is the first time you have been prescribed Sodium Valproate Oral Solution, your specialist will have explained the risks to an unborn child if you become pregnant. If 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 Sodium Valproate Oral Solution. Talk to your GP, specialist or sexual health and contraception clinic if you need advice on birth control (contraception).

Key messages:

- Pregnancy must be excluded before start of treatment with Sodium Valproate Oral Solution with the result of a pregnancy test, confirmed by your specialist.
- You must use an effective method of birth control (contraception) at all times during your entire treatment with Sodium Valproate Oral Solution.
- You must discuss appropriate and effective methods of birth control (contraception) with your GP or specialist. Your GP or specialist 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 reassess whether you should continue receiving treatment with valproate or whether another medicine should be prescribed. The specialist will make sure you are well aware of and have understood all the risks and advice related to the use of valproate during pregnancy.
- Tell your specialist if you want to have a baby.
- Tell your specialist **immediately** if you are pregnant or think you might be pregnant.

I AM TAKING SODIUM VALPROATE ORAL SOLUTION AND NOT PLANNING TO HAVE A BABY

If you are a female patient aged under 55 years who is able to have a baby, this medicine can only be prescribed for you if two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks. If you are continuing treatment with Sodium Valproate Oral Solution and 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 Sodium Valproate Oral Solution. Talk to your GP, specialist or sexual health and contraception 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 Sodium Valproate Oral Solution.
- You must discuss appropriate and effective methods of birth control (contraception) with your GP or specialist. They 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 reassess whether you should continue receiving treatment with valproate or whether another medicine should be prescribed. They will make sure you are well aware and have understood all the risks and advice related to the use of valproate during pregnancy.
- Tell your GP or specialist if you want to have a baby.
- Tell your specialist, or GP to be urgently referred to your specialist, **immediately** if you are pregnant or think you might be pregnant.

I AM TAKING SODIUM VALPROATE ORAL SOLUTION AND PLANNING TO HAVE A BABY

If you are planning to have a baby, first schedule an appointment with your GP. Your GP will urgently refer you to your specialist.

Do not stop taking Sodium Valproate Oral Solution 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 (behaviour and learning disorders), which can be seriously debilitating and/or permanent. Babies are also at risk of lower weight than expected for their age at birth. Your GP will refer you to a specialist experienced in the management of epilepsy, so that other 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.

You must not use Sodium Valproate Oral Solution if you are pregnant, unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks. Your specialist may decide to change the dose of Sodium Valproate Oral Solution, switch you to another medicine and stop treatment with Sodium Valproate Oral Solution a long time before you become pregnant – this is to make sure your illness is stable.

Ask your specialist 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 Sodium Valproate Oral Solution unless your specialist tells you to.
- Do not stop using your 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 you and your baby are reduced.
- First schedule an appointment with your specialist. During this visit your specialist will reassess whether you should continue receiving treatment with valproate or whether another medicine should be prescribed. They will make sure you are well aware of and have understood all the risks and advice related to the use of valproate during pregnancy.
- Your specialist will try to switch you to another medicine or stop treatment with Sodium Valproate Oral Solution a long time before you become pregnant.
- Schedule an urgent appointment with your GP to be urgently referred to your specialist, immediately if you are pregnant or think you might be pregnant.

I AM PREGNANT AND I AM USING SODIUM VALPROATE ORAL SOLUTION

Do not stop taking Sodium Valproate Oral Solution unless your specialist tells you to as your condition may become worse.

Schedule an urgent appointment with your GP. Your GP will refer you immediately to your specialist, if you are pregnant or think you might be pregnant. Your specialist will then advise you further.

Babies born to mothers who have been on valproate are at serious risk of birth defects and problems with development (behaviour and learning disorders) which can be seriously debilitating and/or permanent. Babies are also at risk of lower weight than expected for their age at birth. Your GP will refer you to your specialist experienced in the management of epilepsy, so that other treatment options can be evaluated.

In the exceptional circumstances when two specialists have agreed that Sodium Valproate Oral Solution 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 should receive counselling and support regarding the valproate- exposed pregnancy.

Ask your specialist 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 GP. Your GP will refer you immediately to your specialist if you are pregnant or think you might be pregnant. Your specialist will then advise you further.
- Do not stop taking Sodium Valproate Oral Solution unless your specialist tells you to.
- Make sure you are referred to a specialist experienced in the treatment of epilepsy to evaluate the possibility of other treatment options.
- You must get thorough counselling on the risks of Sodium Valproate Oral Solution during pregnancy, including malformations and physical and mental developmental disorders in children.
- Make sure you are referred to specialist for prenatal monitoring to examine potential malformations.

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