

HOVID-VALPROATE LIQUID 200MG/5ML

Sodium Valproate (200mg/5ml)

What is in this leaflet

1. What hovid Valproate Liquid is used for
2. How hovid Valproate Liquid works
3. Before you use hovid Valproate Liquid
4. How to use hovid Valproate Liquid
5. While you are using it
6. Side effects
7. Storage and disposal of hovid Valproate Liquid
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What hovid Valproate Liquid is used for

hovid Valproate Liquid is used for the treatment of generalized (affects the entire brain) or partial (only affects a small part of the brain) epilepsy (fits) with the following pattern of seizures:

- Absence (a short period of “blanking out”)
- Myoclonic (brief, shock-like jerks of muscles)
- Tonic-clonic (muscles stiffen, and jerking movements)
- Atonic (muscles suddenly lose strength)
- Mixed
- Simple (awareness is retained) or complex (impairment of awareness) seizures
- Secondary generalized seizure (spread to both sides of the brain after the initial event)
- Specific syndromes (Wes, Lennox-Gastaut)

Hovid Valproate Liquid may also be used to control bipolar disorder, a mental condition with mania symptoms (an elevation of mood).

How hovid Valproate Liquid works

hovid Valproate Liquid contains a medicine called sodium valproate. This belongs to a group of medicines called anticonvulsants or anti-epileptic agents.

It works by controlling brain chemicals which send signals to nerves so that seizures do not happen.

Before you use hovid Valproate Liquid

WARNING FOR WOMEN AND GIRLS

Before you start to use it:

This medicine can seriously harm an unborn baby

Always use effective contraception during treatment with sodium valproate

If you are thinking about becoming pregnant, or if you are pregnant, contact your doctor urgently.

You must CONTINUE taking sodium valproate unless your doctor tells you to stop

- When you must not use it

Do not take this medicine if:

- You are hypersensitive to sodium valproate or any other ingredients of hovid Valproate Liquid listed in this leaflet.
- You have liver problems or your family has a history of liver problems.
- You have a rare illness called porphyria (a group of disorders where there is a problem with the production of haem within the body. Haem is used to make haemoglobin in red blood cells.)
- You have mitochondrial disorders (e.g. Alpers-Huttenlocher Syndrome).

If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor.

- Before you start to use it

Tell your doctor if:

- You are pregnant
- You are a woman able to have a baby you must not take sodium valproate unless you use an effective method of birth control (contraception) at all times during your treatment with sodium valproate.
- Your liver function is impaired.
- You suffer from pancreatitis.

- You have suicidal ideation and behavior (thoughts killing themselves).
- You are taking carbapenem agents.
- You have mitochondrial disorders (e.g. Alpers-Huttenlocher Syndrome).
- You have kidney problems.
- You have an illness called “systemic lupus erythematosus (SLE)” – an immune system disease affects skin, bones, joints and internal organs.
- You have a ‘urea cycle disorder’ where too much ammonia builds up in the body.
- You have diabetes. This medicine may affect the results of urine tests.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking hovid Valproate Liquid.

Taking hovid Valproate Liquid with drink: Alcohol intake is not recommended during treatment with this medicine.

Blood tests: Your doctor may wish to do blood tests before you start taking hovid Valproate Liquid and during your treatment.

- Taking other medicines

The following medicines can increase the chance of you getting side effects when taken with hovid Valproate Liquid:

- Some medicines used for pain and inflammation such as aspirin.
- Some other medicines used to treat fits (epilepsy) such as phenobarbital, primidone, phenytoin, carbamazepine, topiramate, lamotrigine and felbamate.

Hovid Valproate Liquid may increase the effect of the following medicines:

- Medicines used for thinning the blood (such as warfarin).
- Zidovudine used to treat HIV infection.
- Temozolomide used to treat cancer.

HOVID-VALPROATE LIQUID 200MG/5ML

Sodium Valproate (200mg/5ml)

- Medicines for depression.
- Monoamine oxidase inhibitors (MAOI) such as moclobemide, selegiline and linezolid.
- Medicines used to calm emotional and mental conditions such as diazepam.

The following medicines can affect the way hovid Valproate Liquid works:

- Some medicines used for the prevention and treatment of malaria such as mefloquine and chloroquine.
- Cimetidine used for stomach ulcers.
- Some medicines used for infection (antibiotics) such as rifampicin and erythromycin.
- Carbapenem agents (antibiotics used to treat bacterial infections) such as imipenem, meropenem and panipenem. The combination of hovid Valproate Liquid and Carbapenem agents should be avoided because it may decrease the effect of your medicine.
- Cholestyramine used to lower blood fat (cholesterol) levels.

Some medicines and sodium valproate may interfere with each other, these include propofol (a medicine used before and during general anesthesia). Tell your doctor that you are taking hovid Valproate Liquid if you are going for an operation.

How to use hovid Valproate Liquid

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Adults (including elderly): The maintenance dose is 1000-2000mg/kg/day. The starting dose is 600 mg daily. Your doctor should gradually increase this dose by 200 mg every 3 days depending on your condition. The usual dose is between 1000 mg and 2000 mg (20-30 mg per kilogram of body weight) each day.

This may be increased each day to 2500 mg depending on your illness. The maintenance dose: 1000-2000 mg/day (20-30 mg/kg/day).

Children over 20 kg: The starting dose should be 400 mg daily. Your doctor should increase this dose depending on your child's illness. The usual dose is then between 20 mg and 30 mg for each kilogram of body weight each day. This may be further increased to 35 mg for each kilogram of body weight each day depending on your child's illness.

Children under 20 kg: The usual dose is 20 mg for each kilogram of body weight each day. Depending on the child's condition your child's doctor may decide to increase this dose which above 40 mg/kg/day will require monitoring.

In patients with kidney problems: Your doctor may decide to adjust the dosage.

If you are taking other medicines for 'fits' (epilepsy): Your doctor may increase the dose of Valproate Liquid by 5 to 10 mg for each kilogram of body weight each day depending on which other medicines you are taking.

Adults with mania associated with bipolar disorders: The starting dose is 1000 mg daily. Your doctor should increase your dose rapidly to achieve the desired effects. The usual dose is then between 1000mg and 2000 mg each day. This may be increased to not more than 3000 mg each day depending on your illness.

- When to use it

Take hovid Valproate Liquid at about the same time each day unless your doctor tells you otherwise.

-How long to use it

Keep taking until your doctor tells you to stop. Do not stop taking hovid Valproate Liquid just because you feel better. If you stop your fits may come back.

- If your forget to use it

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you take more hovid Valproate Liquid than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. The following effects may happen: feeling sick or being sick, pupils of the eye become smaller, dizziness, weak muscles and poor reflexes, breathing problems, and fits (seizures).

While you are using it

- Things you must do

Schedule an urgent appointment with doctor if you want to become pregnant or if you think you are pregnant. If you are a parent or a caregiver of a female child treated with sodium valproate, you should contact their doctor once your child experiences their first period (menarche).

Tell your doctor:

- If you experience allergic reactions/ any of the unwanted side effects while using this medicine.
- If you become pregnant while using this medication.

Women taking hovid Valproate Liquid during pregnancy have a higher risk of having a child with abnormality. These abnormalities include:

- Head and face deformities including cleft palate (a gap or depression in the lip).
- Malformations of the arms and legs.
- Deformities of the tube from the bladder to the penis, where the opening is formed in a different place.
- Heart and blood vessel malformations, including heart defects.
- An abnormality of the spinal cord called 'Spina bifida'.
- Malformations of the urethra.

HOVID-VALPROATE LIQUID 200MG/5ML

Sodium Valproate (200mg/5ml)

Taking folic acid 5mg each day as soon as you stop contraception may lower the risk of having a baby with spina bifida. These other defects can usually be detected with specialized prenatal monitoring.

Pregnant mothers who take hovid Valproate Liquid may have babies with:

- Blood clotting problem.
- Hypoglycaemia (low blood sugar).
- Hypothyroidism (underactive thyroid gland).
- Withdrawal syndromes (such as, in particular agitation, irritability, hyper-excitability, jitteriness, hyperkinesia, tonic-clonic disorders, tremor, convulsions and feeding disorders) if valproate is taken during the last trimester of pregnancy.

Some babies born to mothers who took hovid Valproate Liquid during pregnancy may develop less quickly than normal or have autistic disorders.

Tell all the doctors, dentists and pharmacists treating you that you are using hovid Valproate Liquid.

Use this medicine exactly as your doctor has told you.

- Things you must not do

Continue taking sodium valproate or using your birth control (contraception) until you have discussed your pregnancy or your plan to get pregnant with your doctor.

Do not:

- Stop taking the medicines unless advised by your doctor.
- Give hovid Valproate Liquid to anyone else even if they have the same symptoms or condition as you.
- Take any new medicines without consulting your doctor.
- Use hovid Valproate Liquid after the expiry date.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.

- Do not stop taking hovid Valproate Liquid, or change the dosage, without checking with your doctor.

- Things to be careful of

Driving and using machines:

You may feel sleepy when taking hovid Valproate Liquid. If this happens to you, do not drive or use any tools or machines. Taking with other antiepileptic medicines may increase sleepiness.

Pregnancy:

- Sodium valproate can seriously harm an unborn baby when taken during pregnancy.
- The higher the dose, the higher the risks but all doses carry a risk.
- It can cause serious birth defects and can affect the way in which the child develops as it grows. Birth defects which have been reported 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.
- If you take sodium valproate during pregnancy you have a higher risk than other women of having a child with birth defects that require medical treatment, because sodium valproate has been used for so many years it is known that in women who take sodium valproate around 10 babies in every 100 will have birth defects. This compares to 2-3 babies in every 100 born to women who don't have epilepsy.
- It is estimated that up to 30-40% of preschool children whose mothers took sodium 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.
- Autistic spectrum disorders are more often diagnosed in children exposed to sodium valproate and there is some evidence children may be more likely to develop

symptoms of Attention Deficit Hyperactivity Disorder (ADHD).

Breast-feeding:

There is risk of hematological disorders (blood disorders e.g. anaemia) in breastfed newborns/infants of treated women. A decision must be made whether to discontinue breast-feeding or to discontinue from hovid Valproate Liquid therapy.

Pancreatitis: Cases of life-threatening pancreatitis have been reported in both children and adults receiving valproate. Some of the cases have been described as hemorrhagic with a rapid progression from initial symptoms to death. Cases have been reported shortly after initial use as well as after several years of use. Patients and guardians should be warned that abdominal pain, nausea, vomiting, and/or anorexia can be symptoms of pancreatitis that require prompt medical evaluation. If pancreatitis is diagnosed, valproate should be discontinued.

Important advice for male patients able to father a child

Potential risk related to taking valproate in the 3 months prior to conception

A study suggests that if you take valproate in the 3 months prior to conception, your child may have a higher risk for impaired mental and/or motor development compared to children born to fathers who used lamotrigine or levetiracetam, other medicines that can be used to treat your disease. In this study, around 5 children in 100 had such disorders when born from fathers treated with valproate, and around 3 children in 100 when born from fathers treated with the other medicines. There are no data on this potential risk to children fathered more than 3 months after stopping valproate treatment (the time needed for new sperm to be formed).

As a precautionary measure, your doctor will discuss with you

HOVID-VALPROATE LIQUID 200MG/5ML

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- The potential risk when fathering a child if you are treated with valproate,
- The need to use effective contraception (birth control) for you and your female partner during the treatment and for 3 months after stopping valproate
- The need to consult your doctor to discuss alternative treatment options, as soon as you are planning to father a child and before discontinuing contraception (birth control),
- To not donate sperm during treatment and for 3 months after stopping treatment.

Do not stop your treatment without talking to your doctor. If you stop your treatment, your symptoms may become worse. If your female partner becomes pregnant while you used valproate in the 3 months prior to conception, both of you should contact the doctor for counselling.

You should get regular (at least annual) appointments with your doctor. During this visit your doctor will make sure you acknowledge the risk and precautions associated with valproate use. Make sure you read the patient guide that you will receive from your doctor.

Side Effects

Like all medicines, hovid Valproate Liquid 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. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue. Hands, feet or genitals may also be affected.
- 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 hovid Valproate

Liquid. It includes feeling and being sick any times, being very tired sleepy and weak, stomach pain including very bad upper stomach pain, jaundice (yellowing of the skin or whites of the eyes), loss of appetite, swelling (especially of the legs and feet but may 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 hovid Valproate Liquid immediately if you have these symptoms:

- Severe sometimes life threatening skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme).
- There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacists if you are on long-term antiepileptic medication, or have a history of osteoporosis.
- A decrease in the number of blood platelets (thrombocytopenia); a decrease on the number of red blood cells (anaemia).
- Blood clotting problems (bleeding for longer than normal), bruising or bleeding for no reason.
- Changes in mood, loss of memory, confusion, lack of concentration and deep loss of consciousness (coma).
- Underactive thyroid gland, which may cause tiredness or weight gain (hypothyroidism).
- Breathing difficulty and pain due to inflammation on the lungs (pleural effusion).

Tell your doctor as soon as possible if you have any of the following side effects:

- Changes in behaviours including being very alert, and sometimes also aggressive, hyper-active and unusual or inappropriate behavior. This is more likely if other medicines to treat fits such as phenobarbital and topiramate are taken at the same time or if the hovid Valproate liquid starting dose

is high or has been suddenly increased.

- Changes in the amount of ammonia in the blood. Symptoms of this condition are being sick, problems with balance and co-ordination, feeling lethargic or less alert.
- Feeling shaky (tremor), sleepy or unsteady when walking or jerky muscle movements.
- Rapid, uncontrolled movement of the eyes.
- Feeling sick, stomach ache or diarrhoea, especially when starting treatment. This may be helped by taking hovid Valproate Liquid with food.
- Extrapyrmidal disorders.
- Hearing loss.
- Rashes.
- Acne.
- Hair loss which is usually temporary. When it grows back it may be curlier than before. Skin rash caused by narrow or blocked blood vessels (vasculitis).
- Changes in women's periods and increased hair growth on women.
- Breast enlargement in men.
- Swelling if the feet and legs (oedema).
- Weight gain.
- Kidney problems, increased need to pass urine.
- Headache.
- Aggression, agitation, disturbance in attention, abnormal behavior, restlessness/hyperactivity, and learning disorder.
- Tingling or numbness in the hands and feet.
- Male infertility (may be reversible after dose reduction or discontinuation)

Other unwanted side effects not listed may occur. Tell your doctor immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→

HOVID-VALPROATE LIQUID 200MG/5ML

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Reporting Side Effects to Medicines
(ConSERF) or Vaccines (AEFI)].

Serial Number
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Storage and Disposal of hovid

Valproate Liquid

- Storage

Keep out of reach of children.
Store below 30°C.

- Disposal

Medicines should not be disposed of via
wastewater or household waste. Ask
your pharmacist how to dispose of
medicines no longer required. These
measures will help to protect the
environment.

Product Description

- What it looks like

A red, cherry flavoured liquid.

- Ingredients

Active ingredients

- Each 5 ml of hovid Valproate
Liquid contains Sodium Valproate
200 mg.

Inactive ingredients

- Hydroxyethylcellulose
- Methyl hydroxybenzoate
- Propyl hydroxybenzoate
- Propylene glycol
- Saccharin sodium
- Sorbitol 70%
- Ponceau 4R
- Cherry flavor (Natural)
- Purified water

- MAL Number:

MAL20076036AZ

Manufacturer

HOVID Bhd.
121, Jalan Tunku Abdul Rahman
(Jalan Kuala Kangsar),
30010 Ipoh, Perak, Malaysia.

Product Registration Holder

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07/01/2026