

VALPARIN XR 500 TABLET

Sodium valproate (500mg)

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What Valparin XR is used for

Valparin XR is used for:

- The treatment of generalised or partial epilepsy, particularly with the following patterns of seizures:
 - Absence (short period of “blanking out” or staring into space).
 - Myoclonic (brief shock-like jerks of a muscle).
 - Atonic (abrupt loss of muscle tone).
 - Tonic-clonic (loss of consciousness and violent muscle contractions)
 - Mixed seizures.
- Partial epilepsy:
 - Simple (not affecting awareness or memory).
 - Complex seizures.
 - Secondary generalised seizures (start in one area and spread to both sides of the brain).
 - Specific syndromes (West, Lennox-Gastaut).

How Valparin XR works

Valparin XR contains sodium valproate. It belongs to a group of medicines called anti-convulsants or anti-epileptic agents. These medicines are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

Before you use Valparin XR

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 immediately.

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

- When you must not use it

Do not take Valparin XR:

- If you are allergic (hypersensitive) to sodium valproate or any of the other ingredients.
- If you are having liver problems or you or your family have a history of liver problems.
- If you are having a rare illness called porphyria (a rare hereditary disease in which the blood pigment hemoglobin is abnormally metabolized).

Pregnancy and lactation

If you are a female patient of childbearing age, make sure that you talk to your doctor about the risks associated with taking Valparin XR during pregnancy.

Tell your doctor if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Sodium Valproate **Valparin XR** may affect your developing baby if taken in the first trimester of pregnancy, as it is suspected of causing an increased risk of malformations in the exposed foetus. However, do not stop taking your medication unless your doctor says so as there are risks to the mother and child from uncontrolled epilepsy.

Your doctor may want to adapt your treatment and/or prescribe dietary supplements of folate.

Your doctor will discuss the risks and benefits of taking it if you are pregnant.

Tell your doctor if you are breastfeeding or planning to breastfeed.

Medicines used in the treatment of epilepsy, including **Valparin XR**, pass into breast milk. Your doctor will discuss the risks and benefits of taking

it if you are breastfeeding or planning to breastfeed.

- Before you start use it

Tell your doctor if you have or have had any medical conditions, especially the following:

- Liver problems (liver insufficiency, liver damage).
- Kidney problems
- Have or have had depression, mood problems, or suicidal thoughts or behavior.
- Systemic lupus erythematosus (SLE), an autoimmune disease
- Symptoms of pancreatitis such as abdominal pain, nausea, vomiting or anorexia.
- Tell your healthcare professionals if you are pregnant.
- If 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.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and sodium valproate may interfere with each other. These include:

- Other medicines used to treat epilepsy e.g. phenobarbitone, primidone, phenytoin, carbamazepine, felbamate and lamotrigine.
- Carbapenem agents (antibiotics used to treat bacterial infections) such as imipenem, meropenem, and erythromycin. The combination of Valparin XR and carbapenems should be avoided because it may decrease the effect of your medicine.
- Colestyramine used to lower blood fat (cholesterol) levels.
- Medicines used to treat depression e.g. monoamine oxidase inhibitors (MAOIs).
- Benzodiazepines (medicines used as sedatives or to treat anxiety).

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- Medicines used for prevents clotting (such as warfarin).
- Some medicines used for the prevention and treatment of malaria such as mefloquine and chloroquine.
- Cimetidine used for stomach ulcers.
- Zidovudine (an antiviral agent).
- Aspirin.

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

How to use Valparin XR

- How much to use

Monotherapy

Adults:

- The starting dose is 600mg daily. Your doctor will gradually increase this dose by 200mg every 3 days depending on your condition.
- The usual dose is generally between 1000mg and 2000mg (20-30mg per kilogram of body weight) each day.
- This may be increased to 2500mg each day depending on your illness.

Children over 20 kilograms:

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

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. This may depend on your age, your condition and whether or not you are taking any other medicines. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Valparin XR 500 may be given once or twice daily. The tablet should be swallowed whole and not crushed or chewed.

- How long to use it

Continue taking Valparin XR for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

If you take too much Valparin XR, call your doctor or poison control center right away, or get emergency treatment at nearest hospital as soon as possible.

If you take too much Valparin XR, the following effect may happen: nausea, vomiting, dizziness, coma, weak muscles and poor reflexes, pupils of the eye become smaller, breathing problem, fits (seizure), brain oedema, increased intracranial pressure (pressure inside the skull).

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Valparin XR.
- Tell your doctor immediately if you become pregnant while taking this medication.
- Women taking Valparin XR during pregnancy have a higher risk than other women of having a child with an abnormality (like Head and face deformities including cleft palate (a gap or depression in the lip), abnormality of the spinal cord called 'Spina bifida').
- Schedule an urgent appointment with your 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).

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Valparin XR to anyone else, even if they have the same symptoms or condition as you.
- 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.

- Things to be careful of

This medicine may produce suicidal thoughts or behavior. If this happens contact your doctor immediately.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick or sleepy do not drive or use machines and contact your doctor immediately.

Sodium Valproate

- 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 many years it is known that in women who take sodium valproate around 10 babies in every 100 will have birth defects. This compares 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

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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).

➤ **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:
 - 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, Valparin XR can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine:

- Increased liver enzymes, liver dysfunction, severe liver damage, including liver failure.
- Nausea.
- Pancreatitis (inflammation of pancreas).
- Allergic reactions (ranging from rash to hypersensitivity reactions).
- Lethargy and confusion, deep loss of consciousness (coma), or convulsions.
- Loss of memory (dementia).
- Hair loss.
- Feeling shaky (tremor).
- Sleepy.
- Thrombocytopenia (decrease of platelets in blood).
- Anemia (decrease in red blood cell), leucopenia (decrease in white blood cell) or pancytopenia (decrease in blood cells).
- Blood clotting problems.

- Redness of skin.
- Toxic epidermal necrolysis (Severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body).
- Stevens-Johnson syndrome (Blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals).
- Erythema multiforme (skin rash or skin lesions with a pink/red ring and a pale center which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet).
- Peripheral oedema.
- Amenorrhoea (absence of a menstrual period) and irregular periods.
- Reversible Fanconi's syndrome (kidney malfunction giving rise to glycosuria (excess of sugar in the urine), aminoaciduria (abnormal amount of amino acids in the urine), phosphaturia (presence of an excessive quantity of phosphates in the urine), and uricosuria (presence of excessive amounts of uric acid in the urine)).
- Male infertility (may be reversible after dose reduction or discontinuation)

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following side effects.

The following side effects may be signs of problems with your liver or pancreas such as:

- Asthenia (weakness).
- Anorexia (eating disorder).
- Lethargy.
- Drowsiness.
- Vomiting.
- Abdominal pain.
- Nausea.

This is not a complete list of side effects. Contact your doctor or pharmacist if you experience any side effects.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug

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Reaction Monitoring by visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Valparin XR

- Storage

Keep in a dry place at a temperature not exceeding 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

White, oblong shaped film coated tablets with breakline on both sides.

- Ingredient

Active ingredient(s)

- Sodium Valproate.
- Valproic acid.

Inactive ingredient(s)

- Colloidal silicon dioxide.
- Hydroxypropyl methyl cellulose.
- Ethyl cellulose.
- Hydrated silica.
- Saccharin sodium.
- Glycerin.
- Titanium dioxide.
- Eudragit E 100.
- Eudragit NE 30D.
- Polyethylene glycol.
- Talc.
- Methanol.

-MAL number

MAL05121152AZ

Manufacturer

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Product Registration Holder

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