

VALPARIN XR 500 TABLET

Sodium valproate (500mg)

What is in this leaflet

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

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 “blinking 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

- 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.

- 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).
- 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.

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.

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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').

- 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..

- 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.

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).
- Anaemia (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 centre 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)).

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.

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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 Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

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

- MAL number:

MAL05121152A

Manufacturer

TORRENT PHARMACEUTICALS LTD.
Indrad 382 721, District: Mehsana, INDIA.

Product Registration Holder

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