

PATIENT INFORMATION LEAFLET (PIL)

VALEPSY-300 (GASTRO-RESISTANT SODIUM VALPROATE TABLETS BP 300 MG)

Read this entire leaflet carefully before you starts using 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.
- 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 doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

- What VALEPSY-300 is and what it is used for
- What you need to know before you take VALEPSY-300
- How to take VALEPSY-300
- Possible side effects
- How to store VALEPSY-300
- Contents of the pack and other information

1. WHAT VALEPSY-200 IS AND WHAT IT IS USED FOR:

VALEPSY-300 is indicated for the treatment of epilepsy and bipolar disorder.

2. WHAT YOU NEED TO KNOW BEFORE TAKING VALEPSY-200 :

Do not take VALEPSY-300 and tell your doctor if:

Epilepsy

For epilepsy, you must not use VALEPSY-300 if you are pregnant, unless nothing else works for you.

For epilepsy, if you are a woman able to have a baby, you must not take VALEPSY-300 unless you use effective method of birth control (contraception) during your entire treatment with VALEPSY-300. Do not stop taking VALEPSY-300 or your contraception, until you have discussed this with your doctor. Your doctor will advise you further.

If you are allergic (hypersensitive) to sodium valproate or any of the other ingredients of VALEPSY-300. Signs of an allergic reaction include:

- a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

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- If you have liver problems or you or your family have a history of liver problems
- If you have a rare illness called porphyria
- If you have a genetic problem causing a mitochondrial disorder (e.g. Alpers Hutten locher syndrome)
- If you have a known metabolic disorder, i.e. a urea cycle disorder
- If you have a deficiency in carnitine (a very rare metabolic disease) that is untreated Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking VALEPSY-300.

Precautions with VALEPSY-300

- Inform your doctor or pharmacist before taking **VALEPSY-300**
- If you or your child develops a sudden illness especially if it is within the first six months of treatment and particularly if it includes repeated vomiting, extreme tiredness, abdominal pain, drowsiness, weakness, loss of appetite, upper stomach pain, nausea, jaundice (yellowing of the skin or whites of the eyes), swelling of the legs or worsening of your epilepsy or a general feeling of being unwell. Epilim can affect the liver and pancreas.
- The risk of liver damage is increased if Epilim 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. If you or your child taking Epilim 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.
- If your child is under 3 years of age, Epilim should not be administered together with acetylsalicylic acid (aspirin).
- 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 doctor.
- As with other antiepileptic medicines, some patients may experience a worsening of their symptoms (more frequent or more severe convulsions) when taking this medicine. If this happens contact your doctor immediately.

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Concomitant use of VALEPSY-300 with other medicines

Inform your doctor or pharmacist before taking VALEPSY-300 if you are taking any of the following medicines which may have drug interactions associated with Sodium Valproate.

- Some medicines used for pain and inflammation (salicylates) such as aspirin, see “Take special care with VALEPSY-300.
- Some other medicines used to treat fits (epilepsy) –“Patients taking other medicines for ‘fits’”. This includes medicines such as phenobarbital, primidone, phenytoin, carbamazepine, topiramate, acetazolamide, lamotrigine, rufinamide and felbamate
- Medicines containing quetiapine, which is used to treat schizophrenia or bipolar disorder
- Medicines used for thinning the blood (such as warfarin)
- Zidovudine - used for HIV infection
- Medicines for depression
- Monoamine oxidase (MAO) inhibitors such as moclobemide, selegiline, linezolid
- Medicines used to calm emotional and mental conditions such as diazepam and olanzapine
- Propofol, an anaesthetic
- Nimodipine
- Some medicines used for the prevention and treatment of malaria such as mefloquine and chloroquine
- Cimetidine - used for stomach ulcers
- Colestyramine used to lower blood fat (cholesterol) levels
- Some medicines used for infections (antibiotics) such as rifampicin and erythromycin
- Lopinavir and ritonavir – used for HIV treatment
- Carbapenem agents (antibiotics used to treat bacterial infections)
- Estrogen-containing products (including some birth control pills)
- Metamizole – used to treat pain and fever
- Cannabidiol (used to treat epilepsy and other conditions)
- Methotrexate (used to treat cancer and inflammatory diseases)
- Some anti-infectives that contain pivalate (e.g. pivampicillin, adefovir dipivoxil)

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VALEPSY-300 with alcohol

Alcohol intake is not recommended during treatment.

Weight gain

Taking VALEPSY-300 may make you put on weight. Talk to your doctor about how this will affect you.

Blood tests

Your doctor may wish to do blood tests before you start taking VALEPSY-300 and during your treatment. Blood tests may be required if you are to have surgery, or if you are experiencing unexplained bruising or bleeding.

Pregnancy, breast-feeding and fertility

Important advice for women

You must not stop taking VALEPSY-300 or interrupt your contraception, until you have discussed this with your doctor. Your doctor will advise you further.

Epilepsy

- For epilepsy, you must not use VALEPSY-300 if you are pregnant, unless nothing else works for you.
- For epilepsy, if you are a woman able to have a baby, you must not take VALEPSY-300 unless you use effective method of birth control (contraception) during your entire treatment with VALEPSY-300. Do not stop taking VALEPSY-300 or your contraception, until you have discussed this with your doctor. Your doctor will advise you further

The risks of valproate when taken during pregnancy (irrespective of the disease for which valproate is used)

- 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. The most frequently reported birth defects include spina bifida (where the bones of the spine are not properly developed); facial and skull malformations;

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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.

- 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.
- 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 who don't have epilepsy.
- It is estimated that up to 30-40% of preschool 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.
- Autistic spectrum 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).
- Before prescribing this medicine to you, your doctor 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 child you must not stop taking your medicine or your method of contraception until you have discussed this with your doctor.
- If you are a parent or a caregiver of a female child treated with valproate, you should contact the doctor once your child using valproate experiences 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 contraception (birth control) that is the most appropriate for you.

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- Ask your doctor about taking folic acid when trying for 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.
- There may be blood clotting problems, such as blood not clotting very well which 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) in newborns of mothers who have taken valproate during pregnancy.
- There may be a withdrawal syndrome (including agitation, irritability, hyperexcitability, jitteriness, excessive restlessness and uncontrollable movements (hyperkinesia), muscle problems, tremor, convulsions and feeding problems) in newborns of mothers who have taken valproate during the last trimester of their pregnancy.

Breast-feeding

Very little VALEPSY-300 gets into the breast milk. However, talk to your doctor about whether you should breast-feed your baby. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You may feel sleepy when taking VALEPSY-300. If this happens to you, do not drive or use any tools or machines. Taking other medicines used to treat fits or calm emotional and mental health problems may increase sleepiness.

3. HOW TO TAKE VALEPSY-300 :

Female children and women of childbearing potential

VALEPSY-300 treatment must be started and supervised by a doctor specialised in the treatment of epilepsy.

Male patients

It is recommended that VALEPSY-300 is initiated and supervised by a specialist experienced in the management of epilepsy – see section 2 Important advice for male patients.

Always take VALEPSY-300 exactly as your doctor has told you. You should check with

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your doctor or pharmacist if you are not sure. VALEPSY-300 treatment must be started and supervised by a doctor specialised in the treatment of epilepsy.

Taking this medicine

- Your doctor will decide how much VALEPSY-300 to give you or your child depending on your or your child's body weight
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself but ask your doctor

Adults (including the elderly)

- The starting dose is 600 mg daily. Your doctor will gradually increase this dose by 500 mg every 3 days depending on your condition
- The usual dose is generally between 1000 mg and 2000 mg (20-30 mg per kilogram of body weight) each day
- This may be increased to 2500 mg each day depending on your illness

Children over 20 kilograms

- 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 kilograms

- 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

Patients with kidney problems

- Your doctor may decide to adjust your or your child's dose

Patients taking other medicines for 'fits' (epilepsy)

- You or your child may be taking other medicines for epilepsy at the same time as VALEPSY-300. If so, your doctor should gradually initiate treatment depending on you or your child's condition

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- Your doctor may increase the dose of VALEPSY-300 by 5 to 10 mg for each kilogram of body weight each day depending on which other medicines you are taking

How to take this medicine

- Take this medicine by mouth
- Take VALEPSY-300 with or after food. This will help to stop the feelings of sickness that may happen after taking VALEPSY-300
- Do not crush or chew the tablets
- The dose is normally split and given half in the morning and half in the evening

If you have taken more VALEPSY-300 than prescribed

If you take more VALEPSY-300 than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen: feeling sick or being sick, pupils of the eye become smaller, dizziness, loss of consciousness, weak muscles and poor reflexes, breathing problems, headaches, fits (seizures), confusion, memory loss, low blood pressure and unusual or inappropriate behaviour.

Taking too much Epilim may result in too much sodium in your blood (hyponatraemia).

If forget to take VALEPSY-300

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 stop taking VALEPSY-300

Keep taking until your doctor tells you to stop. Do not stop taking VALEPSY-300 just because you feel better. If you stop your fits may come back.

4. POSSIBLE SIDE EFFECTS :

Like all medicines, VALEPSY-300 can cause side effects, although not everybody them.

Tell your doctor immediately 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:

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- Blisters with skin detachment (blistering, peeling or bleeding on any part of your skin (including you lips, eyes, mouth, nose, genitals, hands or feet) with or without a rash, with sometimes flu-like symptoms such as fever, chills or aching muscle – these may be signs of conditions named ‘toxic epidermal necrolysis’ or ‘Stevens Johnson syndrome’. These may happen more often in people also taking lamotrigine.
- 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’.
- An allergy triggered swelling with painful itchy welts (most often around the eyes, lips, throat and sometimes hands and feet) – these may be signs of ‘angioedema’.
- Syndrome with skin rash, fever, lymph node enlargement and possible impairment of other organs – these may be signs of a condition named ‘DRESS’ or Drug Rash with Eosinophilia and Systemic Symptoms.
- Problems with balance and co-ordination, feeling lethargic or less alert, associated with vomiting. This may be due to increased amount of ammonia in your blood.
- Repeated vomiting, extreme tiredness, abdominal pain, drowsiness, weakness or loss of appetite, severe upper stomach pain, nausea, jaundice (yellowing of the skin or whites of the eyes), swelling of the legs or worsening of your epilepsy or a general feeling of being unwell. These may be signs of severe liver or pancreas disorders (see Section 2 above).
- Drowsiness, changes in consciousness level (including coma), confusion, sluggishness or abnormal behaviour and memory loss, associated or not with more frequent or more severe fits, particularly if phenobarbital and topiramate are taken at the same time or if Epilim dose has been suddenly increased.
- Confusion, that could be due to decreased levels of sodium in your blood or to a condition named ‘SIADH’ or Syndrome of Inappropriate Antidiuretic Hormone secretion.
- An increase in the number and severity of convulsions.
- Spontaneous bruising or bleeding, due to blood clotting problems shown in blood tests.
- Severe decrease of white blood cells or bone marrow failure shown in blood tests, sometimes revealed by fever and breathing difficulty, getting more infections than usual.

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- Underactive thyroid gland, which may cause tiredness or weight gain (hypothyroidism).
- Joint pain, fever, fatigue, rash. These may be signs of systemic lupus erythematosus.
- Shakiness (tremor), uncontrollable muscle contractions, unsteadiness when walking (parkinsonism, extrapyramidal disorder, ataxia).
- Muscle pain and muscle weakness (rhabdomyolysis).
- Breathing difficulty and pain due to inflammation of the envelop of the lungs (pleural effusion).
- Kidney disease (renal failure, tubulointerstitial nephritis), which may manifest as reduced urinary output, loss of appetite, feeling and being sick, fits or loss of consciousness.

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:

Very common (may affect more than 1 in 10 people):

- Nausea

Common (may affect up to 1 in 10 people):

- Decreased platelet count or decreased red blood cell count or abnormally increased red blood cell size, or bone marrow disorders (shown in blood tests)
- Weight gain, obesity
- Seeing, feeling or hearing things that are not there (hallucinations)
- Headache
- Rapid, uncontrollable movement of the eyes
- Hearing problems or deafness
- Vomiting, stomach ache, diarrhoea especially when starting the treatment, see section 2 "How to take this medicine"
- Gingival problems (mainly hypertrophy (overgrowth of gums))
- Sore mouth, swollen mouth, mouth ulcers and burning feeling of mouth (stomatitis)
- Transient hair loss, nail and nail bed disorders
- Urinary incontinence (unintentional passing of urine)
- Pain during women's period

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Uncommon (may affect up to 1 in 100 people):

Tingling or numbness of the hands or feet

- Inflammation of small blood vessels (vasculitis)
- Skin reactions, such as rashes.
- Abnormal hair growth, abnormal hair texture, changes in hair colour
- Excessive hairiness, particularly in women, male pattern hair growth (virilism), acne (hyperandrogenism)
- 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 any long-term antiepileptic medication, have a history of osteoporosis, or take steroids.
- Irregular or absence of women's period
- Swelling of the feet and legs (oedema)
- Decrease in body temperature

Rare (may affect up to 1 in 1000 people):

- Aggression, agitation, disturbance in attention, abnormal behaviour and psychomotor hyperactivity
- Learning disorder
- Memory impairment and cognitive disorders
- Double vision
- Bedwetting or increased need to pass urine
- Passing a lot of urine and feeling thirsty (Fanconi syndrome)
- Male infertility is usually reversible after treatment discontinuation and may be reversible after dose reduction. Do not stop your treatment without speaking to your doctor first.
- Cysts in the ovaries (polycystic ovaries)
- Reduced body levels of Vitamin B8 (biotin deficiency), symptoms include a rash occurring around the eyes, nose and mouth, weak brittle nails, hair loss, loss of appetite, nausea, feeling depressed or having hallucinations

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Very rare (may affect up to 1 in 10,000 people):

- Breast enlargement in men

5. HOW TO STORE VALEPSY-300 :

Keep this medicine out of the sight and reach of children. Do not take this medicine after the expiry date shown on the blister and carton after EXP. The expiry date refers to the last day of that month. Do not remove the tablets from the foil until just before you take them. Do not cut the blister strips. Store in a dry place. Do not store above 30°C. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. PACK CONTENT AND OTHER INFORMATION

What is the composition of VALEPSY-300

Each enteric coated tablet contains:

Sodium Valproate BP.....300 mg

Excipients.....q.s

Colour : Red Oxide of Iron

Excipients:

Microcrystalline Cellulose

Colloidal Silicon Dioxide

Sodium Lauryl Sulphate

Magnesium Aluminium Silicate

Ethyl Cellulose

Methylene Dichloride

Croscarmellose Sodium

Doshion Resin

Purified Talc

Magnesium Stearate

Seal Coat

Isopropyl Alcohol

Enteric coated Titanium White Ready Mix

Red Oxide of Iron.

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Aspect of VALEPSY-300 and pack content

10 Tablets are packed in alu/alu blister. Such 10 blister packed in a printed carton with packaging insert.

7. Supplier and Manufacturer

Manufactured By:

Maxtar Bio-Genics (Formulations division).

K. No. 705, Vill. Malku Majra, Nalagarh Road
(Baddi), Tehsil Nalagarh, Distt. Solan (H.P.)

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