

PATIENT INFORMATION LEAFLET

VALEPTIC SYRUP can seriously harm an unborn child when taken during pregnancy. It can cause serious birth defects to body organs and/or body structures as well as harm the developing brain of the foetus and can also affect the way in which the child develops as it grows. Children whose mothers took VALEPTIC SYRUP during pregnancy may have problems with early childhood development. Children affected can be slow to walk and talk, be intellectually less able than other children, and have difficulties with language and memory.

Children whose mothers took VALEPTIC SYRUP during pregnancy have an increased risk of developing autistic spectrum disorders, childhood autism and attention deficit hyperactivity disorder (ADHD).

VALEPTIC SYRUP treatment should be started and supervised by a medical practitioner experienced in the treatment of epilepsy or bipolar disorder.

You should not take VALEPTIC SYRUP if the Risk Minimisation Measures (Pregnancy Prevention Programme), have not been explained to you and if you cannot commit to follow the pregnancy risk minimisation measures.

SCHEDULING STATUS:

S3

VALEPTIC SYRUP 200 mg/5 mL

Sodium Valproate

Contains sugar (sorbitol 800 mg/5 mL)

Read all of this leaflet carefully before you start taking VALEPTIC SYRUP.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- VALEPTIC SYRUP has been prescribed for you personally and you should not share VALEPTIC SYRUP with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What VALEPTIC SYRUP is and what it is used for

Sodium Valproate, the active ingredient in VALEPTIC SYRUP, belongs to a group of medicines called anti-convulsants or anti-epileptics.

VALEPTIC SYRUP is used in the treatment of epilepsy (fits) or seizures. It works by controlling the activity of the brain.

2. What you need to know before you take VALEPTIC SYRUP

Do not take VALEPTIC SYRUP:

- if you are hypersensitive (allergic) to sodium valproate or any of the other ingredients of VALEPTIC SYRUP (listed in section 6).
- If you are a woman able to have a baby, you must not take VALEPTIC SYRUP unless you use an effective method of birth control (contraception) at all times during your treatment with VALEPTIC SYRUP. Do not stop taking VALEPTIC SYRUP or your contraception until you have discussed this with your doctor. Your doctor will advise you further (see below under ‘Pregnancy, breastfeeding and fertility – Important advice for women’).
- if you are pregnant or breastfeeding (see Pregnancy, Breastfeeding and fertility).
- if you have liver disease such as: inflammation (pain, swelling) of the liver, family history of liver disorders.
- if you have a known metabolic disorder, i.e a urea cycle disorder.
- if you have a rare illness called porphyria (enzyme deficiency in the liver that affects the breakdown of components of red blood cells).
- if you are taking medicines that are part of a class of medicines known as Monoamine Oxidase Inhibitors (MAOI) used to treat depression.
- if you have a genetic problem caused by a mitochondrial disorder (e.g. Alpers-Huttenlocher syndrome).

Warnings and precautions

Take special care with VALEPTIC SYRUP:

- VALEPTIC SYRUP can cause severe liver damage and can result in death. You are most at risk if you are an infant or a young child under the age of 3 with severe disorders particularly those with brain damage, reduced mental abilities and (or) diseases present since birth. After the age of 3, the

incidence of occurrence is reduced and decreases with age. In most cases, such liver damage occurs during the first 6 months of therapy.

- If you have any of the following symptoms or notice any of the following symptoms in your child contact your doctor or healthcare professional immediately.
- Sudden onset of feeling of weakness, loss of appetite, tiredness, oedema and drowsiness which are sometimes associated with repeated vomiting and abdominal pain.
- If you are suffering from epilepsy (fits), you may experience a recurrence of seizures.
- Investigations including clinical examination and biological assessment of the liver function will be undertaken immediately by your doctor. Liver function tests will be performed before treatment and then will periodically be monitored during the first 6 months of therapy. Your doctor will then decide whether to continue your treatment with VALEPTIC SYRUP.
- If you are using salicylates (medicines such as aspirin) with VALEPTIC SYRUP these will be discontinued.
- You may experience severe pancreatitis (swelling and constant pain in the abdomen or reaching to the back and other areas) and death may even result. If you are a young child you are at particular risk. This risk is decreased with increasing age. If you suffer from severe fits, neurological (nerve) damage, or are taking medicines for fits you may be at risk to develop pancreatitis (swelling and constant pain in the abdomen or reaching to the back and other areas). Liver failure with pancreatitis (swelling and constant pain in the abdomen or reaching to the back and other areas) increases the risk of death.
- If you experience sudden stomach pain contact your doctor or healthcare practitioner immediately. If you are diagnosed with pancreatitis (swelling and constant pain in the abdomen, or reaching to the back and other areas) VALEPTIC SYRUP should be discontinued.
- If you are a woman or female able to have a baby:

If you are a woman or female adolescent that is old enough to become pregnant your doctor should only treat you with VALEPTIC SYRUP if you are not pregnant and you fulfil the requirements of the pregnancy prevention programme. See “Pregnancy and Breastfeeding: Pregnancy: Important information for women”. If you are taking VALEPTIC SYRUP and you decide you want to start a family, talk to your doctor about this as soon as possible. Do not stop VALEPTIC SYRUP or using birth control (contraception) - until you have been able to discuss this with your doctor. You need to talk to your doctor about the risks for your baby’s health while keeping your illness under control. You and your doctor should agree on what to do with your treatment before you start trying for a baby. See ‘Pregnancy and Breastfeeding: Pregnancy: Important information for women’. Parents or caregivers of a female (girl) child treated for epilepsy with VALEPTIC SYRUP, must contact the doctor once the female child using VALEPTIC SYRUP experiences her first menstrual period. If you are pregnant, talk to your doctor immediately. See “Do not take VALEPTIC SYRUP or give VALEPTIC SYRUP to your child” and “Pregnancy and Breastfeeding”.

- VALEPTIC SYRUP should not be used during pregnancy and lactation.
- As with other anti-epileptic drugs, convulsions may become worse or happen more frequently whilst taking this medicine. If this happens contact your doctor immediately.
- You will be monitored for signs of suicidal tendencies or behaviour, and appropriate treatment will be considered.
- You should seek medical advice immediately should signs of suicidal tendencies or behaviour emerge.
- If you know that there is a genetic problem caused by a mitochondrial disorder in your family.
- If your doctor may wish to do blood tests before you or your child start taking VALEPTIC SYRUP and during your treatment.

- If you have kidney function impairment (inability of the kidney to work properly). Your doctor may give you a lower dose.
- If you have an illness called ‘systemic lupus erythematosus (SLE)’ – a disease of the immune system which affects skin, bones, joints and internal organs.
- If you have a ‘urea cycle disorders’ where too much ammonia builds up in your body
- If you put on weight as your appetite may be increased. Talk to your doctor about how this will affect you.
- If you have diabetes. VALEPTIC SYRUP may affect the results of urine tests.
- If you have a carnitine palmitoyltransferase type II deficiency.
- VALEPTIC SYRUP should only be used in adult males who plan to father a child if alternative treatment options are not suitable.

Children and adolescents

- VALEPTIC SYRUP should be used with caution in male and female children less than 18 years of age, for the treatment of epilepsy.

Other medicines and VALEPTIC SYRUP

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Do not take VALEPTIC SYRUP at the same time as the following medicines:

- neuroleptics (medicines used to treat mental illnesses)
- monoamine oxidase inhibitors (MAOIs) used to treat depression such as moclobemide, selegiline or related medicines such as linezolid
- antidepressants (medicines used to treat depression such as citalopram)

- benzodiazepines (medicines used to calm emotional and mental conditions and to treat sleep disorders such as diazepam, olanzapine)
- barbiturates (medicines that depress the central nervous system such as phenobarbital)
- phenobarbital (medicines used to treat epilepsy (fits) or seizures)
- primidone (medicines used to treat epilepsy (fits) or seizures)
- phenytoin, and possibly other hydantoin anticonvulsants (medicines used to treat epilepsy (fits) or seizures)
- carbamazepine (medicines used to treat epilepsy (fits) or seizures)
- lamotrigine (medicines used to treat epilepsy (fits) or seizures)
- felbamate (medicines used to treat epilepsy (fits) or seizures)
- rufinamide (medicines used to treat epilepsy (fits) or seizures)
- propofol – used for anaesthesia.
- zidovudine (medicines used to treat HIV infection)
- Nimodipine (calcium channel blockers)
- Temozolomide used to treat cancer.
- mefloquine and chloroquine (medicines used to prevent malaria)
- anticoagulants (medicines that thin the blood) and other products which have anticoagulant properties (e.g. warfarin which is used to treat blood disorders and salicylates which are medicines used to treat inflammation (pain, swelling) such as aspirin)
- cimetidine (medicines used for hyperacidity and to treat stomach acid or ulcers)
- erythromycin (antibiotic medicine)
- clonazepam used to calm emotional and mental conditions

- carbapenem antibiotics (antibiotics used to treat bacterial infections) such as imipenem, meropenem, rifampicin and erythromycin. The combination of VALEPTIC SYRUP and carapenems should be avoided because it may decrease the effect of your medicine.
- rifampicin
- protease inhibitors (used to treat HIV) such as lopinavir and ritonavir
- cholestyramine used to lower blood fat (cholesterol) levels.
- oestrogen-containing products (including some birth control pills).
- acetazolamide (used to treat glaucoma, seizures or brain swelling). The combination with VALEPTIC SYRUP may cause a build-up of ammonia in the body.
- quetiapine to treat mental or mood disorders

VALEPTIC SYRUP with food and drink:

VALEPTIC SYRUP can be taken with or after food.

VALEPTIC SYRUP should not be diluted.

You should not drink alcohol whilst taking VALEPTIC SYRUP.

Pregnancy, breastfeeding and fertility:

Pregnancy:

- If you are pregnant or planning to become pregnant you should not take VALEPTIC SYRUP.
- VALEPTIC SYRUP crosses the placenta and may increase the risk of developmental disorders and malformations in the unborn baby.

Important advice for women:

If you or your female (girl) child are pregnant, you must not use VALEPTIC SYRUP, unless your doctor has determined there is no suitable alternative treatment.

If you or your female (girl) child are able to have a baby, you must not use VALEPTIC SYRUP unless the conditions of the pregnancy prevention programme are met.

VALEPTIC SYRUP can be harmful to unborn children when taken by a woman during pregnancy. VALEPTIC SYRUP can cause serious birth defects and can affect the way in which the child develops as it grows.

The conditions of the pregnancy prevention programme require that before VALEPTIC SYRUP is prescribed for you:

- your doctor must explain what might happen to your baby if you become pregnant while taking VALEPTIC SYRUP. You need to ensure you understand these risks.
- you will be asked to perform a pregnancy test before starting VALEPTIC SYRUP, or thereafter if needed. This is to make sure you are not pregnant
- effective birth control (contraception) will be recommended for you to avoid becoming pregnant while taking VALEPTIC SYRUP.
- your doctor will assess your understanding of contraception and the need for contraception without interruption during the entire duration of treatment with VALEPTIC SYRUP.
- your doctor will review your treatment regularly (at least once a year).
- your doctor will ask you to read and sign an “Annual Risk Acknowledgement Form” to make sure you are well aware and have understood all the risks related to the use of VALEPTIC SYRUP during pregnancy and are aware and understand the recommendations to avoid becoming pregnant.

- a Patient Guide will be given to you by your doctor. Make sure you read the Patient Guide that you will receive from your doctor.
- you will also receive a Patient Card from your pharmacist to remind you of the risks of using VALEPTIC SYRUP in pregnancy.
- your doctor will explain what to do if you decide later that you want to have a baby. If you are planning a baby, you must first discuss this with your doctor. You must not stop taking VALEPTIC SYRUP or interrupt your method of contraception until you have discussed this with your doctor.
- parents or caregivers of a female (girl) child treated with VALEPTIC SYRUP, must contact the doctor once the female child using VALEPTIC SYRUP experiences her first menstrual period.

Please choose the situations which apply to you and read the descriptions that follow:

- AM STARTING TREATMENT WITH VALEPTIC SYRUP (First Prescription)
- I AM TAKING VALEPTIC SYRUP AND I AM NOT PLANNING TO HAVE A BABY
- I AM TAKING VALEPTIC SYRUP AND I AM PLANNING TO HAVE A BABY
- I AM PREGNANT AND I AM TAKING VALEPTIC SYRUP

I AM STARTING TREATMENT WITH VALEPTIC SYRUP (First Prescription):

- If this is the first time you have been prescribed VALEPTIC SYRUP, your doctor will have explained the risks to an unborn child if you become pregnant.
- If you are able to have a baby or once you are able to have a baby, you will need to make sure that you use an effective method of birth control (contraception) throughout your treatment. Talk to your doctor or family planning clinic if you need advice on contraception.
- Pregnancy must be excluded before start of treatment with VALEPTIC SYRUP through the result of a pregnancy (blood) test, to be confirmed by your doctor.

- You must discuss appropriate methods of birth control (contraception) with your doctor.
- You must make sure you are using an effective method of birth control (contraception) during your entire treatment.
- You must get regular (at least annual) appointments with a medical practitioner experienced in the management of epilepsy or bipolar disorder.
- Tell your doctor at once if you are pregnant or think you might be pregnant.
- Tell your doctor if you plan to become pregnant.
- It is important you contact your doctor if your female (girl) child, treated with VALEPTIC SYRUP, experiences her first menstrual period.

I AM TAKING VALEPTIC SYRUP AND I AM NOT PLANNING TO HAVE A BABY:

If you are continuing treatment with VALEPTIC SYRUP and you do not plan to have a baby, make sure you are using an effective method of birth control (contraception) without interruption during your entire treatment with VALEPTIC SYRUP. Talk to your doctor or family planning clinic if you need advice on contraception.

- Make sure you are using an effective method of contraception during your entire treatment.
- You must get regular (at least annual) appointments with a medical practitioner experienced in the management of epilepsy or bipolar disorder.
- Tell your doctor immediately if you are pregnant or think you might be pregnant.
- Tell your doctor if you plan to become pregnant.
- Parents or caregivers of a female child (girl) treated with VALEPTIC SYRUP, must contact the doctor once the female child using VALEPTIC SYRUP experiences her first menstrual period.

AM TAKING VALEPTIC SYRUP AND I AM PLANNING TO HAVE A BABY:

If you are on treatment with VALEPTIC SYRUP and planning to have a baby, first schedule an appointment with your doctor. You should talk to your doctor long enough before you become pregnant so that you and your doctor can put several actions in place to ensure that your pregnancy goes as smoothly as possible, and any risks to you and your unborn child are reduced as much as possible. Your doctor may prescribe another medicine for your epilepsy which may have less risk for your baby.

Do not stop taking VALEPTIC SYRUP or your birth control (contraception) until you have discussed this with your doctor. Your doctor will advise you on when you can stop your contraception.

Babies born to mothers who have been on VALEPTIC SYRUP are at serious risk of birth defects and problems with development, which can be seriously debilitating.

Your doctor may want to adjust your treatment and/or prescribe dietary supplements of folic acid. Folic acid may lower the risk of spina bifida (a birth defect) and early miscarriage. However, it is unlikely that folic acid will reduce the risk of birth defects associated with VALEPTIC SYRUP use.

You must not stop taking VALEPTIC SYRUP unless your doctor agrees, as there are severe risks to yourself and your developing baby if your epilepsy is not controlled.

If you are pregnant, or think you might be pregnant, see your doctor immediately

I AM PREGNANT AND I AM TAKING VALEPTIC SYRUP:

Women should not become pregnant while receiving VALEPTIC SYRUP. You should use an effective method of birth control (contraception) and consult your doctor before planning pregnancy.

VALEPTIC SYRUP has no effect on the efficacy of your oral contraceptive pill.

Schedule an urgent appointment with your doctor if you are pregnant or think you might be pregnant.

Your doctor will advise you further

Do not stop taking VALEPTIC SYRUP unless your doctor tells you to as your condition may become worse.

During pregnancy, should a mother suffer from a serious type of seizure, where the oxygen supply to her and her unborn baby may be cut off, the risk of death to the mother and unborn child is increased. Your doctor will advise you further.

Make sure you are referred to a medical practitioner experienced in the treatment of epilepsy or bipolar disorder to re-assess your treatment options

You must get thorough counselling on the risks of VALEPTIC SYRUP during pregnancy, including malformations and developmental effects in children.

Make sure you are referred to a medical practitioner for prenatal monitoring in order to detect possible occurrences of malformations.

The risks of VALEPTIC SYRUP when taken during pregnancy:

- Babies born to mothers who are taking VALEPTIC SYRUP, are at serious risk of birth defects and problems with development which can be seriously debilitating.
- It is known that in women who take VALEPTIC SYRUP, around 10 babies in every 100 will have birth defects, as compared to 2 – 3 babies in every 100 born to women who do not have epilepsy.
- These birth defects to your developing baby include spina bifida (condition where bones of the spine are not properly developed), craniofacial defects (face and skull malformations), malformation of the limbs, heart, kidney and sexual organ malformations, hypospadias (malformation of the urethra) and multiple anomalies involving various body systems.
- Children born to mothers who take VALEPTIC SYRUP during pregnancy, may have impaired physical and mental development or autistic disorders.
- It is estimated that up to 30 to 40 % of preschool children whose mothers took VALEPTIC SYRUP during pregnancy may have problems with early childhood development. Children affected can be

slow to walk and talk, less intellectually able than other children, and have difficulty with language and memory.

- It is therefore essential that you discuss your treatment with your doctor if you are thinking of becoming pregnant or tell your doctor as soon as you know you are pregnant.
- Your doctor may want to adjust your treatment and/or prescribe dietary supplements of folate.
- You must not stop taking VALEPTIC SYRUP unless your doctor agrees, as there are severe risks to yourself and your developing baby if you have uncontrolled epilepsy.

Newborn babies of mothers who took VALEPTIC SYRUP during pregnancy may have:

- blood clotting problems (blood not clotting very well). This may appear as bruising or bleeding which takes a long time to stop.
- hypoglycaemia (low blood sugar levels).
- hypothyroidism (underactive thyroid gland, which can cause tiredness or weight gain).
- withdrawal syndrome (agitation, irritability, hyper-excitability, jitteriness, hyperkinesia (muscle spasm), muscle problems, tremor, convulsions and feeding problems); when taken during the last trimester of pregnancy.

Breastfeeding

VALEPTIC SYRUP passes into breast milk and should be avoided during breastfeeding.

Fertility:

VALEPTIC SYRUP can cause infertility in both men and women that may not always be reversible

You should not stop taking VALEPTIC SYRUP suddenly as this may result in you having fits.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking VALEPTIC SYRUP.

Driving and using machines:

VALEPTIC SYRUP may make you feel sleepy; especially if you are taking it together with other medicines also used to treat fits or medicines used for anxiety or sleep disorders

VALEPTIC SYRUP may affect your ability to drive safely

do not drive while you are taking VALEPTIC SYRUP

do not operate any tools or machines while taking VALEPTIC SYRUP.

It is not always possible to predict to what extent VALEPTIC SYRUP may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which VALEPTIC SYRUP affects them.

VALEPTIC SYRUP contains sorbitol

VALEPTIC SYRUP contains 800 mg sorbitol in each 5 mL dose.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive VALEPTIC SYRUP.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

VALEPTIC SYRUP contains sodium

VALEPTIC SYRUP contains less than 1 mmol sodium (23 mg) per 5 mL, that is to say essentially 'sodium-free'.

VALEPTIC SYRUP contains sodium methylparaben and sodium propylparaben

This may cause allergic reactions (may not happen straight away).

3. How to take VALEPTIC SYRUP

Do not share medicines prescribed for you with any other person.

Always take VALEPTIC SYRUP exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you sure.

- Your doctor will decide how much VALEPTIC SYRUP to give you or your child depending on the child's body weight.
- VALEPTIC SYRUP should be taken by mouth.
- Take VALEPTIC SYRUP in 2 separate doses.

The usual dose of VALEPTIC SYRUP is:

Adults:

Initially 600 mg/day, in divided doses. Your doctor may increase it by 200 mg/day at three day intervals until control is achieved; this is generally within the range of 1000 to 2 000 mg/day. If adequate control has not been achieved after two weeks, your doctor may further increase the dose in stages, to a maximum of 2 500 mg/day, or one other medication used for fits may be added at a low dosage.

Children weighing more than 20 kg:

Initial dosage is 400 mg/day. The doctor may increase the dose gradually until control is achieved. This is usually within the range of 20 to 30 mg/kg of body mass per day. If adequate control is not achieved within this range, your doctor may increase the dose to 35 mg/kg body mass per day.

Children weighing less than 20 kg:

The usual dose is 20 mg/kg of body mass per day in severe cases. Your doctor may increase this dose.

Elderly patients – If you are old you may be given a lower dosage of VALEPTIC SYRUP.

Your doctor will tell you how long your treatment with VALEPTIC SYRUP will last. Do not stop treatment early. If you have the impression that the effect of VALEPTIC SYRUP is too strong or too weak, tell your doctor or pharmacist.

If you take more VALEPTIC SYRUP than you should

Symptoms of VALEPTIC SYRUP overdose include:

- Coma
- reduced muscle strength
- poor reflexes
- constriction of the pupils of the eyes
- poor breathing
- Metabolic acidosis – which occurs when the body produces excess quantities of acid or the kidneys are unable to remove enough acid from the body
- Decrease in blood pressure and subsequent shutdown of the body due to shortage of blood flow
- Death may occur in case of a large overdose
- fits or epileptic attacks
- increased pressure inside the skull and swelling of the brain.

- The content of sodium in VALEPTIC SYRUP may cause hypernatraemia (excessive sodium content in the body) when taken in excess.

Hospital management of overdose should be symptomatic, including cardio-respiratory monitoring. Gastric lavage may be useful up to 10 to 12 hours after ingestion. In case of massive overdose, kidney dialysis and filtering of blood extracorporeally (outside the body) to remove toxins have been used successfully.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take VALEPTIC SYRUP:

Do not take a double dose to make up for forgotten individual doses.

If you stop taking VALEPTIC SYRUP

Do not stop taking VALEPTIC SYRUP until your doctor tells you to stop. Do not stop taking VALEPTIC SYRUP just because you feel better. If you stop using VALEPTIC SYRUP your fits may come back.

4. Possible side effects

VALEPTIC SYRUP can have side effects.

Not all side effects reported for VALEPTIC SYRUP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VALEPTIC SYRUP, please consult your health care provider for advice.

If any of the following happens, stop taking VALEPTIC SYRUP and tell your doctor immediately or go to the casualty department at your nearest hospital.

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting
- sudden life-threatening severe allergic reactions which may cause difficulty in swallowing and breathing

These are all very serious side effects. If you have them, you may have had a serious reaction to VALEPTIC SYRUP. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Group of disorders caused by blood cells that are poorly formed or don't work properly (myelodysplastic syndrome).
- a disease in which the functioning of the brain is affected by some agent or condition (such as viral infection or toxins in the blood) (encephalopathy in patients with urea cycle disorders).
- difficult breathing (dyspnoea)
- Pancreatitis (swelling and constant pain in the abdomen, or reaching to the back and other areas).
This condition can result in death.
- Liver failure. This may show as a sudden illness which may happen in the first six months of treatment. This happens in a small number of people taking VALEPTIC SYRUP. It includes feeling sick being very tired, sleepy and weak. You may have 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 general feelings of being unwell.

- decrease in coagulation factors typically means severe liver damage
- irregular heart beat
- toxic epidermal necrolysis (severe blistering rash where layers of skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles.
- stevens-Johnsons syndrome (blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu- like symptoms and fever).
- erythema multiforme is a skin immune reaction that an infection or medication can trigger. Its name combines the Latin “erythema” (redness), “multi” (many), and “forme” (shapes) and describes the main symptom, which is a rash on the body where each mark resembles a bullseye
- syndrome with medicine rash, fever, lymph node enlargement and possible impairment of other organs (DRESS syndrome)
- allergic reactions, which cause joint pain, skin rashes and fever (systemic lupus erythematosus)
- A condition in which the kidneys lose the ability to remove waste and balance fluids (renal failure)
- Tubulointerstitial nephritis is inflammation that affects the tubules of the kidneys and the tissues that surround them (interstitial tissue). This disorder may be caused by diseases, drugs, and toxins that damage the kidneys. People may have excessive urination, urinate at night, or have fever and/or a rash.
- Fanconi syndrome is a disorder of the kidney tubes in which certain substances normally absorbed into the bloodstream by the kidneys are released into the urine instead.
- the condition of having an abnormally (typically dangerously) low body temperature (hypothermia)

These are all serious side effects of VALEPTIC SYRUP. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- low amount of red blood cells in your blood (anaemia)
- bleeding disorders, decreased blood platelets, bruising more easily and getting more infections than usual (thrombocytopenia)
- confusion that may be due to decreased levels of sodium in your blood (hyponatraemia)
- weight increased
- confusion
- seeing or hearing things that are not there (hallucinations)
- aggression, agitation, disturbance in attention, abnormal behaviour, restlessness/hyperactivity, and learning disorder
- inability to remember (amnesia)
- thinking about or planning suicide
- convulsion
- headache, sleeplessness, nervousness
- rapid involuntary movements of the eyes (nystagmus)
- memory loss
- strong desire for sleep and feeling of drowsiness.
- involuntary shaking or movements, ranging from slight to severe and commonly affecting hands, legs, face, head or vocal cords
- a state of near-unconsciousness (stupor)

- dim vision without obvious defect or change in the eye
- ringing in the ears (tinnitus)
- hearing loss (deafness)
- an escape of blood from a ruptured blood vessel (haemorrhage)
- flu-like symptoms
- inflammation (pain, swelling) of the throat
- nausea, vomiting, abdominal pain, diarrhoea, indigestion and stomach irritation
- diarrhoea
- Indigestion (dyspepsia)
- stomatitis
- stomach pain (gastralgia)
- gingival (gum) problems especially overgrowth (gingival hyperplasia)
- hair loss, when it grows back it may be more curly than before
- nail and nail bed disorders
- trembling of hands, arms and back pain
- loss of bladder control (urinary incontinence)
- irregular or painful periods
- redness

Less frequent side effects:

- bruising
- rare disorder of blood production in which the bone marrow fails to function properly.
- a fall in the number of white blood cells, bone marrow depression or another condition that affects red blood cells and platelets (pancytopenia)

- severe decrease of white blood cells or bone marrow failure, sometimes, revealed by fever and breathing difficulty or recurring infection
- high blood sugar levels
- high levels of hormones cause the body to retain water (syndrome of inappropriate secretion of ADH)
- increased levels of some hormones (androgens), which may lead to increased hair growth on the face, breasts or chest, acne or thinning hair.
- underactive thyroid gland, which causes tiredness or weight gain (hypothyroidism)
- increased ammonia in the blood. Symptoms of this condition are feeling and being sick, problems with balance and co-ordination, feeling lethargic or less alert (hyperammonaemia)
- overweight
- behavioural changes, mood or mental changes
- insensibility or extreme tiredness, depression, irritation
- abnormal behaviour, restlessness/hyperactivity, and learning disorder
- clouding of consciousness, sedation, increased activity, tremor
- coma
- lack of energy
- reversible parkinsonism, ataxia (loss of control of bodily movements)
- tingling or numbness of the hands or feet
- an increase in the number and severity of convulsions
- memory disorders (e.g. forgetfulness), unusual excitement
- any disorder that significantly impairs the cognitive function of an individual to the point where normal functioning in society is impossible without treatment (cognitive disorder)

- double vision (diplopia)
- inflammation of the conjunctiva of the eye (conjunctivitis)
- dry eyes, painful eyes or inflammation (pain, swelling) of the eyes
- middle ear infection, dizziness or ear pain
- swelling of the hands and feet (oedema)
- low blood pressure that happens when standing up from sitting or lying down (postural hypotension)
- dizziness
- high blood pressure (hypertension)
- skin rash caused by narrow or blocked blood vessels (vasculitis)
- inflammation (pain, swelling) or infections of the lung, runny nose, inflammation (pain, swelling) of the sinuses
- nose bleeding (epitaxis)
- rhinitis
- sinusitis
- increased cough
- fluid between the tissues that line the lungs and the chest (pleural effusion)
- vomiting of blood (haematemesis)
- periodontal abscess
- anorexia
- dry mouth, constipation, taste disorder, excess gas or wind, increase in appetite
- intestinal infection marked by diarrhoea, cramps, nausea, vomiting and fever (gastroenteritis)
- tongue is swollen and inflamed (glossitis)
- dry skin, bruising, painful boil on the skin

- Unwanted male-pattern hair growth on a woman's face, chest and back (hirsutism)
- hair disorders (changes in texture, colour or growth)
- leg cramps and feeling of discomfort (malaise)
- neck pain or stiffness, painful muscles
- joint pain (arthralgia)
- an abnormally high level of muscle tone or tension (hypertonia)
- pain and weakness in a muscle or group of muscles (myalgia and myasthenia)
- 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 long-term antiepileptic medication, have a history of osteoporosis, or take steroids.
- muscle pain and weakness (rhabdomyolysis)
- nighttime loss of bladder control, or bed-wetting, usually in children (enuresis)
- abnormal amount of amino acids in the urine (amino aciduria)
- the excretion of excessive amounts of phosphate in the urine (phosphaturia)
- the excretion of uric acid in the urine especially in excessive amounts (uricosuria)
- inflammation (pain, swelling) of the vagina (vaginitis)
- heavy vaginal bleeding, unrelated to normal menstruation (vaginal haemorrhage)
- no period (amenorrhoea)
- breast enlargement in men (gynaecomastia)
- male infertility means that a man has a problem with his reproductive system.
- hair, including body and facial hair, grows more than normal in women (polycystic ovarian syndrome)
- impairment of fertility

- peripheral oedema

Frequency unknown:

- reduction of fibrinogen may affect your ability to form a stable blood clot

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of VALEPTIC SYRUP.

5. How to store VALEPTIC SYRUP

Store all medicines out of reach of children.

Store in a dry place at or below 25 °C, away from direct sunlight.

Protect from light

Do not use after the expiry date stated on the pack.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What VALEPTIC SYRUP contains

The active substance is sodium valproate.

The other ingredients are sodium methylparaben 0,1 %, sodium propylparaben 0,04 %, liquid sorbitol, hydroxyethylcellulose/natrosol, saccharin sodium, citric acid monohydrate, cherry sweet flavour 96475-33, colour carmoisine red (14720), purified water.

What VALEPTIC SYRUP looks like and contents of the pack

VALEPTIC SYRUP is a clear, red, syrup with a cherry caramel odour. It is free from visible matter.

VALEPTIC SYRUP is packed in:

- 150 ml 28 mm medical round amber PET bottle fitted with a White PP 28 mm ROPP closure with 3 PCS TE.
- 150 ml 28 mm MEDROPP generic amber glass bottle fitted with a white 28 mm EXPE Screw Generic Closure.
- 300 ml 28 mm medical round amber PET bottle fitted with a White PP 28 mm ROPP closure with 3 PCS TE.

Holder of Certificate of Registration

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