1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

NAVALPRO LIQUID 200 mg/5 ml

Sodium valproate

Contains sweeteners:

Saccharin sodium 4 mg, liquid sorbitol 1 750 mg

Sorbitol is a source of fructose

Read all of this leaflet carefully before you start taking/are given NAVALPRO LIQUID

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

What is in this leaflet

1. What NAVALPRO LIQUID is and what it is used for

NAVALPRO LIQUID belongs to a group of medicines called anticonvulsants or anti-epileptics. It is used to treat epilepsy (fits) in adults and children.

2. What you need to know before you take NAVALPRO LIQUID

Do not take/give NAVALPRO LIQUID:

- if you or your child are hypersensitive (allergic) to sodium valproate or any of the other ingredients of NAVALPRO LIQUID (listed in section 6),
- if you are breastfeeding your baby (see section titled Pregnancy, breastfeeding and fertility).
- if you are pregnant -

  For the treatment of epilepsy:
- if you or your female (girl) child are pregnant, unless there is no suitable alternative treatment (see section titled Pregnancy, breastfeeding and fertility),
- if you or your female child are a female able to have a baby, you must not take NAVALPRO LIQUID unless you use an effective method of birth control (contraception) at all times during your treatment with NAVALPRO LIQUID and the conditions of the pregnancy prevention programme are met. Do not stop taking NAVALPRO LIQUID or your contraception until you have discussed this with your doctor. Your doctor will advise you further (see section Pregnancy, breastfeeding and fertility),
- if you or your child have liver problems, or you or your family have a history of liver problems,
- if you or your child have a known metabolic disorder (urea cycle disorder),
- if you or your child have a rare illness called porphyria,
- if you have a genetic problem caused by a mitochondrial disorder (e.g. Alpers-Huttenlocher syndrome),

- if your child is under 2 years of age and may have a genetic problem caused by a mitochondrial disorder (e.g. Alpers-Huttenlocher syndrome).

Warnings and precautions

Take special care with NAVALPRO LIQUID:

NAVALPRO LIQUID contains sodium valproate which can seriously harm an unborn baby when taken during pregnancy. If you are a female able to have a baby you should use an effective method of birth control (contraception) without interruption during your entire treatment with NAVALPRO LIQUID. Your doctor will discuss this with you, but you must also follow the advice in section 2 of this leaflet.

Schedule an urgent appointment with your doctor if you want to become pregnant or if you think you are pregnant.

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

If you are a parent or caregiver of a female child treated with NAVALPRO LIQUID, you must also read section 2 of this leaflet carefully and contact your child's doctor once the child experiences her first period (see section Pregnancy, breastfeeding and fertility).

- if your child is below the age of 3 years as NAVALPRO LIQUID may damage the liver. Your doctor will monitor the liver by doing blood tests,

- if you notice any signs of liver damage such as yellowing of the skin or eyes (jaundice), extreme tiredness (asthenia), loss of appetite (anorexia), lack of energy (lethargy), sleepiness (drowsiness), vomiting or abdominal pain. You should tell your doctor immediately,
- if you notice severe abdominal pain, nausea or vomiting, as this may be a sign of swelling of the pancreas (pancreatitis). Tell your doctor immediately,
- if you have thoughts of harming or killing yourself, tell your doctor immediately,
- as with other anti-epileptic medicines, fits (convulsions) may become worse or happen more frequently whilst taking NAVALPRO LIQUID. If this happens contact your doctor immediately,
- if you are taking antibiotic medicines to treat an infection such as carbapenem while you take NAVALPRO LIQUID (see section Other medicines and NAVALPRO LIQUID),
- if you know that there is a genetic problem caused by a mitochondrial disorder in your family. This disorder causes symptoms of recurrent fits (epilepsy), muscle weakness (myopathy) and problems with coordination and balance (ataxia),
- your doctor may wish to do blood tests before you start taking NAVALPRO LIQUID and during your treatment,
- if you have kidney problems. Your doctor may give you a lower dose,
- if you have an illness or disease of the immune system which affects skin, bones, joints and internal organs, called systemic lupus erythematosus (SLE),
- if you have a urea cycle disorder where too much ammonia builds up in the body,
- as taking NAVALPRO LIQUID may make you put on weight. Talk to your doctor about how this will affect you,
- if you have diabetes. NAVALPRO LIQUID may affect the results of urine tests,
- if you have a rare disorder that prevents the body from using certain fats for energy, called carnitine palmitoyl transferase type II deficiency,

- you should not drink alcohol while taking NAVALPRO LIQUID (see section Taking NAVALPRO LIQUID with food and alcohol).

Children and adolescents

NAVALPRO LIQUID should not be given to children under the age of 2 years who may have a genetic problem caused by a mitochondrial disorder (e.g. Alpers-Huttenlocher syndrome).

NAVALPRO LIQUID may damage the liver. Children are at risk of liver damage, especially children who are:

- taking more than one anti-epileptic medicine,
- infants and young children under the age of 3 with severe fits (seizure), brain damage, mental retardation and/or genetic defects (congenital metabolic or degenerative disease).

After the age of 3, the risk of liver damage is reduced and decreases with age (see section Take special care with NAVALPRO LIQUID).

If you are a parent or caregiver of a female child treated with NAVALPRO LIQUID, you must also read section 2 of this leaflet carefully and contact your child's doctor once the child experiences her first menstrual period (see sections 2 and Pregnancy, breastfeeding and fertility).

Children (male and female) less than 18 years of age:

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

Other medicines and NAVALPRO LIQUID

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

Tell your doctor if you are taking any of the following:

- Neuroleptics (e.g. quetiapine and olanzapine): Medicines used to calm emotional and mental health problems, including schizophrenia, bipolar disorder and depression.
- Monoamine oxidase inhibitors (MAOIs) (e.g. moclobemide, selegiline, linezolid): medicines used to treat depression and other mental disorders.
- Antidepressants: medicines used to treat depression.
- Benzodiazepines (e.g. diazepam): Medicines used to treat anxiety, alcohol withdrawal, seizures, muscle spasms and to provide sedation before medical procedures. These medicines work by calming the brain and nerves.
- Other anti-epileptics (e.g. phenobarbitone, primidone, phenytoin, carbamazepine, lamotrigine, felbamate, rufinamide, topiramate, acetazolamide): medicines used to treat fits (epilepsy).
- Propofol: medicines used for anaesthesia before a surgical procedure.
- Zidovudine: medicine used to treat HIV infection.
- Nimodipine: medicine used to decrease problems due to a certain type of bleeding in the brain.
- Temozolomide: medicines used to treat cancer.
- Anti-malarials (e.g. mefloquine, chloroquine): medicines used for the prevention and treatment of malaria.
- Salicylates (e.g. aspirin): medicines used to treat pain and inflammation.
- Anticoagulants (e.g. warfarin): medicines used for thinning the blood.
- Cimetidine: medicines used to treat stomach ulcers.

- Antibiotics including carbapenem antibiotics (e.g. imipenem, meropenem, rifampicin, erythromycin): medicines used to treat bacterial infections. The combination of NAVALPRO LIQUID and carbapenems should be avoided because it may decrease the effect of NAVALPRO LIQUID.
- Protease inhibitors (e.g. lopinavir, ritonavir): medicines used to treat HIV infection and AIDS.
- Colestyramine: medicine used to lower cholesterol levels.

NAVALPRO LIQUID with food and alcohol

NAVALPRO LIQUID should preferably be taken with or after food.

Alcohol intake is not recommended during treatment with NAVALPRO LIQUID.

Pregnancy, breastfeeding and fertility

You should not take NAVALPRO LIQUID if you are pregnant, breastfeeding your baby, or planning to have a baby.

Important advice for women

- You must not take NAVALPRO LIQUID if you are pregnant**.**
- If you are a woman able to have a baby, you must not take NAVALPRO LIQUID unless you use an effective method of birth control (contraception) during your entire treatment with NAVALPRO LIQUID.
- Do not stop taking NAVALPRO LIQUID or your birth control (contraception), until you have discussed this with your doctor. Your doctor will advise you further.

The risks of NAVALPRO LIQUID when taken during pregnancy

- Talk to your doctor immediately if you are planning to have a baby or are pregnant.

- NAVALPRO LIQUID contains valproate, which carries a risk if 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 and limb defects.
- If you take NAVALPRO LIQUID during pregnancy you have a higher risk than other women of having a child with birth defects that require medical treatment. In women who take this medicine, around 10 babies in every 100 will have birth defects.
- It is estimated that up to 30 % to 40 % of preschool children whose mothers took this medicine 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 and there is some evidence that children may be more likely to develop symptoms of Attention Deficit Hyperactivity Disorder (ADHD).
- Before prescribing NAVALPRO LIQUID to you, your doctor will have explained what might happen to your baby if you become pregnant whilst taking it.
- If you decide later that you want to have a child, you should not stop taking your medicine or your method of birth control (contraception) until you have discussed this with your doctor.
- If you are a parent or a caregiver of a female child treated with NAVALPRO LIQUID, you should contact their doctor once your child experiences their first period (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 birth control (contraception) that is the most appropriate for you.

In the list below, please choose the situations which apply to you and read the descriptions below:

(a) **I AM STARTING TREATMENT WITH NAVALPRO LIQUID**

(b) **I AM TAKING NAVALPRO LIQUID AND NOT PLANNING TO HAVE A BABY**

(c) **I AM TAKING NAVALPRO LIQUID AND PLANNING TO HAVE A BABY**

(d) **I AM PREGNANT AND I AM TAKING NAVALPRO LIQUID**

(a) I AM STARTING TREATMENT WITH NAVALPRO LIQUID

If this is the first time you have been prescribed NAVALPRO LIQUID your doctor will have explained the risks to an unborn child if you become pregnant. Once you are able to have a baby, you will need to make sure you use an effective method of birth control (contraception) without interruption throughout your treatment with NAVALPRO LIQUID. Talk to your doctor or family planning clinic if you need advice on birth control (contraception).

Key messages:

- Pregnancy must be excluded before the start of treatment with NAVALPRO LIQUID with the result of a pregnancy test, confirmed by your doctor.
- You must use an effective method of birth control (contraception) during your entire treatment with NAVALPRO LIQUID.
- You must discuss appropriate methods of birth control (contraception) with your doctor. Your doctor will give you information on preventing pregnancy, and may refer you to a specialist for advice on birth control (contraception).

- You must have regular (at least annual) appointments with a specialist experienced in the management of epilepsy. During this visit your doctor will make sure you are well aware of and have understood all the risks and advice related to the use of NAVALPRO LIQUID during pregnancy.
- Tell your doctor if you want to have a baby.
- Tell your doctor immediately if you are pregnant or think you might be pregnant.

(b) I AM TAKING NAVALPRO LIQUID AND NOT PLANNING TO HAVE A BABY

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

Key messages:

- You must use an effective method of birth control (contraception) during your entire treatment with NAVALPRO LIQUID.
- You must discuss birth control (contraception) with your doctor. Your doctor will give you information on preventing pregnancy, and may refer you to a specialist for advice on birth control (contraception).
- You must have regular (at least annual) appointments with a specialist experienced in the management of epilepsy. During this visit your doctor will make sure you are well aware of and have understood all the risks and advice related to the use of valproate during pregnancy.
- Tell your doctor if you want to have a baby.
- Tell your doctor immediately if you are pregnant or think you might be pregnant.

(c) I AM TAKING NAVALPRO LIQUID AND PLANNING TO HAVE A BABY

If you are planning to have a baby, first schedule an appointment with your doctor. Do not stop taking NAVALPRO LIQUID or your birth control (contraception) until you have discussed this with your doctor. Your doctor will advise you further. Babies born to mothers who have been on valproate are at serious risk of birth defects and problems with development, which can be seriously debilitating. Your doctor will refer you to a specialist experienced in the management of epilepsy, so that alternative treatment options can be evaluated early on. Your specialist can put several actions in place so that your pregnancy goes as smoothly as possible and any risks to you and your unborn child are reduced as much as possible. Your specialist may decide to change the dose of NAVALPRO LIQUID, switch you to another medicine, or stop treatment with NAVALPRO LIQUID a long time before you become pregnant – this is to make sure your illness is stable.

Key messages:

- Do not stop taking NAVALPRO LIQUID unless your doctor tells you to.
- Do not stop using your birth control (contraception) before you have talked to your doctor and worked together on a plan to ensure your condition is controlled and the risks to your baby are reduced.
- First schedule an appointment with your doctor. During this visit your doctor will make sure you are well aware of and have understood all the risks and advice related to the use of valproate during pregnancy.
- Your doctor will try to switch you to another medicine or stop treatment with NAVALPRO LIQUID a long time before you become pregnant.
- Schedule an urgent appointment with your doctor if you are pregnant or think you might be pregnant.

(d) I AM PREGNANT AND I AM TAKING NAVALPRO LIQUID

You should not take NAVALPRO LIQUID if you are pregnant (see section Pregnancy, breastfeeding and fertility).

Do not stop taking NAVALPRO LIQUID unless your doctor tells you to as your condition may become worse. Schedule an urgent appointment with your doctor if you are pregnant or think you might be pregnant. Your doctor will advise you further. Babies born to mothers who have been on valproate are at serious risk of birth defects and problems with development which can be seriously debilitating. You will be referred to a specialist experienced in the management of epilepsy so that alternative treatment options can be evaluated. In the exceptional circumstances when NAVALPRO LIQUID is the only available treatment option during pregnancy, you will be monitored very closely both for the management of your underlying condition and to check how your unborn child is developing. You and your partner should receive counselling and support regarding the valproate exposed pregnancy.

Key messages:

- Schedule an urgent appointment with your doctor if you are pregnant or think you might be pregnant.
- Do not stop taking NAVALPRO LIQUID unless your doctor tells you to.
- Make sure you are referred to a specialist experienced in the treatment of epilepsy to evaluate the need for alternative treatment options.
- You must get thorough counselling on the risks of NAVALPRO LIQUID during pregnancy, including malformations and developmental effects in children.
- Make sure you are referred to a specialist for prenatal monitoring in order to detect possible occurrences of malformations.

Make sure you read the Patient Card that you will receive from your doctor and/or pharmacist. Your doctor will discuss the Annual Risk Acknowledgement Form and

will ask you to sign it and keep it. You will also receive a Patient Card from your doctor and/or pharmacist to remind you of valproate risks in pregnancy.

New-born babies of mothers who took NAVALPRO LIQUID during pregnancy may have:

- Blood clotting problems, such as blood not clotting very well. This may appear as bruising or bleeding which takes a long time to stop,
- low blood sugar (hypoglycaemia),
- underactive thyroid gland, which can cause tiredness or weight gain (hypothyroidism),
- withdrawal syndrome (including agitation, irritability, hyperexcitability, jitteriness, hyperkinesia, muscle problems, tremor, convulsions and feeding problems). In particular, this may occur in new-borns whose mothers have taken NAVALPRO LIQUID during the last trimester of their pregnancy.

NAVALPRO LIQUID is excreted into breast milk. However, talk to your doctor about whether you should breastfeed your baby.

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 healthcare provider for advice before taking this medicine.

Fertility

NAVALPRO LIQUID can cause infertility in both men and women that may not always be reversible.

Driving and using machines

You may feel sleepy when taking NAVALPRO LIQUID. 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.

It is not always possible to predict to what extent NAVALPRO LIQUID may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which NAVALPRO LIQUID affects you (see section 4).

NAVALPRO LIQUID contains liquid sorbitol

NAVALPRO LIQUID contains 1 750 mg liquid sorbitol in each 5 ml.

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 NAVALPRO LIQUID.

Sorbitol may cause gastrointestinal discomfort and a mild laxative effect.

3. How to take/give NAVALPRO LIQUID

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

Always take/give NAVALPRO LIQUID exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will calculate your/your child’s dose according to age and body weight.

NAVALPRO LIQUID should preferably be taken with or after food.

NAVALPRO LIQUID should not be mixed with water or any other liquid. NAVALPRO LIQUID should be given in divided doses e.g. doses should be taken/given 2 or 3 times a day.

Your doctor will tell you how long your treatment with NAVALPRO LIQUID will last. If you have the impression that the effect of NAVALPRO LIQUID is too strong or too weak, tell your doctor or pharmacist.

If you take more NAVALPRO LIQUID than you should

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

If you forget to take/give NAVALPRO LIQUID

Do not take/give your child a double dose to make up for forgotten individual doses.
If you or your child have missed a dose of NAVALPRO LIQUID, take/give your child the dose that has been missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take/give your child several doses, contact your doctor without delay.

If you stop taking NAVALPRO LIQUID

NAVALPRO LIQUID should be stopped in a gradual manner under the supervision of a doctor.

4. Possible side effects

NAVALPRO LIQUID can have side effects.

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

If any of the following happens, stop taking/giving NAVALPRO LIQUID 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,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS),
- 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 could be signs of a serious allergy called ‘erythema multiforme.’

These are all very serious side effects. If you have them, you may have had a serious reaction to NAVALPRO LIQUID. 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:

- shortness of breath, fatigue, easy bruising or paleness. This may be a sign of the bone marrow failing, or a type of cancer in which the blood-forming cells in the bone marrow become abnormal. This leads to low numbers of one or more types of blood cells (myelodysplastic syndromes (MDS)),
- blood disorders which are usually detected in blood tests, but may be seen as pale skin, tiredness, fever, sore throat and mouth, small red spots on the skin,

bruising or prolonged bleeding after injury. Blood disorders (such as thrombocytopenia, anaemia, leucopenia, pancytopenia) may be seen with symptoms of severe chills, mouth ulcers, headache, shortness of breath and dizziness,

- nausea, vomiting, headache, confusion, weakness or fatigue. These may be signs of a condition in which there are high levels of a hormone which causes the body to retain water (Syndrome of Inappropriate Secretion of ADH (SIADH)),
- too much ammonia in your body (hyperammonaemia) which can cause problems like confusion, tiredness, and possibly coma or death. A child's reaction to too much ammonia can include seizures, breathing trouble, lower response, and potentially death,
- thoughts of harming or killing yourself (suicidal ideation),
- memory loss, personality changes, fits (seizures), loss of consciousness (coma). These may be signs of brain damage (encephalopathy),
- worsened memory, thinking, behaviour and the ability to perform everyday activities (dementia, brain deterioration),
- uncontrollable muscle movements, abnormal muscle twitches or restlessness which may be signs of an extrapyramidal disorder,
- fever, tiredness, weight loss, muscle and joint pain, tingling under the skin. These may be signs of swelling of blood vessels (vasculitis), which causes changes in the blood vessel walls, including thickening, weakening, narrowing or scarring,
- uncontrollable bleeding from any part of your body (haemorrhage),
- coughing, sharp chest pain or shortness of breath. These may be signs of fluid building up in the lungs (pleural effusion),
- severe upper stomach pain, nausea, vomiting. This may be a sign of swelling of the pancreas (pancreatitis). Young children are at risk of pancreatitis,

- yellowing of the skin or eyes (jaundice), extreme tiredness (asthenia), loss of appetite (anorexia), lack of energy (lethargy), sleepiness (drowsiness), vomiting or abdominal pain. These may be signs of liver damage or liver failure (hepatic failure),
- tiredness, joint pain, rash, fever, muscle pain. These may be signs of a disease of the immune system which affects skin, bones, joints and internal organs, called systemic lupus erythematosus (SLE),
- dark, reddish urine, a decreased amount of urine, weakness, muscle aches. These may be signs of an abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis),
- a reduced amount of urine, swelling of your legs, ankles and feet, shortness of breath, extreme tiredness, nausea, chest pain. These may be signs of kidney failure,
- inability of a male to father a child (male infertility),
- bruising or bleeding which takes a long time to stop. These may be signs of blood clotting problems, such as blood not clotting very well (coagulation factors decreased).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma (hyponatraemia),
- increased weight,
- confusional state, seeing or hearing things that are not really there (hallucinations), feeling extreme anger which may lead to violence (aggression),

feeling extremely restless or irritated (agitation), inability to pay attention (mostly seen in children),

- shaking or quivering (tremor), sleepiness (somnolence), loss of memory, headache, involuntary, rapid movement of one or both eyes (nystagmus),
- nausea, stomach pain (gastralgia), loose stools (diarrhoea), vomiting, overgrowth of gum tissue (gingival hyperplasia) (mostly seen in children),
- swelling in the mouth (stomatitis),
- hair loss,
- nail and nail bed disorders,
- inability to control the flow of urine (urinary incontinence),
- painful menstrual periods (dysmenorrhoea), hormonal disorder causing acne, irregular menstrual cycle, weight gain or facial hair (polycystic ovaries), swelling of breast tissue in males (gynecomastia).

Less frequent side effects:

- Increased levels of some hormones (androgens), which may lead to acne, thinning hair or increased hair growth on the face, breasts or chest (hyperandrogenism),
- underactive thyroid gland which can cause tiredness or weight gain (hypothyroidism),
- obesity,
- abnormal behaviour, restlessness (psychomotor hyperactivity), learning disorder (mostly seen in children),
- confusion, a state of near-unconsciousness or insensibility (stupor), abnormal lack of energy (lethargy),
- fits (convulsions), reversible tremor, stiffness and shuffling (parkinsonism),

- difficulty in controlling movements (ataxia), tingling sensation under the skin (paraesthesia), increase in alertness, hyperactivity, disturbances in behaviour,
- seeing double (diplopia),
- hearing loss,
- abnormal hair texture, hair colour changes, abnormal hair growth,
- weakening of bones (osteopenia), thinning of bones (osteoporosis), breaks in bones (fractures),
- absence of menstrual period (amenorrhoea), irregular periods, impairment of ovarian function and of fertility in females,
- swelling of hands and feet due to retained fluid (peripheral oedema),
- abnormally low body temperature (hypothermia).

Side effects with an unknown frequency:

- Bed-wetting (enuresis) (mostly seen in children).

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: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of NAVALPRO LIQUID.

5. How to store NAVALPRO LIQUID

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not store in a bathroom.

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

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 NAVALPRO LIQUID contains

The active substance is 200 mg sodium valproate per 5 ml.

The other ingredients are cherry flavour, concentrated hydrochloric acid (for pH-adjustment), hydroxyethyl cellulose, liquid sorbitol, ponceau 4R supra (E124), purified water, saccharin sodium, sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate.

Preservatives:

Sodium methyl parahydroxybenzoate 0,1 % *m/v*

Sodium propyl parahydroxybenzoate 0,04 % *m/v*

Contains sweeteners:

Saccharin sodium 4 mg

Liquid sorbitol 1 750 mg

Sorbitol is a source of fructose.

What NAVALPRO LIQUID looks like and contents of the pack

NAVALPRO LIQUID is a clear, red coloured liquid.

300 ml liquid in an amber coloured, glass bottle in a carton.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

This leaflet was last revised in

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Registration number

46/2.5/0796

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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