1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

NAVALPRO 400 mg/4 ml Powder and solvent for injectable solution

Sugar free

WARNING

NAVALPRO 400 mg/4 ml can seriously harm an unborn baby when administered 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 400 mg/4 ml. Your doctor will discuss this with you, but you must also follow the advice in the section named Pregnancy and breastfeeding 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 using NAVALPRO 400 mg/4 ml 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 400 mg/4 ml, you must also read the section named Pregnancy and breastfeeding of this leaflet carefully and contact your child's doctor once they experience their first period.

Read this leaflet carefully before you start receiving NAVALPRO 400 mg/4 ml.

- 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.

What is in this leaflet

1. What NAVALPRO 400 mg/4 ml is and what it is used for
2. What you need to know before you receive 400 mg/4 ml
3. How to receive NAVALPRO 400 mg/4 ml
4. Possible side effects
5. How to store 400 mg/4 ml
6. Contents of the pack and other information

1. What NAVALPRO 400 mg/4 ml is and what it is used for

NAVALPRO 400 mg/4 ml contains a medicine called sodium valproate.

This belongs to a group of medicines called anticonvulsants or antiepileptic medicines.

NAVALPRO 400 mg/4 ml is used to treat epilepsy (fits) in adults and children. The injection is given when it is not possible to have your medicine by mouth.

2 .What you need to know before you receive NAVALPRO 400 mg/4 ml

NAVALPRO 400 mg/4 ml should not be administered to you:

- if you are allergic (hypersensitive) to sodium valproate or any of the other ingredients of NAVALPRO 400 mg/4 ml ((listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

- if you have a known metabolic disorder, i.e. a urea cycle disorder.
- if you have a genetic problem caused by a mitochondrial disorder (e.g. Alpers-Huttenlocher syndrome).

- 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 (girl) child are able to have a baby, unless you use an effective method of birth control (contraception) at all times during your treatment with NAVALPRO INJECTION 400 mg/4 ml and the conditions of the pregnancy prevention programme are met (see section titled Pregnancy, breastfeeding and fertility).
- If you or your child have an active disease of the liver, including the following:
  - if you or your child have short or long-term (severe) hepatitis (inflammation of the liver).
  - if you or your child (or any of your close relatives) have a past history of severe hepatitis (inflammation of the liver), especially when caused by medicines.
  - if you or your child suffer from liver porphyria (a rare metabolic disease caused by problems with how your body makes a substance called heme, a component of hemoglobin, the red pigment in blood).

Warnings and precautions

Tell your doctor or healthcare provider before being given NAVALPRO 400 mg/4 ml:

- if you have diabetes. NAVALPRO 400 mg/4 ml may affect the results of your urine tests.
- if you experience nausea, vomiting or sudden stomach pain, you should tell your doctor immediately as these may be signs of inflammation of the pancreas or liver

damage. Other symptoms to be on the lookout for is sudden abnormal physical weakness or lack of energy, tiredness, no appetite, swelling of your feet or hands, drowsiness and if the whites of your eyes and skin turn yellow. Your doctor will need to do blood tests.

- if you experience any type of fit (epilepsy), confusion, forgetfulness, tremor or abnormal sleepiness.
- if you have had thoughts of harming or killing yourself. If at any time you have these thoughts, immediately contact your doctor.
- if you have a carnitine palmitoyltransferase type II deficiency.
- if you have kidney problems. Your doctor may give you a lower dose.
- if you have brain disease or a metabolic condition affecting your brain.
- if you have a 'urea cycle disorder' where too much ammonia builds up in the body.
- 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 experienced weight gain.
- if you know that there is a genetic problem caused by a mitochondrial disorder in your family.
- if NAVALPRO INJECTION 400 mg/4 ml is administered to your child who is less than 3 years of age, and who is taking other anti-epileptic medicines at the same time or has other neurological or metabolic diseases and severe forms of epilepsy.
- NAVALPRO INJECTION 400 mg/4 ml should only be used in adult males who plan to father a child if alternative treatment options are not suitable.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before receiving NAVALPRO 400 mg/4 ml.

NAVALPRO 400 mg/4 ml should not be stopped suddenly as your original symptoms may

come back.

Children and adolescents

Salicylates should not be used in children under 16 years. In addition, in conjunction with sodium valproate concomitant use in children under 3 years can increase the risk of liver toxicity.

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

NAVALPRO 400 mg/4 ml 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 400 mg/4 ml

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

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

- Some medicines used for pain and inflammation (salicylates) such as aspirin.
- Some other medicines used to treat fits (epilepsy). This includes medicines such as phenobarbitone, primidone, phenytoin, carbamazepine, rufinamide, topiramate, acetazolamide, felbamate and lamotrigine.

NAVALPRO 400 mg/4 ml may increase the effect of the following medicines:

- Medicines used for thinning the blood (such as warfarin).
- Zidovudine used to treat HIV infection.
- Temozolomide used to treat cancer.
- Medicines used for depression.
- Monoamine oxidase inhibitors (MAOIs) such as moclobemide, selegiline, linezolid.

- Medicines used to calm emotional and mental conditions (including schizophrenia, bipolar disorder and depression), such as diazepam, lithium, clonazepam and olanzapine.
- Nimodipine, used to treat high blood pressure.
- Propofol, used for anaesthesia.

The following medicines can affect the way NAVALPRO 400 mg/4 ml works:

- Some medicines used for the prevention and treatment of malaria such as mefloquine and chloroquine.
- Cimetidine used for stomach ulcers.
- Some medicines used for infections (antibiotics) such as imipenem, meropenem, ertapenem, panipenem, rifampicin and erythromycin.
- Protease inhibitors such as lopinavir and ritonavir, used to treat HIV infection.
- Colestyramine used to lower blood fat (cholesterol) levels.
- Aspirin used to treat inflammation or heart conditions.

Tell your doctor if you take the following medicines:

- Quetiapine used to treat certain mental conditions.
- Contraception, 'The Pil'.

Receiving NAVALPRO 400 mg/4 ml with food, drink and alcohol.

Alcohol intake is not recommended during treatment with NAVALPRO 400 mg/4 ml.

Pregnancy, breastfeeding and fertility

You should not receive NAVALPRO 400 mg/4 ml if you are pregnant or breastfeeding your baby.

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby while receiving NAVALPRO 400 mg/4 ml, please consult your doctor, pharmacist or other healthcare provider for advice.

Important advice for women

- You must not be given NAVALPRO 400 mg/4 ml if you are pregnant, unless nothing else works for you.
- If you are a woman able to have a baby, you must not be given NAVALPRO 400 mg/4 ml unless you are using an effective method of birth control (contraception) during your entire treatment with NAVALPRO 400 mg/4 ml.
- Do not stop being administered NAVALPRO 400 mg/4 ml or your birth control (contraception), until you have discussed this with your doctor. Your doctor will advise you further.

The risks of valproate, as in NAVALPRO 400 mg/4 ml when used during pregnancy

- Talk to your doctor immediately if you are planning to have a baby or are pregnant.
- Valproate, as contained in NAVALPRO 400 mg/4 ml carries a risk if used during pregnancy. The higher the dose, the higher the risks but all doses carry a risk.
- It can cause serious birth defects and can affect the way in which the child develops as it grows. Birth defects which have been reported include *spina bifida* (where the bones of the spine are not properly developed); facial and skull malformations; heart, kidney, urinary tract and sexual organ malformations; limb defects.
- If you are given valproate, as in NAVALPRO 400 mg/4 ml during pregnancy you have a higher risk than other women of having a child with birth defects that require medical treatment. Because valproate, as in NAVALPRO 400 mg/4 ml has been used for many years we know that in women who are given valproate around 10

babies in every 100 will have birth defects. This compares to 2 to 3 babies in every 100 born to women who don't have epilepsy.

- It is estimated that up to 30 % to 40 % of preschool children whose mothers took or was given valproate, as in NAVALPRO 400 mg/4 ml, 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, as in NAVALPRO 400 mg/4 ml and there is some evidence children may be more likely to develop symptoms of Attention Deficit Hyperactivity Disorder (ADHD).
- Before prescribing or administering NAVALPRO 400 mg/4 ml to you, your doctor will have explained what might happen to your baby if you become pregnant whilst using NAVALPRO 400 mg/4 ml. If you decide later you want to have a child you should not stop using 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 valproate, as in NAVALPRO 400 mg/4 ml, you should contact their doctor once your child experiences their first period (menarche).
- 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, as in NAVALPRO 400 mg/4 ml use.

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

- I AM STARTING TREATMENT WITH NAVALPRO 400 mg/4 ml
- I AM USING NAVALPRO 400 mg/4 ml AND NOT PLANNING TO HAVE A BABY

- I AM USING NAVALPRO 400 mg/4 ml AND PLANNING TO HAVE A BABY
- I AM PREGNANT AND I AM USING NAVALPRO 400 mg/4 ml

I AM STARTING TREATMENT WITH NAVALPRO 400 mg/4 ml

If this is the first time you have been prescribed NAVALPRO 400 mg/4 ml 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 400 mg/4 ml. Talk to your doctor or family planning clinic if you need advice on birth control (contraception).

Key messages:

- Pregnancy must be excluded before start of treatment with NAVALPRO 400 mg/4 ml with the result of a pregnancy test, confirmed by your healthcare provider.
- You must use an effective method of birth control (contraception) during your entire treatment with NAVALPRO 400 mg/4 ml.
- You must discuss appropriate methods of birth control (contraception) with your healthcare provider. Your doctor will give you information on preventing pregnancy, and birth control (contraception).
- You must get regular (at least annual) appointments with a doctor 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, as in NAVALPRO 400 mg/4 ml 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.

I AM USING NAVALPRO 400 mg/4 ml AND NOT PLANNING TO HAVE A BABY

If you are continuing treatment with NAVALPRO 400 mg/4 ml but 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 400 mg/4 ml. 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 400 mg/4 ml.
- You must discuss birth control (contraception) with your doctor. Your doctor will give you information on preventing pregnancy, and birth control (contraception).
- You must get regular (at least annual) appointments with a doctor 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, as in NAVALPRO 400 mg/4 ml 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.

I AM USING NAVALPRO 400 mg/4 ml AND PLANNING TO HAVE A BABY

If you are planning to have a baby, first schedule an appointment with your doctor. Do not stop using NAVALPRO 400 mg/4 ml 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, as in NAVALPRO 400 mg/4 ml 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 400 mg/4 ml, switch you to another medicine, or stop treatment with NAVALPRO 400 mg/4 ml a long time before you become pregnant – this is to make sure your illness is stable. 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, as in NAVALPRO 400 mg/4 ml use.

Key messages:

- Do not stop using NAVALPRO 400 mg/4 ml 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 epilepsy 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, as in NAVALPRO 400 mg/4 ml during pregnancy.
- Your doctor will try to switch you to another medicine or stop treatment with NAVALPRO 400 mg/4 ml a long time before you become pregnant.
- Schedule an urgent appointment with your doctor if you are pregnant or think you might be pregnant.

I AM PREGNANT AND I AM USING NAVALPRO 400 mg/4 ml

Do not stop using NAVALPRO 400 mg/4 ml 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, as in NAVALPRO 400 mg/4 ml are at serious risk of birth defects and problems with development which can be seriously debilitating. You will be referred to a doctor experienced in the management of epilepsy so that alternative treatment options can

be evaluated. In the exceptional circumstances when valproate, as in NAVALPRO 400 mg/4 ml 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. Ask your doctor about taking folic acid. 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, as in NAVALPRO 400 mg/4 ml use.

Key messages:

- Schedule an urgent appointment with your doctor if you are pregnant or think you might be pregnant.
- Do not stop using NAVALPRO 400 mg/4 ml unless your doctor tells you to.
- Make sure you are referred to a doctor experienced in the treatment of epilepsy to evaluate the need for alternative treatment options.
- You must get thorough counselling on the risks of NAVALPRO 400 mg/4 ml 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.

Newborn babies of mothers who used or was given valproate, as in NAVALPRO 400 mg/4 ml 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, jitteriness, hyperactivity, muscle problems, tremor, fits (convulsions) and feeding problems). In particular, this may occur in new-borns whose mothers have been given valproate, as in NAVALPRO 400 mg/4 ml during the last trimester of their pregnancy.

Fertility:

NAVALPRO 400 mg/4 ml can cause infertility in both men and women that may not always be reversible.

Driving and using machines

NAVALPRO 400 mg/4 ml can influence your ability to drive. You should not drive, use machinery or perform any tasks that require concentration until you are certain that NAVALPRO 400 mg/4 ml does not adversely affect your ability to do so safely (see section 4).

3. How to use NAVALPRO 400 mg/4 ml

NAVALPRO 400 mg/4 ml is always given to you by a doctor or nurse. This is because it needs to be given as a slow injection or infusion into the vein.

If you are not sure why you are being given NAVALPRO 400 mg/4 ml or have any questions about how much NAVALPRO 400 mg/4 ml is being given to you, speak to your doctor or nurse.

Your doctor will stop giving you NAVALPRO 400 mg/4 ml and change you to tablets, granules, syrup or liquid as soon as possible.

Your doctor will decide how much to give you depending on your condition. The amount of

NAVALPRO 400 mg/4 ml given to you or your child will depend on you or your child's age or body weight.

If you have the impression that the effect of NAVALPRO 400 mg/4 ml is too strong or too weak, tell your doctor or pharmacist.

You will not be expected to give yourself NAVALPRO 400 mg/4 ml. It will be given to you by a person who is qualified to do so.

If you receive more NAVALPRO 400 mg/4 ml than you should

Since a healthcare provider will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

An overdosage of NAVALPRO 400 mg/4 ml can lead to the following symptoms: 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 and unusual or inappropriate behaviour.

If you missed a dose of NAVALPRO 400 mg/4 ml

Since a healthcare provider will administer NAVALPRO 400 mg/4 ml, it is unlikely that the dose will be missed.

4. Possible side effects

NAVALPRO 400 mg/4 ml can have side effects.

Not all side effects reported for NAVALPRO 400 mg/4 ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being administered NAVALPRO 400 mg/4 ml, please consult your doctor, pharmacist or other

healthcare provider for advice.

If any of the following happens, stop receiving NAVALPRO 400 mg/4 ml and tell your doctor immediately or go to the casualty department at your nearest hospital:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue. Hands, feet or genitals may also be affected. More severe allergic reactions can lead to fever, lymph node enlargement and possible impairment of other organs. This type of reaction to medicine is also called drug reaction with eosinophilia and systemic symptoms (DRESS),
- you have a 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 could be signs of a serious allergy to the medicine called 'erythema multiforme',
- blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also, flu-like symptoms and fever. This may be something called 'Stevens-Johnson syndrome',
- severe blistering rash where layers of the 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. This may be something called 'toxic epidermal necrolysis'.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NAVALPRO 400 mg/4 ml. 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:

- liver problems and problems of the pancreas may show as a sudden illness which may happen in the first six months of treatment. It includes feeling and being sick, being very tired, sleepy and weak, 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 a general feeling of being unwell,
- bruising more easily and getting more infections than usual. This could be a blood problem called 'thrombocytopenia'. It can also be due to a fall in the number of white blood cells, bone marrow depression or another condition that affects red blood cells, white blood cells and platelets (pancytopenia),
- poorly formed blood cells or blood cells that do not function normally (myelodysplastic syndrome). Symptoms are unusual tiredness, shortness of breath and unusual paleness. These symptoms may also be caused due to a low red blood cell count (anaemia),
- painful or swollen joints and muscle pain, unexplained fever, red rashes, most commonly on the face, chest pain upon deep breathing, unusual loss of hair, pale or purple fingers or toes from cold or stress, sensitivity to the sun and swelling of your legs or around your eyes. These are all symptoms of Systemic Lupus Erythematosus,
- blood clotting problems (bleeding for longer than normal), bruising or bleeding,
- changes in behaviour or mood including being very alert, and sometimes also aggressive, hyper-active and unusual or inappropriate behaviour. This is more likely if other medicine to treat fits, such as phenobarbitone, are taken at the same time or if the NAVALPRO 400 mg/4 ml starting dose is high or has been suddenly increased,
- breathing difficulty and pain due to inflammation of the lungs (pleural effusion),
- changes in the amount of ammonia in the blood. Symptoms of this condition are

being sick, problems with balance and co-ordination, feeling mentally and physically sluggish or less alert,

- feeling tired or confused with loss of consciousness (coma) sometimes accompanied by hallucinations or fits,
- rapid uncontrollable movement of the eyes (nystagmus),
- an increase in the number and severity of fits (convulsions),
- brain injury (encephalopathy),
- kidney problems, including kidney failure, inflammation of the spaces between the small tubes in the kidney, defective kidney function causing sugar, protein, phosphates and uric acid to be excreted in the urine, bedwetting or increased need to pass urine,
- deafness.

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:

- feeling sick, stomach ache or diarrhoea, especially when starting treatment, swelling of gums or sore mouth, thirst or excessive drinking,
- weight gain - as your appetite may be increased,
- nausea, vomiting, headache, confusion, loss of energy, drowsiness and fatigue, due to low sodium levels in your blood (hyponatraemia),
- seeing or hearing things that are not there (hallucinations), confusion, *aggression, *agitation, *disturbance in attention or lack of concentration (*These side effects are mainly seen in children),
- feeling shaky (tremor), sleepy or unsteady when walking, loss of memory, dizziness, headache,

- hair loss which is usually temporary. When it grows back it may be more curly than before,
- nail and nail bed disorders,
- painful menstrual cramps during menstruation (dysmenorrhea).

Less frequent side effects:

- hearing loss,
- acne,
- increased levels of some hormones (androgens), which may lead to increased hair growth in women, including on the face, breasts or chest, acne or thinning hair,
- skin rash caused by narrow or blocked blood vessels (vasculitis),
- changes in women's periods (irregular periods or no period), hormonal disorder where the ovaries may develop small collections of fluid (follicles) and fail to release eggs (polycystic ovaries), impairment of ovarian function and of fertility in females,
- breast enlargement in men, male infertility,
- swelling of the feet and legs (oedema),
- underactive thyroid gland, which may cause tiredness or weight gain (hypothyroidism),
- Syndrome of Inappropriate Secretion of ADH (SIADH). SIADH is a condition in which the body makes too much antidiuretic hormone (ADH). This hormone helps the kidneys control the amount of water your body loses through the urine. You may experience a buildup of fluid in your body,
- abnormal behaviour, restlessness/hyperactivity and learning disorders (These side effects are mainly seen in children),
- tiredness, jerky muscle movement (ataxia), tingling or numbness of the hands or feet (pins and needles sensation),
- hair disorders (changes in texture, colour or growth), abnormal sweating,

- bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures,
- muscle pain and weakness (rhabdomyolysis),
- lowering of normal body temperature (hypothermia),
- abnormal blood clotting factors,
- obesity.

Side effects with an unknown frequency:

- inflammation and pain at the site of injection.

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 400 mg/4 ml.

5. How to store NAVALPRO 400 mg/4 ml

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Keep the vial and ampoule in the outer carton, until required for use.

The solutions must be used immediately after reconstitution, and other conditions of use are the responsibility of the user and should not be more than 24 hours in a fridge, unless controlled and validated aseptic conditions are applied.

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 400 mg/4 ml contains

The active substance is 400 mg of freeze-dried sodium valproate.

The other ingredient is water for injection.

What NAVALPRO 400 mg/4 ml looks like and contents of the pack

NAVALPRO 400 mg/4 ml

Vial: A white lyophilised powder.

Ampoule: A transparent and colourless liquid.

Reconstituted solution: A clear, colourless solution

1 x 20 ml transparent and colourless Type I glass vial containing a white lyophilised powder with an aluminium seal, chlorobutyl rubber stopper, and a plastic flip off cap.

1 x transparent and colourless Type I glass ampoule containing a solvent.

Both the vial and ampoule are packed together in a plastic tray and in an outer cardboard carton.

Holder of the certificate of registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 118 088

This leaflet was last revised in

03 August 2021

Registration number

A40/2.5/0342

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

ZA_NAVAINJ_2108_00