1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

PROPRIETARY NAME AND DOSAGE FORM

NAVALPRO 400 mg/4 ml

Powder and solvent for injectable solution

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 or pharmacist.
- NAVALPRO 400 mg/4 ml 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 NAVALPRO 400 mg/4 ml CONTAINS

Each vial of NAVALPRO 400 mg/4 ml contains 400 mg freeze-dried sodium valproate.

Each ampoule of NAVALPRO 400 mg/4 ml contains 4 ml sterile water for injection.

Sugar free

WHAT NAVALPRO 400 mg/4 ml 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.

BEFORE YOU RECEIVE NAVALPRO 400 mg/4 ml

Do not receive NAVALPRO 400 mg/4 ml and tell your doctor if:

- You are allergic (hypersensitive) to sodium valproate or any of the other ingredients of NAVALPRO 400 mg/4 ml. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You are pregnant or breastfeeding your baby.
- You have liver problems or you or your family have a history of liver problems.
- You have a rare illness called porphyria.

Take special care with NAVALPRO 400 mg/4 ml if:

- You have diabetes. NAVALPRO 400 mg/4 ml may affect the results of your urine tests.
- You have kidney problems. Your doctor may give you a lower dose.
- You have brain disease or a metabolic condition affecting your brain.
- You have a 'urea cycle disorder' where too much ammonia builds up in the body.
- 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 are not sure if any of the above applies to you, talk to your doctor or pharmacist before receiving NAVALPRO 400 mg/4 ml.

Pregnancy and Breastfeeding

NAVALPRO 400 mg/4 ml should not be used in pregnancy or while breastfeeding.

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.

Driving and using machinery

You may feel sleepy when receiving NAVALPRO 400 mg/4 ml. 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.

Taking other medicines with NAVALPRO 400 mg/4 ml

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of NAVALPRO 400 mg/4 ml with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare provider, for advice.

The following medicines can increase the chance of you getting side effects, when taken with NAVALPRO 400 mg/4 ml:

- Some medicines used for pain and inflammation (salicylates) such as aspirin.
- Some other medicines used to treat fits (epilepsy). This includes medicines such as phenobarbital, primidone, phenytoin, carbamazepine 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.
- Medicines used for depression, such as monoamine oxidase inhibitors (MAOI).
- Medicines used to calm emotional and mental conditions, such as diazepam.

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 and erythromycin.

HOW NAVALPRO 400 mg/4 ml is GIVEN

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.

How much will be given to you

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.

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

An overdosage is highly unlikely with NAVALPRO 400 mg/4 ml since it will only be administered by your doctor or nurse. Your doctor will be checking your progress and the medicine that you are given.

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.

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 taking NAVALPRO 400 mg/4 ml, please consult your doctor, pharmacist or other healthcare provider for advice**.**

If any of the following happens, stop taking 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 lymph node enlargement and possible impairment of other organs.
- 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).
- Blood clotting problems (bleeding for longer than normal), bruising or bleeding.
- Changes in mood, loss of memory, lack of concentration and coma.
- Changes in behaviour 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 phenobarbital, are taken at the same time or if the NAVALPRO 400 mg/4 ml starting dose is high or has been suddenly increased.
- 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 shaky (tremor), sleepy or unsteady when walking or jerky muscle movements.
- Feeling tired or confused with loss of consciousness sometimes accompanied by hallucinations or fits.

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

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- Feeling sick, stomach ache or diarrhoea, especially when starting treatment.
- Weight gain - as your appetite may be increased.

The following side effects have been reported less frequently:

- Hearing loss.
- Acne.
- Hair loss which is usually temporary. When it grows back it may be more curly than before.
- Skin rash caused by narrow or blocked blood vessels (vasculitis).
- Changes in women's periods and increased hair growth in women.
- Breast enlargement in men.
- Swelling of the feet and legs (oedema).
- Kidney problems, bedwetting or increased need to pass urine.

The following side effects have been reported but the frequency is unknown:

- Fainting.

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

STORING AND DISPOSING OF NAVALPRO 400 mg/4 ml

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).

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

PRESENTATION

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.

IDENTIFICATION

Vial: A white lyophilised powder.

Ampoule: A transparent and colourless liquid.

Reconstituted solution: A clear, colourless solution.

REGISTRATION NUMBER

A40/2.5/0342

NAME BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

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