PATIENT INFORMATION LEAFLET

Valproate, as in NAVALZYD™ IV, may cause birth defects and problems with early development of the child if it is given during pregnancy. If you are a female of childbearing age, you should use an effective method of contraception throughout your treatment (see "Pregnancy, breastfeeding and fertility"). Tell your doctor at once if you want to become pregnant or think you might be pregnant. If you are the parent or caregiver of a female child being treated with NAVALZYD IV, read the section on Pregnancy and breastfeeding in this leaflet carefully.

SCHEDULING STATUS: S3

NAVALZYD™ 300 mg IV

NAVALZYD™ 400 mg IV

NAVALZYD™ 1 g IV

Solution for injection or infusion (100 mg/ml)

Sodium valproate

Sugar free

Contains sodium:

44,5 mg/3 ml; 59,2 mg/4 ml and 148,2 mg/10 ml

Read all of this leaflet carefully before you are given NAVALZYD IV

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What NAVALZYD IV is and what it is used for
2. What you need to know before you are given NAVALZYD IV
3. How NAVALZYD IV will be administered
4. Possible side effects
5. How NAVALZYD IV will be stored
6. Contents of the pack and other information

1. What NAVALZYD IV is and what it is used for

NAVALZYD IV contains sodium valproate, which belongs to a group of medicines called antiepileptics. These are used to control epileptic seizures. NAVALZYD IV solution for injection is used to treat various types of epileptic seizures (fits) when it is not possible to take sodium valproate tablets.

NAVALZYD IV is also used in mania in adults: where you may feel excited, elated, agitated, enthusiastic or hyperactive. Mania occurs in an illness called ‘‘bipolar disorder’’.

2. What you need to know before you are given NAVALZYD IV

NAVALZYD IV should not be administered to you:

- if you are hypersensitive (allergic) to sodium valproate or any of the ingredients of NAVALZYD IV (listed in Section 6)
- if you have liver problems, or have a family history of liver problems
- if you suffer from porphyria (a rare condition that affects the breakdown of components of red blood cells)
- if you have a genetic problem causing a mitochondrial disorder (e.g. Alpers-Huttenlocher syndrome)
- if you suffer from urea cycle disorder (a certain metabolic disorder)
- if you are breastfeeding your baby. See “Pregnancy, breastfeeding and fertility”
- if you are pregnant for the treatment of epilepsy, unless there is no suitable alternative treatment. See “Warnings and precautions” and “Pregnancy, breastfeeding and fertility”
- if you are pregnant for the treatment of bipolar disorder
- if you are a woman able to have a baby, unless you use an effective method of birth control (contraception) at all times during your treatment with NAVALZYD IV and the conditions of the Pregnancy Prevention Programme are met. See “Warnings and precautions” and “Pregnancy, breastfeeding and fertility”
- if you have an inborn deficiency in carnitine (a very rare metabolic disease) that is untreated.

Warnings and precautions

Talk to your doctor or healthcare provider before you are given NAVALZYD IV, if you:

- are a woman able to have a baby, your doctor should only treat you with NAVALZYD IV if you are not pregnant and you fulfil the requirements of the Pregnancy Prevention Programme (see “Pregnancy, breastfeeding and fertility”)
- are pregnant or planning to have a baby, talk to your doctor immediately (see section 2 and “Pregnancy, breastfeeding and fertility”)
- have diabetes. NAVALZYD IV may affect the results of urine tests
- have a carnitine palmitoyltransferase type II deficiency, which prevents the body from using certain fats for energy, as you may be more prone to serious side effects. Your doctor may decide to prescribe carnitine supplements
- have a low dietary intake of carnitine, found in meat and dairy products, especially in children less than 10 years old. Deficiency in carnitine can result in too much ammonia. Signs of too much ammonia may be a loss of coordination, balance and speech difficulties (ataxia), impaired consciousness or vomiting. Tell your doctor immediately if you have these symptoms. Your doctor may prescribe carnitine supplements for a deficiency in carnitine if you:
- have a deficiency in carnitine and are already taking carnitine
- have kidney problems. Your doctor may give you a lower dose
- have a brain disease or a metabolic condition affecting your brain

- have a 'urea cycle disorder' where too much ammonia builds up in the body
- have an illness called 'systemic lupus erythematosus (SLE)' – a disease of the immune system which affects skin, bones, joints and internal organs
- know that there is a genetic problem caused by a mitochondrial disorder in your family. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking NAVALZYD IV
- are having surgery, including dental surgery, tell the doctor or dentist that you are receiving NAVALZYD IV. You will need to take extra care in cleaning your teeth to prevent infection, as side effects of NAVALZYD IV include bleeding and swelling of the gums (see section 4).

Male children and men

If you are a man receiving NAVALZYD IV or if you are a woman who is a sexual partner of a man receiving NAVALZYD IV, your doctor will inform you about the possible risks of neuro-developmental disorders (NDDs) to your future children. NDDs can include problems like autism spectrum disorder, intellectual disability, communication disorders, attention deficit/hyperactivity disorders (ADHD), movement disorders in children if the father receives valproate (as in NAVALZYD IV) 3 months before conception and during pregnancy.

If you are a woman who is a sexual partner of a man receiving NAVALZYD IV, you should ask for a pregnancy test to be performed before your partner starts receiving the medicine.

If you are a man receiving NAVALZYD IV, or if you are a woman who is a sexual partner of a man receiving NAVALZYD IV you should use highly

effective contraception while receiving the medicine and for three months after stopping it.

If your female partner becomes pregnant while you used valproate in the 3 months period before conception and you have questions, contact your healthcare professional. Do not stop your treatment without talking to your specialist. If you stop your treatment, your symptoms may become worse.

Male patients should not donate sperm during treatment or for at least 3 months after treatment discontinuation.

If you are a man receiving NAVALZYD IV, or if you are a woman who is a sexual partner of a man receiving NAVALZYD IV and you plan to have a baby within the next year, talk to your specialist about your treatment options.

See “Important advice for male patients” under “Pregnancy, breastfeeding and fertility”.

Liver damage

NAVALZYD IV may cause severe and life-threatening damage to your liver. Signs that you may notice include seizures that are becoming more severe or happen more often, or excessive tiredness, lack of energy, weakness, stomach pain, loss of appetite, nausea, vomiting, yellow skin and eye whites or swelling of the face. Tell your doctor immediately if you notice these symptoms.

If your child is under 3 years of age, NAVALZYD IV should not be administered together with aspirin.

Pancreas damage

NAVALZYD IV may cause serious or life-threatening damage to the pancreas. This may occur at any time during your treatment. If you experience any of the following symptoms, tell your doctor immediately: stomach pain, nausea, vomiting, or loss of appetite.

Suicidal thoughts and behaviour

A small number of people being treated with antiepileptics such as sodium valproate have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

There may also be a risk that you will experience changes in your mental health if your condition is not treated.

Severe skin reactions and serious allergic reactions

Severe adverse reactions on the skin may occur, such as blisters with skin detachment (blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet) with or without rash), sometimes with flu-like symptoms such as fever, chills, or aching muscles. These may be signs of conditions named ‘Toxic epidermal necrolysis’ or ‘Stevens-Johnson Syndrome’. If you or your child develops an allergic reaction, seek medical attention immediately.

Convulsions

Convulsions may become worse or happen more frequently while taking this medicine. If this happens contact your doctor immediately.

Weight gain

Having NAVALZYD IV may make you put on weight. Talk to your doctor about how this will affect you.

Blood tests

Your doctor may wish to do blood tests before you are given NAVALZYD IV and during your treatment.

Children and adolescents

While treated with NAVALZYD IV, do not give salicylates (aspirin) to children under 3 years due to the risk of liver toxicity. Additionally, do not use salicylates in children under 16 years as it can increase the risk of Reye's syndrome (an acute condition that causes swelling in the brain and liver).

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

Epilepsy:

NAVALZYD IV should be used with caution in male and female children under the age of 18 years, for the treatment of epilepsy.

For female children, ensure that the conditions of the Pregnancy Prevention Programme are met.

Some psychiatric disorders, including aggression, agitation, disturbance in attention, abnormal behaviour, psychomotor hyperactivity and learning disorder, may be observed in paediatric patients receiving NAVALZYD IV (see "Possible side effects"). Current evidence is inconclusive as to the possibility of harm to reproductive organs, skeletal system growth or developing brain of patients less than 18 years of age.

Bipolar disorder:

NAVALZYD IV should not be used for manic episodes in bipolar disorder in children.

Other medicines and NAVALZYD IV

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

The following medicines can increase the chance of you getting side effects, when given with NAVALZYD IV:

- some medicines used for pain and inflammation (salicylates) such as aspirin
- some other medicines used to treat fits – see section 3, 'Patients taking other medicines for fits (epilepsy)'. This includes medicines such as phenobarbital, primidone, phenytoin, carbamazepine, rufinamide, topiramate, lamotrigine and felbamate
- clozapine, used to treat mental health conditions
- acetazolamide used to treat glaucoma, oedema or fits
- pivalate containing medicines. When NAVALZYD IV is received along with certain medicines (like cefditoren pivoxil, adefovir dipivoxil, pivmecillinam, and pivampicillin), there is a risk of carnitine depletion. This means that it's generally best to avoid using them together. If it is absolutely necessary to use both, your doctor will closely monitor you for signs of low carnitine levels.

NAVALZYD IV Injection may increase the effect of the following medicines:

- medicines for depression, for example, monoamine oxidase inhibitors (MAOI) such as moclobemide, selegiline
- medicines used to calm emotional and mental health problems (including schizophrenia, bipolar disorder and depression) such as quetiapine, diazepam, olanzapine and lithium

- propofol – used for anaesthesia
- zidovudine used to treat HIV infection
- nimodipine (used to decrease problems due to a certain type of bleeding in the brain)
- temozolomide used to treat cancer
- medicines used for thinning the blood (such as warfarin).

The following medicines can affect the way NAVALZYD IV works:

- some medicines used for the prevention and treatment of malaria such as mefloquine and chloroquine
- cimetidine used for stomach ulcers
- antibiotics e.g. erythromycin, carbapenems (antibiotics used to treat bacterial infections). The combination of valproic acid and carbapenems should be avoided because it may decrease the effect of sodium valproate
- rifampicin used to treat tuberculosis and other infections
- protease inhibitors such as lopinavir and ritonavir – used for HIV infection and AIDS
- cholestyramine used to lower blood fat (cholesterol) levels. It may still be possible for you to be given NAVALZYD IV; your doctor will advise you on what is suitable for you
- oestrogen-containing products (including some birth control pills)
- metamizole, a pain killer, may reduce the effect of NAVALZYD IV
- methotrexate, used for rheumatoid arthritis and certain cancers.

Using NAVALZYD IV with food and drink

Alcohol intake is not recommended during treatment.

You should not drink alcoholic drinks while you are treated with NAVALZYD IV.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your doctor, pharmacist or other healthcare provider for advice before this medicine is administered to you.

Pregnancy

If you are pregnant, you should not be given NAVALZYD IV for the treatment of epilepsy, unless other treatments are not effective or well tolerated.

If you are pregnant, you should not be given NAVALZYD IV for treatment of bipolar disorder.

Do not stop receiving NAVALZYD IV without consulting your doctor as doing so could cause harm to you or an unborn child.

If you are a woman able to have a baby, you must not receive NAVALZYD IV unless you use an effective method of birth control (contraception) during your entire treatment with NAVALZYD IV. Speak to your doctor if you have any questions about which contraceptive method is appropriate for you.

NAVALZYD IV can cause malformation and problems with early development of children if they are exposed to valproates in the womb.

NAVALZYD IV 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.

Hearing problems or deafness have been reported in children exposed to valproate during pregnancy.

It is reported that children who were exposed to valproate (such as NAVALZYD IV) before birth tend to have IQ scores that are 7 to 10 points lower at age 6 compared to children who were exposed to other epilepsy medicines. While other factors could also play a role, there's evidence suggesting that this risk of lower IQ might not be related to the mother's IQ. There isn't much information on the long-term effects.

It is estimated that up to 30 - 40 % of preschool children whose mothers took sodium valproate during pregnancy may have problems with early childhood development. Children affected can be slow to walk and talk, intellectually less able than other children, and have difficulty with language and memory. Autistic spectrum disorders are more often diagnosed in children exposed to valproate during pregnancy and there is some evidence that children exposed to sodium valproate during pregnancy are at increased risk of developing attention deficit hyperactivity disorder (ADHD).

Babies are also at risk of lower weight than expected for their age at birth.

Before prescribing this medicine to you, your doctor will have explained what might happen to your baby if you become pregnant whilst taking NAVALZYD IV. If you decide later, 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.

Tell your doctor at once if you become pregnant, think you might be pregnant or are planning to become pregnant. Your doctor will urgently review your treatment.

If you are a parent or a caregiver of a female child treated with valproate, as in NAVALZYD IV, you should contact their doctor once your child experiences their first period.

Breastfeeding

Sodium valproate, the active substance of NAVALZYD IV, gets into the breast milk. You should not breastfeed your baby if you are receiving NAVALZYD IV.

Fertility

NAVALZYD IV may decrease your fertility. It is unclear if this effect is reversible after discontinuation of NAVALZYD IV.

Male fertility: Using NAVALZYD IV can be a contributing factor in male infertility.

Important advice for male patients

Potential risks related to using valproate in the 3 months before conception of a child

Reportedly an increased risk was found of mental or movement-related developmental disorders in children (from 0 to 11 years old) born to fathers treated with valproate within 3 months before conception. See “Warnings and precautions”.

Your doctor will discuss with you:

- The potential risk in children born to fathers treated with valproate
- The need to use effective contraception (birth control) for you and your female partner during treatment and for 3 months after stopping treatment
- You should not donate sperm during treatment or for at least 3 months after treatment discontinuation
- The need for regular appointments with your doctor or specialist
- The need to see your specialist when you are planning to conceive a child and before stopping contraception (birth control)
- The possibility of other treatments that can be used to treat your disease, depending on your individual situation.

Driving and using machines

You may experience drowsiness when you are first given NAVALZYD IV, or if you are also taking other medicines, such as other antiepileptic medicines or benzodiazepines. If affected, you should not drive or operate machinery.

It is not always possible to predict to what extent NAVALZYD IV may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which NAVALZYD IV affects you.

NAVALZYD IV contains sodium

Each 3 ml ampoule contains 44,5 mg sodium (cooking/table salt). This is equivalent to 2 % of the recommended maximum daily dietary intake of 2 g sodium for an adult.

Each 4 ml ampoule contains 59,2 mg sodium (cooking/table salt). This is equivalent to 3 % of the recommended maximum daily dietary intake of 2 g sodium for an adult.

Each 10 ml ampoule contains 148,2 mg sodium (cooking/table salt). This is equivalent to 7 % of the recommended maximum daily dietary intake of 2 g sodium for an adult.

3. How NAVALZYD IV will be administered

You will not be expected to give yourself NAVALZYD IV. It will be given to you by a person who is qualified to do so.

NAVALZYD IV treatment must be started and supervised by a doctor specialised in the treatment of epilepsy and bipolar disorders.

Dosage

Your doctor will decide on the amount of NAVALZYD IV you will be given. This will depend on your age and weight and will be adjusted to achieve adequate control of your seizures. If you have been taking sodium valproate by mouth, the dose given to you will be the same by injection. Your doctor will tell you when you are ready to switch over to an oral dosage form of valproate.

If you have been receiving other medicines for epilepsy the dose of NAVALZYD IV will be increased gradually over about 2 weeks. The total daily dose will normally be given by three or four slow injections, lasting 3-5 minutes, into your veins during the day, or by a continuous infusion (drip).

Patients with kidney problems

Your doctor may decide to adjust your or your child’s dose.

Patients taking other medicines for fits (epilepsy)

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

If you have any concerns, tell your doctor or nurse. It is important for you to keep having your NAVALZYD IV treatment until your doctor decides to stop. If you stop, your seizures may return.

Tests

Make sure you or your child keep your regular appointments for a check-up. They are very important as your or your child's dose may need to be changed. NAVALZYD IV can change the levels of liver enzymes shown up in blood tests. This can mean that your or your child's liver is not working properly.

If you receive more NAVALZYD IV than you should

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

If you miss a dose of NAVALZYD IV

Since a healthcare provider will administer NAVALZYD IV, it is unlikely that the dose will be missed.

4. Possible side effects

NAVALZYD IV can have side effects.

Not all side effects reported for NAVALZYD IV are included in this leaflet. Should your general health worsen or if you experience any untoward effects

while using NAVALZYD IV, please consult your doctor or healthcare provider for advice.

If any of the following happens, tell your doctor immediately:

- You have an allergic reaction.

  The signs include: a rash, joint pain, fever (systemic lupus erythematosus), 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 (also known as DRESS syndrome).

- Liver problems and problems of the pancreas:

  A sudden illness which may happen in the first six months of treatment. It includes feeling and being sick many times; being very tired, sleepy and weak; 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 a general feeling of being unwell. It may sometimes even lead to death.

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

Tell your doctor immediately if you notice any of the following:

- 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'.
- 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) or how the blood clots.
- Blood clotting problems (bleeding for longer than normal), bruising or bleeding for no reason.
- Changes in mood, loss of memory, lack of concentration and deep loss of consciousness (coma).
- Underactive thyroid gland, which may cause tiredness or weight gain (hypothyroidism).
- Breathing difficulty and pain due to inflammation of the lungs (pleural effusion).
- Changes in behaviour including being very alert, and sometimes also aggressive, hyperactive and unusual or inappropriate behaviour. This is more likely if other medicines to treat fits, such as phenobarbital and topiramate, are taken at the same time or if the starting dose of NAVALZYD IV is high or has been suddenly increased.
- An increase in the number and severity of convulsions.

- Changes in the amount of ammonia in the blood. Symptoms of this condition are being sick, problems with balance and coordination, feeling lethargic 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:

Frequent side effects:

- Anaemia (the number of red blood cells in your body is too low), causing weakness, fatigue, pale skin
- Too low blood sodium concentration (signs may be mental changes, headache, nausea, vomiting, tiredness, muscle spasms)
- Weight gain (see “Warnings and precautions”)
- State of confusion, hallucinations (seeing and hearing things that do not exist)
- Aggression, agitation
- Attention disturbances
- Sleepiness
- Convulsions
- Trembling of hands and arms, clumsiness or unsteadiness
- Headache
- Involuntary eye movements (nystagmus)
- Dizziness

- Hearing loss (which may be irreversible)
- Diarrhoea
- Nausea, vomiting
- Indigestion
- Gum disease (swollen gums)
- Stomach or abdominal pain
- Sore mouth
- Hair loss or thinning of hair
- Nail and nail bed disorders
- Losing bladder control (incontinence)
- Painful menstrual periods.

Less frequent side effects

- Hyperandrogenism (excessive presence of male hormones in females including symptoms like excessive hair growth, acne, male pattern hair loss)
- Double vision (diplopia)
- Encephalopathy (an altered mental state – declining ability to reason and concentrate, memory loss, personality change, seizures and twitching may be experienced)
- Lethargy (a lack of energy)
- Parkinsonism (which is reversible), lack of muscle control, affected movement, speech (ataxia)
- Pins and needles sensation in arms, hands, legs and feet (paraesthesia)
- Dementia (which is reversible)
- Trouble understanding things (cognitive disorder)
- Sedation

- Vasculitis (inflammation of the blood vessels – you may experience fever, fatigue, weight loss and muscle and joint pain)
- Build-up of fluid in the area between the layers of tissue that line the lungs causing chest pain, cough, difficulty breathing
- Skin rash
- Change in hair texture, colour, growth
- Decreased bone mineral density (brittle bones and fractures)
- Osteoporosis (brittle bones), osteopenia (reduced bone mass)
- Frequent urination at night
- Inflammation of the kidneys (back pain, fever)
- Fanconi syndrome: a rare disorder of kidney tubule function that causes increased urination, increased thirst, pain and weakness in muscle and bones
- Absent menstrual periods or abnormal bleeding from uterus
- Male infertility
- Polycystic ovaries (symptoms may be weight gain, irregular periods, heavy bleeding)
- Swollen breasts in males
- Feeling very cold, shivering (hypothermia)
- Swelling of the hands, ankles and feet
- Myelodysplastic syndrome (symptoms may include fatigue, shortness of breath and unusual paleness). This is a condition where immature blood cells in the bone marrow do not mature and therefore do not become healthy blood cells.

Frequency unknown

- Malformation of the foetus and developmental disorders (see “Pregnancy, breastfeeding and fertility” and “Warnings and precautions”).
- Acquired Pelger-Huet anomaly (this is a disorder of certain white blood cells showing abnormal shapes (confirmed by laboratory tests)).
- Hypocarnitinaemia (confirmed by laboratory tests). This condition occurs if you have abnormally low levels of carnitine (a naturally occurring compound) in the blood.
- Hyperpigmentation (areas of skin that become darker than the surrounding skin).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of NAVALZYD.

5. How NAVALZYD IV will be stored

Store all medicines out of reach of children.

Store at or below 25 °C. Keep ampoules in their original package until required for use.

The contents of the ampoule are for single use only.

Do not use NAVALZYD IV after the expiry date on the label or carton.

Return any expired or unused medicine to your pharmacist for safe disposal.

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

6. Content of the pack and other information

What NAVALZYD IV contains:

- The active substance is sodium valproate 100 mg per ml.

  Each 3 ml ampoule contains 300 mg sodium valproate.

  Each 4 ml ampoule contains 400 mg sodium valproate.

  Each 10 ml ampoule contains 1 000 mg sodium valproate.

- The other ingredients are potassium dihydrogen phosphate (buffer), disodium phosphate dodecahydrate (buffer) and water for injections.

What NAVALZYD IV looks like and contents of the pack

NAVALZYD IV solution for injection or infusion is a clear colourless solution, free from visible particles.

The clear solution for injection or infusion is packed in type I transparent glass ampoules in a carton containing 1, 4, 5 or 10 ampoules.

NAVALZYD 300 mg IV: 3 ml of solution is packed in a 5 ml capacity ampoule.

NAVALZYD 400 mg IV: 4 ml of solution is packed in a 5 ml capacity ampoule.

NAVALZYD 1 g IV: 10 ml of solution is packed in a 10 ml capacity ampoule.

Not all pack sizes and strengths may be marketed at one time.

Holder of the Certificate of Registration

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