DEPAKINE 200 mg / ml, oral solution

Sodium valproate

[QR code (Quick Response): the packaging and the leaflet must include a QR code, the location of which will be chosen taking into account general readability.]

Framed

This medicine is subject to additional monitoring. This will allow quick identification of new safety information.You can help by reporting any side effects you see. See the end of section 4 for how to report side effects.

CAUTION

DEPAKINE MAY SERIOUSLY HARM AN UNBORN CHILD IF TAKEN DURING PREGNANCY.
Children exposed in utero to valproate are at high risk for serious developmental (intellectual and motor) and behavioral disorders (up to 30 to 40% of cases) and / or deformities (approximately 10% of cases).
If you are a girl, a teenager, a woman of childbearing age:

–**your specialist doctor will not be able to prescribe valproate, except in the event of ineffectiveness or intolerance to other treatments;**

–**If no other treatment is possible, valproate will be prescribed and dispensed under strict conditions of a pregnancy prevention program aiming to avoid pregnancy.**

–**If you have been prescribed valproate and you are a woman of childbearing age, you should, in particular:**

–**Use at least one effective method of contraception, without interruption, for the duration of your treatment DEPAKINE. Your doctor will discuss this with you, but you should also follow the advice given in section 2 of this leaflet.**

–**Make an emergency appointment with your specialist doctor if you are planning to become pregnant or think you may be pregnant.**

–**Do not stop taking DEPAKINE without your doctor instructs you to; it could make your illness worse.**

Make sure you have read and understood the patient information leaflet and signed the annual care agreement form which will be given to you by your specialist doctor experienced in the management of epilepsy.
Ask your doctor or pharmacist for advice.

Read all of this leaflet carefully before taking this medicine because it contains important information for you.

–Keep this leaflet. You might need to read it again.

–If you have any further questions, ask your doctor or pharmacist.

–This medicine has been prescribed. Do not give this to anyone else. It may harm them, even if their signs of illness are the same as yours.

–If you get any side effects talk to your doctor or pharmacist. This also applies to any side effects that are not mentioned in this leaflet. See section 4.

What does this booklet contain ?

1. WHAT DEPAKINE 200 mg / ml, oral solution IS AND WHAT IT IS USED FOR?

Pharmacotherapeutic group: ANTIEPILEPTIC, ATC code: N03AG01.
DEPAKINE belongs to a family of medicines called antiepileptics.
This medicine is used for the treatment of different forms of epilepsy in adults and children. In children, it is also used for the preventive treatment of seizures associated with fever.

2. WHAT YOU NEED TO KNOW BEFORE TAKING DEPAKINE 200 mg / ml, oral solution?

Never take DEPAKINE 200 mg / ml, oral solution:

– if you are pregnant, unless no other treatment for epilepsy works for you (see “Pregnancy, breast-feeding and fertility - Important advice for women” below),

• If you are a woman age to have children, unless no other treatment of epilepsy is effective for you and that you are able to comply with all measures of the prevention plan to prevent pregnancy (see below “Pregnancy, breastfeeding and fertility - Important tips for women”).

• If you are allergic to the active substance (sodium valproate) or one of the other ingredients of this medicine listed in section 6,

• If you are allergic to a drug in the same family as valproate (divalproex, valpromide)

• If you have liver disease (acute or chronic hepatitis)

• If you or a member of your family have had a severe hepatitis in particular related to taking a medication,

• If you suffer from porphyria (hereditary disease of the liver)

• If you have a genetic problem causing mitochondrial disease (eg. The syndrome Alpers-Huttenlocher)

– if you have a known metabolic disorder, such as a urea cycle disorder (see section “Warnings and precautions”),

• If you take the same time:

○ St. John's Wort (a plant used to treat depression).

Warnings and Precautions

This medicine can very rarely cause damage to the liver (hepatitis) or pancreas (pancreatitis) which can be serious and could be life threatening.
Your doctor will order blood tests to regularly monitor how well your liver is working, especially during the first 6 months of treatment.
Tell your doctor immediately if the following signs appear:

· Sudden fatigue, loss of appetite, depression, drowsiness, leg swelling, general malaise,

· Repeated vomiting, nausea, pain in the abdomen and stomach, yellowing of the skin or eyes (jaundice),

· Recurrence of crises while you follow your treatment correctly.

• Before taking this medication, tell your doctor if you have kidney disease (kidney failure), systemic lupus erythematosus (rare), especially hereditary enzyme deficiencies enzyme deficiency in the urea cycle which can result in increased the amount of ammonium in the blood or a genetic problem causing a mitochondrial disorder (including in your family).

• If you need surgery, you should tell the medical staff that you are taking this medicine.

• At the start of treatment, the doctor will make sure that you are not pregnant and that you have contraception (see “pregnancy” section).

• As with other antiepileptic drugs, after taking this drug, seizures may aggravate, occur more frequently or different types of attacks may occur.

• This medicine may cause weight gain. Your doctor will advise you to take certain dietary measures and monitor your weight.

• The self-destructive or suicidal thoughts were also observed in a small number of people being treated with anti-epileptics such as Depakine. If you have these thoughts, contact your doctor immediately.

- If you have a deficiency of carnitine palmitoyltransferase (CPT) type II (inherited metabolic disease), occurrence of serious muscle problems risk (rhabdomyolysis) with this drug will be most important.

– If symptoms such as tremors, stiffness in limbs and difficulty walking (extrapyramidal disorders) or problems with memory and mental capacity appear, tell your doctor. An underlying pathology or the responsibility of DEPAKINE 200 mg / ml, oral solution should be investigated. Discontinuation of treatment may be necessary.

Tell your doctor if your child is taking any other antiepileptic medication or has any other neurological or metabolic disease and severe forms of epilepsy.

Other medicines and DEPAKINE 200 mg / ml, oral solution

You should never take this medicine if you are taking the following medicine:

- St John's wort (herbal drug used to treat depression).

Unless your doctor tells you otherwise, you should not take this medicine if you are taking:

- Lamotrigine (another medicine used to treat seizures);

– penems (antibiotics to treat bacterial infections).

Tell your doctor if you are taking:

- Medicines containing acetazolamide (medicines used to reduce the pressure at the eye or the rate of carbon dioxide in the blood);

- Antibiotics drugs (aztreonam containing or rifampicin);

- Other antiepileptic drugs (drugs containing carbamazepine, felbamate, phenytoin, fosphenytoin, primidone, phenobarbital, rufinamide, topiramate or zonisamide);

- Nimodipine: DEPAKINE may increase the effects of nimodipine (medicine used to prevent complications that can occur after bleeding in the brain);

- Drugs containing estrogen (including some birth control pills);

- Propofol (anesthetic drug);

- Medicines containing zidovudine (medicines used to treat HIV infection (Human Immunodeficiency Virus));

- Medicines containing lithium (medicines used to treat mood disorders).

In children especially under 3 years of age, you should avoid giving medicines containing aspirin during treatment.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

DEPAKINE 200 mg / ml, oral solution with food, drink and alcohol

It is not recommended to drink alcoholic beverages while taking DEPAKINE.

Pregnancy, breastfeeding and fertility

Pregnancy

Important tips for women

Valproate is dangerous for the unborn child if taken during pregnancy. Therefore :

• If you are a girl, a teenager, a woman old enough to have children, your specialist doctor will not prescribe valproate, except in cases of ineffectiveness or intolerance to other treatments. If no other treatment is possible, you will be prescribed and dispensed with valproate under very strict conditions, described below.

•Make sure you have read the patient information leaflet provided by your specialist doctor. Your doctor will discuss the annual care agreement form with you and ask you to sign and keep it. You must show it to the pharmacist each time you dispense it, along with the specialist's prescription. This form certifies that we have explained the risks to you and that you agree to comply with the conditions below. Your pharmacist will also give you a patient card which reminds you of the risks associated with taking valproate during pregnancy **.**

You must not take DEPAKINE:

• If you are pregnant, unless no other treatment of epilepsy is effective for you.

• If you are a woman age to have children, unless no other treatment of epilepsy is effective for you and that you are able to comply with all measures of the prevention plan to prevent pregnancy.

Risks of taking valproate during pregnancy

• Speak directly to your specialist if you plan to have a child, if you are pregnant or think.

• Valproate puts a risk to the unborn child if it is taken during pregnancy. The higher the dose, the greater the risk; however, **all doses pose a risk.**

• If taken by a pregnant woman, valproate causes severe birth defects and hinders the development of the child (intellectual, motor, behavioral) in a significant number of children.

• Malformations reported include *spina bifida* (bone malformation of the spine), deformities of the face, of the upper lip and palate, skull, heart, kidney, urinary tract and genital organs, and the damage to limbs. Hearing problems or deafness have been reported in children exposed to valproate during pregnancy.

• If you take valproate while pregnant, you have a higher risk than other women to have a child with malformations requiring medical treatment. Since valproate has been used for many years, **it is**

established that almost 10 in 100 babies born to mothers taking valproate have malformations, compared to 2 to 3 in 100 babies in the general population.

•It is estimated that up to 30-40% of preschool children whose mothers took valproate during pregnancy have developmental problems in their early childhood. The children concerned walk and / or speak later, and / or have lower intellectual capacities than the other children and / or have language and / or memory difficulties.

•Autism spectrum disorders are more often diagnosed in children exposed to valproate during pregnancy.

•There is evidence that children exposed to valproate during pregnancy have an increased risk of developing attention deficit hyperactivity disorder (ADHD).

• Before prescribing this drug, **your specialist will have you explained the risks to your baby if you are pregnant while taking valproate.** If you plan to become pregnant in the future, you should not stop taking your medicine or birth control method until you have talked to your doctor.

• If you are a parent or caregiver of a female child treated with valproate, you should contact the specialist doctor as soon as your child has her first period.

• Some contraceptive pills (pills containing estrogen) can lower valproate levels in your blood. Be sure to discuss with your doctor the most suitable method of contraception for you.

Please choose the situation that applies to your case from the list below and read the corresponding paragraph:

• I AM STARTING A TREATMENT WITH DEPAKINE

• I AM TAKING DEPAKINE AND I AM NOT PLANNING TO HAVE A CHILD

• I AM TAKING DEPAKINE AND PLANNING TO HAVE A CHILD

•I AM PREGNANT AND TAKING DEPAKINE

I AM STARTING A TREATMENT WITH DEPAKINE

If this is your first prescription for DEPAKINE, your specialist doctor should explain the risks of the treatment to the unborn child in the event of pregnancy. **If you are of childbearing age, you must use at least one effective method of contraception without interruption while you are taking DEPAKINE.** For advice on contraception, talk to your GP, gynecologist or family planning center.

Key messages:

•Before starting treatment, your doctor will ensure that no other treatment that valproate is not possible for you.

•Before starting treatment, your doctor will ask you to perform a pregnancy test. The result seen by your doctor should confirm that you are not pregnant when you start treatment with DEPAKINE.

•You must use at least one effective method of contraception (preferably an IUD or contraceptive implant) or two effective methods that work differently (eg hormonal pill and a condom) for the duration of your treatment by DEPAKINE.

•You need to discuss suitable methods of contraception with your doctor. Your doctor will give you information on preventing pregnancy and may refer you to a specialist who will give you advice on contraception.

•You should check regularly (at least once a year) an experienced specialist in the treatment of epilepsy. During this consultation, your doctor will make sure that you are aware of the risks and that you understand the information related to the risks of valproate during pregnancy.

•If you want to have a child, talk to your specialist doctor before stopping your contraception.

•If you are pregnant or think you may be, make an appointment with your emergency medical specialist experienced in the treatment of epilepsy.

I AM TAKING DEPAKINE AND I AM NOT PLANNING TO HAVE A CHILD
If you continue to take DEPAKINE and do not plan to have a baby, be sure to use at least one effective method of contraception without interruption while you are taking DEPAKINE. For advice on contraception, talk to your GP, gynecologist or family planning center.
Key messages:

•Your doctor should ensure specialist regularly (at least once a year) no other treatment that valproate is not possible for you.

•You must use at least one effective method of contraception (preferably an IUD or contraceptive implant) or two effective methods that work differently (eg hormonal pill and a condom) for the duration of your treatment with DEPAKINE.

•You need to discuss suitable methods of contraception with your doctor. Your doctor will give you information on preventing pregnancy and may refer you to a specialist who will give you advice on contraception.

• Vous devez consulter régulièrement (au moins une fois par an) un médecin spécialiste expérimenté dans le traitement de l’épilepsie. Lors de cette consultation, votre médecin s’assurera que vous êtes consciente des risques et que vous avez compris les informations liées aux risques du valproate pendant la grossesse.

• Si vous souhaitez avoir un enfant, parlez-en à votre médecin avant d’arrêter votre contraception.

• Si vous êtes enceinte ou si vous pensez l'être, prenez rendez-vous en urgence avec votre médecin spécialiste expérimenté dans le traitement de l’épilepsie.

JE PRENDS DEPAKINE ET JE PRÉVOIS D'AVOIR UN ENFANT

Babies born to mothers treated with valproate are at serious risk of deformities and developmental problems which can be severely disabling. If you are planning to have a child, first make an appointment with your doctor who has experience in the treatment of epilepsy.

Do not stop taking DEPAKINE or your contraception until you have talked to your doctor. Your doctor will provide you with further advice and refer you to a specialist doctor who has experience in the treatment of epilepsy so that you can assess other possible treatments in good time. Your specialist can take various steps to ensure that your pregnancy goes as smoothly as possible and that the risks to you and the unborn child are reduced as much as possible.

Your specialist should do everything possible to stop this treatment with DEPAKINE long before you become pregnant, to make sure that your disease is stable. For exceptional situations where this is not possible, see the following paragraph ("I AM PREGNANT AND TAKING DEPAKINE").

If you are planning to become pregnant, ask your doctor about taking folic acid. Folic acid may decrease the overall risk of *spina bifida* and early miscarriage inherent in any pregnancy. However, it is unlikely to decrease the risk of malformations from the use of valproate.

Key messages:

•Do not stop taking DEPAKINE without your doctor instructs you to.

•Do not stop using your contraceptive methods before discussing it with your doctor and specialist agreed set of treatment, in order to ensure that your disease is under control and that the risks to your baby are reduced.

•First make an appointment with your specialist. During this consultation, your doctor will make sure that you are aware of the risks and that you have understood the information related to the risks of valproate during pregnancy.

•Your medical specialist will try anything to stop treatment with DEPAKINE long before you become pregnant.

•If you are pregnant or think you may be, make an appointment with your emergency medical specialist experienced in the treatment of epilepsy.

I AM PREGNANT AND TAKING DEPAKINE

Babies born to mothers treated with valproate are at serious risk of deformities, intellectual, motor and behavioral development disorders which can be severely disabling. Do not stop taking DEPAKINE without your doctor telling you to. it could make your illness worse. If you are pregnant or think you may be, make an emergency appointment with your specialist doctor experienced in the treatment of epilepsy :

•He will give you additional advice;

•He will try anything to stop treatment, and evaluate all alternative therapies.

In exceptional situations, if DEPAKINE is the only treatment option available during your pregnancy:

•Your doctor may refer you to a specialist so that you and your partner receive assistance and advice on pregnancy as valproate;

•Your medical specialist will try to reduce the prescribed dose;

•You will be monitored closely, both for the treatment of your illness and monitoring the development of the unborn child.

• Ask your doctor about taking folic acid. Folic acid may decrease the overall risk of *spina bifida* and possible early miscarriage during any pregnancy. However, the available data do not show that it reduces the risk of malformations associated with the use of valproate.

•Before birth: your doctor will prescribe certain vitamins to prevent this drug causes bleeding during the first days of life or disorders in the formation of bones of your baby.

•After childbirth: your baby may also be prescribed an injection of vitamin K at birth to prevent bleeding.

•In children: Prevent (s) doctor (s) who will follow (have) your child you have been treated with valproate during pregnancy. He (they) will set up a close follow-up of the neurological development of your child in order to bring him specialized care as soon as possible, if necessary.

Key messages:

•If you are pregnant or think you may be, make an appointment with your emergency medical specialist experienced in the treatment of epilepsy.

•Do not stop taking DEPAKINE without your specialist doctor instructs you to.

•Your doctor specialist experienced in the treatment of epilepsy must assess all the possibilities to stop this treatment.

•Your doctor specialist should give you complete information on the risks associated with taking DEPAKINE during pregnancy, including the risk of defects and effects on child development.

•Make sure you are referred to a doctor specializing in prenatal monitoring in order to detect any malformations.

•Tell the doctors who will follow your child that you have taken DEPAKINE during your pregnancy, they will set up close monitoring of his neurological development.

Feeding with milk

You should not breast-feed if you are taking this medicine unless your doctor tells you otherwise.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

DEPAKINE may make you drowsy, especially if you are taking another medicine that is used for seizure or which may increase drowsiness.

If you experience this effect and your disease is not yet controlled and you continue to have seizures, you should not drive or use machinery.

DEPAKINE 200 mg / ml, oral solution contains sodium.

This medicinal product contains 28 mg of sodium (main component of table / table salt) per 200 mg of sodium valproate. This is equivalent to 1.4% of the recommended maximum daily dietary intake of sodium for an adult. You should take this into account if you are on a salt-free or low-salt diet.

3. HOW TO TAKE DEPAKINE 200 mg / ml, oral solution?

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if in doubt.

Instructions for proper use

Treatment with DEPAKINE should be started and supervised by a doctor who specializes in the treatment of epilepsy. The treatment should not be prescribed in girls, adolescents, women of childbearing age except in cases of ineffectiveness or intolerance to other treatments. If no other treatment is possible, valproate will be prescribed and dispensed to you under very strict conditions (indicated in the pregnancy prevention program). A specialist should reassess the need for treatment at least once a year.

Always take the dose prescribed by your doctor. If in doubt, consult your doctor or pharmacist.

Dosage

- The daily dose to be used is determined and controlled individually by your doctor.

- Your doctor should prescribe a dose in milligrams (mg) and not in milliliters (ml). This information is important because the syringe used to withdraw the correct dose from the vial is graduated in milligrams (mg). If your prescription was written in milliliters (ml), contact your doctor or pharmacist.

- The dose is usually divided into:

- 2 times a day for children under 1 year old.

- 3 times a day, in adults and children over 1 year old.

- Take your dose preferably with your meals.

Administration mode

- The oral solution will be absorbed after dilution in a little non-carbonated drink.

- The bottle of oral solution is accompanied by an oral syringe (piston purple).

- Administer the oral solution only with the syringe provided in this box.

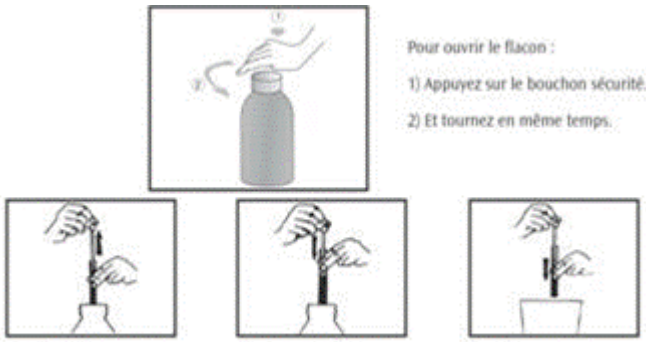
• The graduations indicate the doses expressed as milligrams (one graduation every 25 mg, 50 mg and 400 mg).

• The dose is achieved by pulling the plunger to the graduation corresponding to the quantity in milligrams (mg) prescribed by your doctor. Read the dose from the collar of the syringe.

• Rinse the syringe after use.

Opening the bottle

To open the bottle, turn the child-resistant cap while pressing down. The bottle must be closed after each use.



Utilisation de la seringue pour administration orale.

Duration of treatment

Do not stop taking this medication without medical advice.
If you take more DEPAKINE than you should:
Consult your doctor or medical emergency immediately.
If you forget to take DEPAKINE:
Do not take a double dose to make up for the dose you forgot to take
If you stop taking DEPAKINE:
Do not stop taking DEPAKINE without your doctor's advice. The interruption of your treatment should be carried out gradually. If you stop taking DEPAKINE suddenly or before your doctor tells you to, you are at increased risk for seizures.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Like all medicines, this medicine can cause side effects, although not everybody gets them.
See your doctor or pharmacist immediately if any of the following occurs:

•Liver damage (hepatitis) or pancreas (pancreatitis), which may be serious and put your life in danger and that can start suddenly by fatigue, loss of appetite, depression, drowsiness, nausea, vomiting , pain in the stomach.

•An allergic reaction:

•sudden swelling of the face and / or neck which may cause difficulty in breathing and put you in danger (angioedema),

•serious allergic reaction (drug hypersensitivity syndrome) combining several symptoms such as fever, rash on the skin, enlarged lymph nodes, liver damage, kidney damage, and abnormal blood tests such as 'an increase in the number of certain white blood cells (eosinophils).

•A rash on the skin with some bubbles that can also affect the mouth (erythema multiforme), rash bubbles with skin peeling can spread rapidly throughout the body and put you in danger (toxic epidermal necrolysis syndrome by Stevens-Johnson).

Other possible side effects:

•Congenital malformations and disorders of intellectual and motor development (see Section 2 - Pregnancy, breastfeeding and fertility).

Very common (affecting more than 1 in 10 people):

•Nausea,

•Tremors.

Common (affecting up to 1 in 10 people):

•start of treatment: vomiting, stomach pain, diarrhea,

•Weight gain,

•Headache,

•Drowsiness,

•Seizures,

•Memory impairment,

•Confusion, aggression, agitation, attention disorders, hallucinations (seeing, hearing or feeling things that are not there)

• Extrapyramidal disorder (set of symptoms such as tremors, stiffness of members and difficulty walking) *

•Urinary incontinence (inability to retain urine)

•Movements rapid, uncontrollable eye

•Hearing loss,

•Disorders of gingiva (gum disorders), especially enlargement of the gingiva (gum hypertrophy)

•Sore mouth, swollen, mouth and burning sensation of the mouth (stomatitis)

•Hair loss,

•Menstrual disorders (menstrual irregularity)

•Bleeding,

•Feeling sick or dizzy,

•Nail disorders and nail bed,

•Reduction in the number of platelets (thrombocytopenia), reduced red cell count (anemia),

•Decrease the amount of sodium in the blood (hyponatremia, syndrome of inappropriate secretion of antidiuretic hormone).

Uncommon (affecting up to 1 in 100 people):

•Vigilance disorders, up to coma passenger, who regresses after dose reduction or discontinuation of treatment,

•Difficulties in coordinating its movements,

•Parkinsonian syndrome reversible *

•Numbness or tingling of the hands and feet,

•Abnormal hair texture, change hair color, hair growth abnormal,

•Eruption of pimples or patches on the skin,

•Excessive hair growth, particularly among women, virilization, acne (hyperandrogenism)

•Drop in body temperature (hypothermia)

•Swelling of the extremities (edema),

•Amenorrhea (absence of menstruation)

•Increase in the number and severity of seizures, onset of seizures of different types,

•Difficulty breathing and pain caused by the inflammation of the protective membrane of the lungs (pleural effusion)

•Decrease of all blood cell: WBC, red blood cells and platelets (pancytopenia), decrease in white blood cell count (leucopenia),

•Cases of bone disorders manifested by fragile bones (osteopenia), decreased bone mass (osteoporosis) and fractures have been reported. Consult your doctor or pharmacist in the event of long-term treatment with an anti-epileptic drug, a history of osteoporosis or taking corticosteroids,

•Inflammation of blood vessels.

Rare (affecting up to 1 in 1,000 people):

•Difficulty retaining his urine (enuresis)

•Decrease in sperm motility,

•Abnormal function of the ovaries (PCOS)

•Behavioral disorders, increased psychomotor activity, learning difficulties,

•Autoimmune reaction with joint pain, rashes on the skin and fever (lupus erythematosus)

•Decreased activity of the thyroid gland (hypothyroidism)

•Muscle pain, muscle weakness which can be serious (rhabdomyolysis)

•Obesity

•Kidney disease (renal failure, tubulointerstitial nephritis, Fanconi syndrome)

•Increase in the volume of red blood cells (macrocytosis), significant decrease in white blood cells (agranulocytosis)

•Loss of production of blood cells (bone marrow aplasia), abnormal production of blood cells (MDS)

•Decrease of coagulation factors, abnormal coagulation tests (increased INR, aPTT ...)

•Decrease in the amount of Vitamin B8 (biotin) / biotinidase,

•Increasing the amount of ammonium in blood,

•Double vision,

•Disorders of memory and mental abilities of gradual onset (cognitive impairment, dementia syndrome) *. These disorders decrease a few weeks to a few months after stopping treatment.

* These symptoms may be associated with radiological signs in the brain (cerebral atrophy).

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This also applies to any side effects that are not mentioned in this leaflet. You can also report side effects directly via the national reporting system: National Agency for Medicines and Health Products Safety (ANSM) and network of Regional Pharmacovigilance Centers - Website: www.signalement-sante.gouv.fr .
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DEPAKINE 200 mg / ml, oral solution?

Keep this medication out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the pack.
Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACKAGE AND OTHER INFORMATION

What DEPAKINE 200 mg / ml contains, oral solution

• The active substance is:

Sodium Valproate .... 20.00 g

For 100 ml.

1 ml of solution corresponds to 200 mg of sodium valproate.

• The other ingredients are:

Urea, 30% sodium hydroxide solution and purified water.

What DEPAKINE 200 mg / ml, oral solution looks like and contents of the pack

This medication is in the form of an oral solution. 40 ml bottle.

Marketing authorization holder

SANOFI-AVENTIS FRANCE
82 AVENUE RASPAIL
94250 GENTILLY

Marketing authorization operator

SANOFI-AVENTIS FRANCE
82 AVENUE RASPAIL
94250 GENTILLY

Maker

UNITHER LIQUID MANUFACTURING
1-3, ALLEE DE LA NESTE
31770 COLOMIERS
or
SANOFI WINTHROP INDUSTRY
30-36 AVENUE GUSTAVE EIFFEL
37100 TURNS