PACKAGE LEAFLET : INFORMATION FOR THE USER

Depakine® 200 mg/ml, oral solution

sodium valproate

▼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 may get.

WARNING

DEPAKINE CAN SERIOUSLY HARM AN UNBORN CHILD WHEN TAKEN DURING PREGNANCY.
Children exposed to valproate in utero have a high risk of serious developmental disorders (mental and physical) and behavioural disturbances (up to 30 to 40% of cases) and/or birth defects (approximately 10% of cases).
If you are a female child, a female adolescent, a woman of childbearing age:
- **your doctor will only prescribe valproate for you if other treatments are not effective or not tolerated.**
- **if no other treatment is possible, valproate will be prescribed for you and dispensed under the very strict conditions of a Pregnancy Prevention Program, which aims to prevent any potential pregnancy.**

If valproate has been prescribed for you and you are a woman able to have a baby, you must, in particular:
- **use at least 1 effective method of birth control, without interruptions, during your entire treatment with Depakine. Your doctor will discuss this with you but you must also follow the advice in section 2 of this leaflet.**
- **schedule an urgent appointment with your doctor if you want to become pregnant or if you think you are pregnant.**
- **not stop taking Depakine unless your doctor tells you to as your condition may become worse.**

Make sure that you have read and understood the Patient Guide and signed the Annual Risk Acknowledgement Form given to you by your specialist experienced in the management of epilepsy.
Ask your doctor or pharmacist for advice.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. 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 includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet :

1. What Depakine is and what it is used for
2. What you need to know before you take Depakine
3. How to take Depakine
4. Possible side effects
5. How to store Depakine
6. Contents of the pack and other information.

1. WHAT DEPAKINE IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group : ANTIEPILEPTICS.
Depakine belongs to a family of medicines called antiepileptics.
This medicine is used to treat various types of seizures in adults and children. It is also used in children to prevent fever-related seizures.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DEPAKINE

Contraindications :
Do not take Depakine:
- if you are pregnant, unless no other epilepsy treatment works for you (see below "Pregnancy, breast-feeding and fertility – Important advice for women"),
- if you are a woman able to have a baby, unless no other epilepsy treatment works for you and you are able to follow all the steps of the Pregnancy Prevention Plan (see below "Pregnancy, breast-feeding and fertility – Important advice for women"),
- if you are allergic to the active substance (sodium valproate) or any of the other ingredients of this medicine (listed in section 6),
- if you are allergic to a medicine in the same family as valproate (valproate semisodium, valpromide),
- if you have liver disease (acute or chronic hepatitis),
- if you or a member of your family have ever had serious liver disease, particularly related to use of a medicine,
- if you have hepatic porphyria (hereditary liver disease),
- if you have a genetic problem causing a mitochondrial disorder (e.g. Alpers-Huttenlocher syndrome),
- if you have a known metabolic disorder, such as a urea cycle disorder (see "Warnings and precautions"),
- if you are currently taking St. John's Wort (plant used to treat depression).

Warnings and precautions

This medicine can, in very rare cases, cause liver damage (hepatitis) or pancreas damage (pancreatitis), which can be serious and life-threatening.
Your doctor will prescribe blood tests to regularly monitor your liver function, particularly during the first 6 months of treatment.
Inform your doctor immediately if any of the following signs appear:
- sudden fatigue, loss of appetite, exhaustion, drowsiness, swelling of the legs, general malaise,
- repeated vomiting, nausea, stomach or bowel pain, yellow colour of the skin or eyes (jaundice).
- recurrence of epileptic seizures even though you are taking your treatment correctly.

- Before taking this medicine, tell your doctor if you have kidney disease (renal insufficiency), systemic lupus erythematosus (rare disease) or hereditary enzyme deficiencies, particularly an enzyme deficiency of the urea cycle that can cause increased amounts of ammonium in the blood, or a genetic problem causing a mitochondrial disorder (including in your family).
- If you are scheduled to have surgery, you must inform the medical personnel that you are taking this medicine.
- At the start of treatment, your doctor will check that you are not pregnant and that you have a method of contraception (see "Pregnancy").
- As with other antiepileptics, taking this medicine can lead to your seizures worsening or becoming more frequent; you may even experience a different type of seizure.
- This medicine can cause weight gain. Your doctor will recommend that you take certain dietary measures and will monitor your weight.
- Self-destructive or suicidal thoughts have also been observed in a small number of people treated with antiepileptics such as Depakine. If you have these kinds of thoughts, contact your doctor immediately.
- If you have carnitine plamitoyltransferase (CPT) type II deficiency (hereditary metabolic disease), the risk of developing serious muscle problems (rhabdomyolysis) is higher with this medicine.

- Inform your doctor if you have symptoms such as tremor, stiffness of the limbs and difficulty walking (extrapyramidal disorders) or memory and mental capacity disorders. He or she will try to find out whether they are caused by an underlying disease or by Depakine. It may be necessary to stop treatment.

Inform your doctor if your child is taking another antiepileptic treatment or has another neurological or metabolic disease or severe forms of epilepsy.

Other medicines and Depakine
You must never take this medicine if you are taking the following medicine:
- St. John's Wort (plant-based medicine used to treat depression).

Unless instructed otherwise by your doctor, you should not take this medicine if you are taking:
- Lamotrigine (another medicine used to treat epileptic seizures)
- Penems (antibiotics used to treat bacterial infections).

Tell your doctor if you are taking:
- Acetazolamide-containing medicines (medicines used to lower eye pressure or carbon dioxide levels in the blood).
- Antibiotics (medicines containing aztreonam or rifampicin).
- Other antiepileptic medicines (medicines containing carbamazepine, felbamate, phenytoin, fosphenytoin, primidone, phenobarbital, rufinamide, topiramate or zonisamide).
- Nimodipine: Depakine can increase the effects of nimodipine (medicine used to prevent complications that can occur after bleeding in the brain).
- Oestrogen-containing products (including some birth control pills).
- Propofol (anaesthetic medicine).
- Zidovudine-containing medicines (medicines used to treat HIV infection (Human Immunodeficiency Virus)).
- Lithium-containing medicines (medicines used to treat mood disorders).

Specifically in children under 3 years of age, you must avoid giving medicines that contain aspirin during treatment.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Depakine with food, drink and alcohol
Use of alcoholic beverages is not recommended during treatment with Depakine.

Pregnancy, breast-feeding and fertility
Pregnancy
Important advice for women
Valproate is harmful to unborn babies if taken during pregnancy. Therefore:
- **If you are a female child, female adolescent or woman of childbearing age, your doctor may not prescribe valproate for you unless other treatments are ineffective or not tolerated. If no other treatment is possible, valproate will be prescribed for you and dispensed under the very strict conditions described below.**
- **Make sure that you have read the Patient Guide given to you by your doctor. Your doctor will discuss the Annual Risk Acknowledgement Form with you and ask you to sign and keep it. You must show it to the pharmacist every time you pick up your medicine, along with the doctor's prescription. This Form certifies that the risks have been explained to you and that you agree to comply with the conditions below. Your pharmacist will also give you a Patient Card to remind you of the risks associated with taking valproate during pregnancy.**

You must not take Depakine:
- if you are pregnant, unless no other epilepsy treatment works for you,
- if you are a woman of childbearing age, unless no other epilepsy treatment works for you and you are able to follow all the steps of the Pregnancy Prevention Plan.

The risks of valproate when taken during pregnancy
- Talk to your doctor immediately if you are planning to have a baby, are pregnant or think you might be pregnant.
- Valproate carries a risk for the unborn baby if taken during pregnancy. The higher the dose, the higher the risks **but all doses carry a risk.**
- When taken by pregnant women, valproate causes serious birth defects in a large number of children and also affects the way in which they develop their intellectual, motor and behavioural skills.
- Birth defects which have been reported include *spina bifida* (where the bones of the spine are not properly developed); facial, upper lip, palate and skull malformations; heart, kidney, urinary tract and sexual organ malformations; limb defects. Hearing disorders and hearing loss have been reported in children exposed to valproate during pregnancy.
- If you take valproate during pregnancy you have a higher risk than other women of having a child with birth defects that require medical treatment. Because valproate has been used for many years **we know that in women**

who take valproate around 10 babies in every 100 will have birth defects. This compares to 2-3 babies in every 100 born to women who do not have epilepsy.

- **It is estimated that up to 30-40% of pre-school children whose mothers took 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.**
- **There is some evidence that children exposed to valproate during pregnancy are at increased risk of developing Attention Deficit Hyperactivity Disorder (ADHD).**
- Before prescribing this medicine to you, **your doctor will have explained what might happen to your baby if you become pregnant while taking valproate.** If you decide later you want to have a baby you must not stop taking your medicine or your method of contraception until you have discussed this with your doctor.
- If you are a parent or a caregiver of a female child treated with valproate, you should contact the doctor once your child using valproate experiences menarche.
- Some birth control pills (oestrogen-containing birth control pills) may lower valproate levels in your blood. Make sure you talk to your doctor about the method of birth control that is the most appropriate for you.

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

◦ I AM STARTING TREATMENT WITH DEPAKINE
◦ I AM TAKING DEPAKINE AND NOT PLANNING TO HAVE A BABY
◦ I AM TAKING DEPAKINE AND PLANNING TO HAVE A BABY
◦ I AM PREGNANT AND I AM TAKING DEPAKINE

I AM STARTING TREATMENT WITH DEPAKINE
If this is the first time you have been prescribed Depakine, 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 at least 1 effective method of contraception without interruption throughout your treatment with Depakine.** Talk to your doctor, gynaecologist or family planning clinic if you need advice on contraception.

Key messages:
- Before starting treatment, your doctor will have to make sure that no treatment other than valproate works for you.
- Your doctor will ask you to do a pregnancy test before you start taking this medicine. Pregnancy must be excluded before start of treatment with Depakine with the result of a pregnancy test, confirmed by your doctor.
- You must use at least 1 effective method of birth control (preferably an intrauterine device or a contraceptive implant) or 2 effective methods that work differently (for example, the Pill and a condom) during your entire treatment with Depakine.
- You must discuss the appropriate methods of birth control with your doctor. Your doctor will give you information on preventing pregnancy, and may refer you to a specialist for advice on birth control.
- You must get regular (at least annual) appointments with a specialist experienced in the management of epilepsy. During this visit your doctor will make sure you are well aware and have understood all the risks and advice related to the use of valproate during pregnancy.
- Tell your doctor you want to have a baby before stopping your birth control.
- Schedule an urgent appointment with your specialist experienced in the management of epilepsy if you are pregnant or think you might be pregnant,

I AM TAKING DEPAKINE AND NOT PLANNING TO HAVE A BABY
If you are continuing treatment with Depakine but you are not planning to have a baby make sure you are using at least one effective method of contraception without interruption during your entire treatment with Depakine. Talk to your doctor, gynecologist or family planning clinic if you need advice on contraception.
Key messages:
- Your specialist must check regularly (at least once a year) whether any treatment other than valproate works for you.
- You must use at least 1 effective method of contraception (preferably an intrauterine device or a contraceptive implant) or 2 effective methods that work differently (for example, the Pill and a condom) during your entire treatment with Depakine.
- You must discuss the appropriate methods of birth control with your doctor. Your doctor will give you information on preventing pregnancy, and may refer you to a specialist for advice on birth control.
- You must get regular (at least annual) appointments with a specialist experienced in the management of epilepsy. During this visit your doctor will make sure you are well aware and have understood all the risks and advice related to the use of valproate during pregnancy.
- Tell your doctor you want to have a baby before stopping your birth control.
- Schedule an urgent appointment with your specialist experienced in the management of epilepsy if you are pregnant or think you might be pregnant

I AM TAKING DEPAKINE AND PLANNING TO HAVE A BABY
Babies born to mothers who have been on valproate are at serious risk of birth defects and problems with development which can be seriously debilitating. **If you are planning to have a baby, first schedule an appointment with your specialist experienced in the management of epilepsy.**
Do not stop taking Depakine or your contraception, until you have discussed this with your doctor. Your doctor will advise you further and 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 will have to do everything possible to stop treatment with Depakine a long time before you become pregnant – this is to make sure your illness is stable. In exceptional circumstances when this is not possible, see the following paragraph ("I AM PREGNANT AND I AM TAKING DEPAKINE").
Ask your doctor about taking folic acid when planning to have 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 use.
Key messages:
- Do not stop taking Depakine unless your doctor tells you to.
- Do not stop using your methods of birth control before you have talked to your doctor and worked together on a plan to ensure your condition is controlled and the risks to your baby are reduced.
- First schedule an appointment with your doctor. During this visit your doctor will make sure you are well aware and have understood all the risks and advice related to the use of valproate during pregnancy.
- Your doctor will try to stop treatment with Depakine a long time before you become pregnant.
- Schedule an urgent appointment with your specialist experienced in the management of epilepsy if you are pregnant or think you might be pregnant.

I AM PREGNANT AND I AM USING DEPAKINE
Babies born to mothers who have been on valproate are at serious risk of birth defects and problems with

intellectual, motor and behavioural development which can be seriously debilitating. Do not stop taking Depakine, unless your doctor tells you to as your condition may become worse. **Schedule an urgent appointment with your specialist experienced in the management of epilepsy if you are pregnant or think you might be pregnant :**
- Your doctor will advise you further.
- Your doctor will have to try to stop treatment and evaluate all other treatment options.

In the exceptional circumstances when Depakine is the only available treatment option during pregnancy:
- your doctor can refer you to a specialist so that you and your partner could receive counselling and support regarding the valproate-exposed pregnancy.
- your specialist will try to reduce the prescribed dose.
- you will be monitored very closely both for the management of your underlying condition and to check how your unborn child is developing.
- 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 use.
- **Before the birth:** your doctor will prescribe certain vitamins for you so that this medicine does not cause bleeding during the first few days of your baby's life or bone deformities.
- **After the birth:** an injection of vitamin K may also be prescribed for your baby after birth to prevent bleeding.
- **In the child:** inform the doctor(s) monitoring your child that you were treated with valproate during pregnancy. He or she will implement strict monitoring of your child's neurological development in order to provide your child with specialised care as early as possible if necessary.

Key messages:
- Schedule an urgent appointment with your specialist experienced in the management of epilepsy if you are pregnant or think you might be pregnant.
- Do not stop taking Depakine unless your specialist tells you to.
- Your specialist experienced in the treatment of epilepsy must evaluate all of the options for stopping this treatment. Your specialist must give you complete information about the risks related to the use of Depakine during pregnancy, including teratogenicity and developmental effects in children.
- Make sure you are referred to a specialist for prenatal monitoring in order to detect possible occurrences of malformations.
- Inform the doctors who will be monitoring your child that you took Depakine during your pregnancy. They will implement strict monitoring of the child's neurological development.

Breast-feeding
You must not breast-feed during treatment with this medicine unless otherwise indicated by your doctor.
Talk to your doctor or pharmacist before taking any medicine.

Driving and using machines
Depakine may cause drowsiness, especially if taken in combination with other antiepileptic drugs or medicines that can increase drowsiness.
If you experience this effect or if your condition is not under control yet and you continue to have seizures, you must not drive or operate machinery.

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

3. HOW TO TAKE DEPAKINE

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Instructions for proper use
Depakine treatment must be started and supervised by a doctor specialised in the treatment of epilepsy. This treatment must not be prescribed in female children, female adolescents or women able to have a baby unless other treatments are ineffective or not tolerated. If no other treatment is possible, valproate will be prescribed for you and dispensed under very strict conditions (given in the Pregnancy Prevention Program). A specialist must re-evaluate the need for treatment at least once per year. Always comply with the dose prescribed by your doctor. If you are unsure of anything, talk to your doctor or pharmacist.

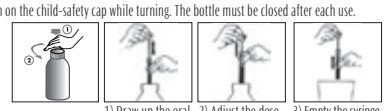
Dosage
- The daily dose will be decided on for you and checked by your doctor.
- Your doctor should prescribe the dose in milligrams (mg) and not in millilitres (mL). This information is important because the syringe used to draw up the correct dose from the bottle is graduated in milligrams (mg). If your prescription has been written in millilitres (mL), contact your doctor or pharmacist.
- The dose is generally divided into:
  - 2 doses per day in children under 1 year of age,
  - 3 doses per day in adults and children over 1 year of age,

The dose should preferably be taken during meals.

Method of administration
- The oral solution should be taken after diluting in a small amount of non-carbonated drink.
- The bottle of oral solution is supplied with a syringe for oral administration (mauve plunger).
- Administer the oral solution only with the syringe supplied in this box.
- The graduation marks indicate the doses in milligrams (mg) (1 graduation mark every 25 mg, from 50 mg to 400 mg).
- The dose to be administered is obtained by drawing the plunger up to the graduation line corresponding to the amount in milligrams (mg) prescribed by your doctor. Read the dose at the top edge of the syringe barrel.
- Rinse the syringe after each use.

Opening the bottle
To open the bottle, push down on the child-safety cap while turning. The bottle must be closed after each use.

To open the bottle:
1) Press down on the child-safety cap.
2) And turn at the same time



1) Draw up the oral solution 2) Adjust the dose. 3) Empty the syringe.

How to use the syringe for oral administration.

Duration of treatment
Do not stop taking this medicine without your doctor's advice.
If you take more Depakine than you should:
Talk to your doctor or go to the emergency room immediately.
If you forget to take Depakine:
Do not take a double dose to make up for a forgotten dose.
If you stop taking Depakine:
Do not stop taking Depakine without asking your doctor's advice. Treatment must be stopped gradually.
If you stop taking Depakine suddenly or before your doctor asks you to, you will be at a higher risk of seizures.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Consult your doctor or pharmacist immediately if you experience any of the following effects:
- Liver damage (hepatitis) or pancreas damage (pancreatitis), which may be serious and life-threatening, and that can start suddenly with fatigue, loss of appetite, exhaustion, drowsiness, nausea, vomiting and bowel pain.
- Allergic reaction:
  - sudden swelling of the face and/or neck that can cause difficulty breathing and be life-threatening (angioedema),
  - serious allergic reaction (drug hypersensitivity syndrome) including several symptoms such as fever, skin rash, increased size of lymph nodes, liver damage, kidney damage and abnormal blood test results such as an increase in the number of certain white blood cells (eosinophils).
- Raised skin rash, sometimes with blisters that can also affect the mouth (erythema multiforme), blisters with detachment of the skin that can rapidly spread to the entire body and be life-threatening (toxic epidermal necrolysis, Stevens-Johnson syndrome).

Other possible side effects:
- Congenital birth defects and mental and physical development disorders (see "Pregnancy, breast-feeding and fertility" in section 2).

Very common (may affect more than 1 in 10 people):
- nausea,
- tremor.

Common (may affect up to 1 in 10 people):
- at the beginning of treatment: vomiting, stomach ache, diarrhoea,
- weight gain,
- headache,
- drowsiness,
- seizures,
- memory disorders,
- confusion, aggressiveness, agitation, attention deficit disorders, hallucinations (seeing, hearing or feeling things that are not there),
- extrapyramidal disorders (a group of symptoms such as tremor, stiffness of the limbs and difficulty walking)*,
- urinary incontinence (unintentional passing of urine),
- rapid and uncontrollable eye movements,
- hearing loss,
- gum disorders (gingival problems), in particular an increase in gum size (gingival hypertrophy),
- painful, swollen mouth, mouth ulcers and burning sensation in the mouth (stomatitis),
- hair loss,
- menstrual problems (irregular menstruation),
- bleeding,
- nausea or dizziness,
- nail and nail bed disorders,
- decrease in the number of platelets (thrombocytopenia), decrease in the number of red blood cells (anaemia),
- decrease in the amount of sodium in the blood (hyponatremia, syndrome of inappropriate antidiuretic hormone secretion).

Uncommon (may affect up to 1 in 100 people):
- impaired alertness that may go as far as transient coma, regressing after the dose is decreased or the treatment stopped,
- difficulty coordinating movements,
- reversible Parkinsonian syndrome*,
- sensation of numbness or prickling in the hands and feet,
- abnormal hair texture, change in hair colour, abnormal hair growth,
- rash or hives on the skin,
- excessive hair growth, particularly in women, virilism, acne (hyperandrogenism),
- decreased body temperature (hypothermia),
- swelling of the extremities (oedema),
- amenorrhea (lack of menstrual period),
- worsening and increased frequency of seizures; onset of a different type of seizure,
- breathing difficulty and pain, due to inflammation of the protective membranes of the lungs (pleural effusion),
- decrease in the numbers of all blood cells: white blood cells, red blood cells and platelets (pancytopenia), decrease in the number of white blood cells (leukopenia),
- cases of bone disorders have been reported, such as the bones becoming more fragile (osteopenia), a decrease in bone mass (osteoporosis) and fractures. Consult your doctor or pharmacist if you are receiving long-term treatment with an antiepileptic drug, if you have a history of osteoporosis or if you are taking corticosteroids,
- blood vessel inflammation.

Rare (may affect up to 1 in 1000 people):
- difficulty retaining urine (enuresis),
- reduced sperm motility,
- abnormal functioning of the ovaries (polycystic ovary syndrome),
- behavioural disturbances, increased psychomotor activity, learning disabilities,
- auto-immune reaction with painful joints, skin rash and fever (systemic lupus erythematosus),

- decreased thyroid gland activity (hypothyroidism),
- muscle pain, muscle weakness that may be serious (rhabdomyolysis),
- obesity,
- kidney damage (kidney failure, tubulointerstitial nephritis, Fanconi syndrome),
- increase in the size of red blood cells (macrocytosis), major decrease in the number of white blood cells (agranulocytosis),
- reduced production of blood cells (bone marrow aplasia), blood cell production abnormality (myelodysplasia),
- decrease in coagulation factors, abnormal blood coagulation test results (increase in INR, increase in activated partial thromboplastin time),
- decrease in the amount of vitamin B8 (biotin)/biotinidase,
- increase in the amount of ammonium in the blood,
- double vision,
- memory and mental capacity disorders that appear gradually (cognitive disorders, dementia)* and regress a few weeks to a few months after stopping treatment.

*These symptoms can be associated with brain imaging signs (cerebral atrophy).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE DEPAKINE

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the packaging.
Store below 30°C.
Do not throw away any medicines 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 PACK AND OTHER INFORMATION

What Depakine 200 mg/ml oral solution contains
- The active substance is:
sodium valproate..... 20.00 g
For 100 mL.

1 mL of solution is equivalent to 200 mg of sodium valproate.

- The other ingredients are:
urea, 30% sodium hydroxide solution, purified water.

What Depakine 200 mg/ml oral solution looks like and contents of the pack
This medicine is supplied as an oral solution. 40 mL bottle.

Marketing Authorization Holder
sanofi-aventis France
82, avenue Raspail
94250 Gentilly – France

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GENERAL ADVICE

Epilepsy is a neurological disease. It is an expression of acute and temporary abnormal function of electrical activity in the brain, resulting in epileptic seizures. The seizures may be repeated throughout a certain period of an individual's life.
There are many forms of expression of these seizures and they may progress in many different ways:
there is not **one type** of epilepsy but **several** different types.
Similarly, there is not one treatment but several possible treatments: your doctor will prescribe the one best suited to you.
To ensure that this medicine is effective, it is essential that you follow your doctor's recommendations and comply with:
- prescribed daily doses,
- the time of the doses,
- treatment duration, generally long-term,
- lifestyle recommendations: avoid overwork, lack of sleep and alcohol.

Changing the doses and, especially, suddenly stopping the treatment, can cause seizures to recur.
DO NOT FORGET TO TAKE YOUR MEDICINE WITH YOU IF YOU TRAVEL.

THIS MEDICAMENT
Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period oftreatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.