DEPAKINE® 200 mg

sodium valproate

gastro-resistant tablets

Read all of this leaflet before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions or are unsure of anything, ask your doctor or pharmacist for more information.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, talk to your doctor or pharmacist.

In this package leaflet:

1. WHAT DEPAKINE 200 mg gastro-resistant tablets ARE AND WHAT THEY ARE USED FOR

Pharmacotherapeutic group

DEPAKINE belongs to a family of medicines called antiepileptics.

Therapeutic indications

This medicine is used to treat various types of seizures in adults and children over 6 years of age. It is also used in children to prevent fever-related seizures.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DEPAKINE 200 mg gastro-resistant tablets

Contraindications

Never take DEPAKINE in the following situations:
- if you are allergic to the active substance of this medicine (sodium valproate) or to any of the other ingredients in DEPAKINE. For the list of ingredients, see Section 6,
- if you are allergic to a medicine in the same family as valproate (divalproate, 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 are currently taking the following medicines:
  - mefloquine (medicine used to treat malaria),
  - St. John's Wort (plant used to treat depression).

Appropriate precautions for use ; special warnings
Take special care with DEPAKINE

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 color 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.
- 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").
- Consult your doctor immediately if the frequency of seizures increases or if you 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.

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

Taking/using other medicines

You must never take this medicine if you are taking any of the following medicines:
- mefloquine (medicine used to treat malaria),
- St. John's Wort (plant-based medicine used to treat depression).

You must tell your doctor if you are taking lamotrigine (another medicine used to treat epilepsy) or penems (antibiotics used to treat bacterial infections).

Specifically in children under 3 years of age, you must avoid giving medicines that contain aspirin during treatment.

Inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Food and drink

Use of alcoholic beverages is not recommended during treatment with DEPAKINE.

Pregnancy

You must not take this medicine if you are pregnant or of childbearing age unless otherwise indicated by your doctor.

If you are of childbearing age, you must use a reliable means of contraception during treatment.

Taking this medicine during pregnancy can cause fetal malformations, coagulation disorders in the newborn baby and developmental disorders or autism in the child.

Before stopping your contraception, tell your doctor that you are planning to have a baby so that the doctor can possibly adjust your treatment and establish a special monitoring program for your pregnancy.

Also, tell your doctor immediately if you discover that you are pregnant. In all cases, you must not stop your treatment of your own accord, without the agreement of your doctor.

Breast-feeding

Breast-feeding is not recommended during treatment with this medicine.

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

Driving and using machines

DEPAKINE can cause drowsiness, particularly if it is taken in combination with other antiepileptics 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 use machines.

Important information about some of the ingredients of DEPAKINE

This medicine contains 28 mg of sodium per tablet. You must take this into account if you are on a salt-free or low-salt diet

3. HOW TO TAKE DEPAKINE 200 mg gastro-resistant tablets

Always comply with the dosage prescribed by your doctor. If you are unsure of anything, consult your doctor or pharmacist.

Dosage

The daily dose to be administered is determined and controlled individually by your doctor. It is generally divided into 2 to 3 doses per day, preferably during meals.

Children from 6 years of age

DEPAKINE is not recommended for children under 6 years of age, as they can have trouble swallowing the tablet and choke. There are other more suitable medicines available.

Method of administration

Always take the tablets whole with a large glass of water.

This tablet is gastro-resistant. In order to remain fully effective, it must not be broken or crushed.

Duration of treatment

Do not stop taking this medicine without asking your doctor's advice.

If you take more DEPAKINE than you should:

Consult your doctor or an emergency medical service 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 exposed to an increased risk of seizures.

4. POSSIBLE SIDE EFFECTS

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

Consult your doctor or pharmacist immediately if you experience any of the following effects:

- In very rare cases, 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 stomach pain.
- Eruption of rash or hives on the skin.
- Very rarely, eruption of rash on the skin, sometimes with blisters that can also affect the mouth (erythema multiforme), eruption of blisters with detachment of the skin that can rapidly spread to the entire body and be life-threatening (toxic epidermal necrolysis, Stevens-Johnson syndrome).
- Allergic reaction:
  - sudden swelling of the face and/or neck that can cause difficulty breathing and be life-threatening (angioedema),
  - serious allergic reaction (drug rash with eosinophilia and systemic symptoms) including several symptoms such as fever, skin eruption, 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).

Other possible side effects:

- at the beginning of treatment: nausea, vomiting, stomach pain, diarrhea,
- hair loss,
- tremor,
- drowsiness,
- menstrual disorders such as amenorrhea (no menstrual periods) and menstrual irregularity,
- weight gain,
- abnormal functioning of the ovaries (polycystic ovary syndrome),
- reduced sperm motility,
- headache,
- difficulty coordinating movements,
- confusion, seizures, alertness disorders that may be isolated or associated with an increase in epileptic seizures, and that can include temporary coma that regresses after a decrease in the dose or stopping treatment,
- extrapyramidal disorders (a group of symptoms such as tremor, stiffness of the limbs and difficulty walking) that are sometimes irreversible. In some cases, the Parkinsonian syndrome may be reversible.
- in very rare cases, memory and mental capacity disorders that appear gradually (cognitive disorders, dementia) and regress a few weeks to a few months after stopping treatment.
- hearing loss, which may be reversible,
- in very rare cases, swelling of the extremities (edema),
- in very rare cases, kidney damage,
- in very rare cases, difficulty or inability to retain urine (enuresis, urinary incontinence),

- blood test result abnormalities:
  - decrease in the number of platelets (thrombocytopenia),
  - decrease in fibrinogen levels, prolonged bleeding time,
  - decrease in the number of red blood cells (anemia), increase in the volume of red blood cells (macrocytosis), decrease in the number of white blood cells (leukopenia, agranulocytosis),
  - in very rare cases, decrease in the numbers of all blood cells: white blood cells, red blood cells and platelets (pancytopenia),
  - reduced production of blood cells (bone marrow aplasia),
  - decrease in the amount of sodium in the blood (hyponatremia, syndrome of inappropriate antidiuretic hormone secretion),
  - increase in the amount of ammonium in the blood.
- 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.

Reporting side effects

If you have any side effects, immediately talk to your doctor, pharmacist or another health professional (e.g. a nurse). This includes side effects not listed in this leaflet.

By reporting side effects, you help improve knowledge about the safety of the medicine.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use DEPAKINE after the expiry date stated on the box.

The expiry date refers to the last day of that month.

Store at a temperature below 30°C in a dry place.

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.

What DEPAKINE 200 mg gastro-resistant tablets contain

The active substance is:

Sodium valproate..... 200 mg

for 1 gastro-resistant tablet.

The other ingredients are:

Povidone K 90, calcium silicate, talc, magnesium stearate, Povidone K 30, macrogol 400, corn starch, titanium dioxide (E171), cellulose acetate phthalate, diethyl phthalate.

What DEPAKINE 200 mg gastro-resistant tablets look like and contents of the pack

This medicine is supplied as gastro-resistant tablets. Boxes of 40.

Marketing Authorization Holder and Operating Company

sanofi-aventis France

75014 Paris – France

Manufacturer

sanofi-aventis, S.A.
Ctra. C-35 - La Batlloria a Hostalrich, Km 63,09
17404 - Riells i Viabrea (Gerona). Spain

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GENERAL ADVICE

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 of treatment 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.