

ENCORATE ENTERIC COATED TABLET

Sodium Valproate (200 mg)

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What Encorate is used for

It is used to treat epilepsy (fits) and to treat and prevent mania (a mental condition with episodes of overactivity, elation or irritability) associated with bipolar disorders (extreme mood swings).

How Encorate work

Encorate contains active ingredient sodium valproate, which belongs to a group of medicines called anti-convulsants or anti-epileptic agents. It works by stabilizing the abnormal electrical signals in the brain.

Before you use Encorate

– When you must not use it

Do not take this medicine if:

- you are allergic to sodium valproate or any other ingredients of this medicine (listed in Product Description)
- you are pregnant
- you are a woman able to have a baby. You must use an effective method of birth control (contraception) at all times during your treatment with sodium valproate. Do not stop taking sodium valproate or your contraception until you have discussed this with your doctor.
- you have liver problems or history or family history of liver problems
- you have a rare illness called porphyria (a rare inherited blood disorders).
- you have urea cycle disorder (a group of conditions where the process that moves urea through your body isn't working as it should)
- you have mitochondrial disorder (genetic disorders) (e.g. Alpers-Huttenlocher syndrome or in children under 2 years old that is suspected to have this disorder).

– Before you start to use it

WARNING FOR WOMEN AND GIRLS

This medicine can seriously harm an unborn baby

Always use effective contraception during treatment with sodium valproate

If you are thinking about becoming pregnant, or if you are pregnant, contact your doctor urgently.

You must CONTINUE taking sodium valproate unless your doctor tells you to stop

Pregnancy and lactation

Please tell your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

Sodium valproate is secreted into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breast feeding while you're taking Encorate.

If you are a woman able to have a baby you must not take sodium valproate unless you use an effective method of birth control (contraception) at all times during your treatment with sodium valproate.

Please tell your doctor if:

- you have an illness called "systemic lupus erythematosus (SLE)" - a disease of the immune system which affects skin, bones, joints and internal organs.
- you have impaired kidney function. Your doctor may want to monitor sodium valproate level or adjust your dose.
- you have a carnitine palmitoyltransferase type II deficiency (a condition that prevents the body from using certain fats for energy, particularly during periods without food) as it may increase the risk for breakdown of muscle tissue.

– Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription including herbal medicines.

The following medicines can increase the chance of you getting side effects, when taken with sodium valproate:

- Salicylates (medicines used in pain and inflammation), for example aspirin. Avoid the concomitant use of

salicylates in children under 3 due to the risk of liver toxicity.

- Other medicines used to treat fits (epilepsy). This includes phenobarbital, primidone, phenytoin, carbamazepine, rufinamide, topiramate, acetazolamide and lamotrigine.

Sodium valproate may increase the effect of the following medicines:

- Anticoagulants (e.g., warfarin).
- Zidovudine (used to treat HIV infection)
- Temozolomide (used to treat brain cancer.)
- Medicines used to treat depression, including Monoamine oxidase inhibitors (MAOIs)
- Olanzapine (medicines for mental problems)
- Nimodipine (used to decrease problems due to a certain type of bleeding in the brain).
- Propofol (used for anaesthesia). Tell your doctor that you are taking Encorate tablet if you are going for an operation.
- Benzodiazepines (used as sleeping tablets or to treat anxiety)

The following medicines can affect the way sodium valproate works:

- Oestrogen-containing products (including some birth control pills).
- Medicines used for the prevention and treatment of malaria such as mefloquine and chloroquine.
- Cimetidine (used for stomach ulcers).
- Protease inhibitors such as lopinavir and ritonavir – (used for HIV infection)
- Carbapenem (antibiotics) such as imipenem, meropenem, and panipenem. The combination of sodium valproate and carbapenems should be avoided because it may decrease the effect of your medicine.
- Rifampicin (used to treat tuberculosis).
- Erythromycin (antibiotic used for bacterial infections).
- Cholestyramine (used to lower cholesterol levels)

How to use Encorate

– How much to take

- Your doctor will decide how much Encorate to give
- When treatment is first started you may be prescribed a lower dose. Your doctor will increase the dosage until your condition is controlled.
- Take this medicine by mouth.

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Epilepsy (fits)

Adults

- The starting dose is 3 tablets (600mg) daily. Your doctor will gradually increase this dose by 1 tablet (200mg) every 3 days depending on your condition.
- The usual dose is between 5 tablets (1000mg) and 10 (2000mg) tablets to be taken each day.

Children over 20 kilograms (who can swallow tablets)

- The starting dose should be 2 (400mg) tablets daily. Your doctor will increase this dose depending on your child's illness.
- The usual dose will be calculated based on the child's weight.

In the elderly

Your doctor will determine your dose based on your seizure control.

People with kidney problem

Your doctor will adjust your dose based on your kidney function.

Combined therapy

If you are taking other medicines to control your epilepsy (phenytoin, phenobarbital, carbamazepine) together with sodium valproate, your doctor may increase the dose of sodium valproate, by 5 to 10 mg for each kg of body weight per day.

Treatment and prevention of mania associated with bipolar disorder

Starting dose is 5 tablets per day.

Your doctor will increase the dose until your condition is well controlled.

The usual maintenance dose is between 5 to 10 tablets every day.

When to take it

Take two times daily or as directed by your doctor or pharmacist. The tablets should be swallowed whole and cannot be crushed.

How long to take it

Take Encorate tablet for the duration that the doctor recommends.

Do not stop taking Encorate or alter your dose without checking with your doctor. If you stop taking the medicine without your doctor's advice, your condition may get worse.

If you forget to use it

If you miss a dose of this medicine, take it as soon as you remember. Take any remaining doses for that day at evenly spaced intervals. Do not take a double dose to make up for forgotten individual doses.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many Encorate tablets may cause nausea, vomiting and dizziness. Signs of massive overdose include slowing down of body's neurological functions or coma with decreased muscle tone, decreased reflex response, excessive constriction of the pupil, impaired respiratory function, build-up of acid in the body, reduced blood pressure and insufficient blood flow to the tissues of the body that may lead to shock.

While you are using Encorate

Things you must do

- Use your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are using Encorate.
- Take Encorate only with a doctor's prescription.
- Schedule an urgent appointment with your doctor if you want to become pregnant or if you think you are pregnant.
- If you are a parent or a caregiver of a female child treated with sodium valproate, you should contact their doctor once your child experiences their first period.
- Make sure you keep your regular check-up appointments. They are very important, as your dosage may need to be changed.

Things you must not do

- Do not use any new medicines without consulting your doctor or pharmacist.
- Do not give Encorate to anyone else, even if they have the same symptoms or condition as you.
- Continue taking sodium valproate or using your birth control (contraception) until you have discussed your pregnancy or your plan to get pregnant with your doctor.
- Alcohol intake is not recommended during treatment.

Things to be careful of

- If you or your child experience abdominal pain, nausea, vomiting and/or eating disorder after taking Encorate, please see your doctor immediately since it can be a symptom of pancreatitis that needs immediate medical attention.

- If you or your child have liver problems or develops a sudden illness, especially if it is within the first six months of treatment, and particularly if it includes repeated vomiting, extreme tiredness, abdominal pain, drowsiness, weakness, loss of appetite, nausea, jaundice (yellowing of the skin or whites of the eyes), swelling of the legs or a general feeling of being unwell, you should tell your doctor immediately.
- Your weight might increase as your appetite may be increased.
- Sodium valproate can seriously harm an unborn baby when taken during pregnancy.
- The higher the dose, the higher the risks but all doses carry a risk.
- It 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.
- If you take sodium valproate during pregnancy you have a higher risk than other women of having a child with birth defects that require medical treatment. Because sodium valproate has been used for many years it is known that in women who take sodium valproate around 10 babies in every 100 will have birth defects. This compares to 2-3 babies in every 100 born to women who don't have epilepsy.
- 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 sodium valproate and there is some evidence children may be more likely to develop symptoms of Attention Deficit Hyperactivity Disorder (ADHD).
- A small number of people being treated with anti-epileptics have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

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- As with other anti-epileptic medication, convulsions may become worse or happen more frequently while taking this medicine. If this happens contact your doctor immediately.
- Your doctor may wish to do blood tests before you start taking sodium valproate and during your treatment.
- Sodium valproate may give false positive readings in the urine testing of possible diabetics.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel drowsy, do not drive or use machines and contact your doctor immediately. The effect is more especially when you are also taking other antiepileptic medicine.

Side effects

Like all medicines, Encorate can have side effects, although not everybody gets them.

Contact a doctor immediately if you notice any of the following serious side effects. You may need urgent medical attention:

- Drowsiness, change in consciousness level (including coma), confusion, sluggishness or abnormal behavior and memory loss, associated or not with more frequent or more severe fits, particularly if phenobarbital and topiramate are taken at the same time or if Encorate dose has been suddenly increased.
- Confusion, that could be due to decreased levels of sodium in your blood or to a condition named "SIADH" or Syndrome of Inappropriate Antidiuretic Hormone secretion.
- Problems with balance and coordination, feeling lethargic or less alert, associated with vomiting. This may be due to increased amount of ammonia in your blood.
- An increase in the number and severity of convulsions
- Repeated vomiting, extreme tiredness, abdominal pain, drowsiness, weakness, loss of appetite, severe upper stomach pain, nausea, jaundice (yellowing of the skin or whites of the eyes), swelling of the legs or worsening of your epilepsy or a general feeling of being unwell. These may be signs of severe liver or pancreas disorders.
- Allergic reactions which may manifest 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 a rash, with sometimes flulike symptoms such as fever, chills or aching muscle - these may be signs of conditions named 'toxic epidermal necrolysis' or 'Stevens Johnson syndrome')
 - Skin rash or skin lesions with a pink/red ring and a pale center which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These may be signs of a condition named 'erythema multiforme'.
 - An allergy-triggered swelling with painful itchy welts (most often around the eyes, lips, throat and sometimes hands and feet) - these may be signs of "angioedema".
- Syndrome with skin rash, fever, lymph node enlargement and possible impairment of other organs - these may be signs of a condition named "DRESS" or Drug Rash with Eosinophilia and Systemic Symptoms.
- Spontaneous bruising or bleeding, due to blood clotting problems shown in blood tests
- Severe decrease of white blood cells or bone marrow failure shown in blood tests, sometimes revealed by fever and breathing difficulty
- Underactive thyroid gland, which may cause tiredness or weight gain (hypothyroidism)
- Joint pain, fever, fatigue, rash. These may be signs of systemic lupus erythematosus.
- Shakiness (tremor), uncontrollable muscle contractions, unsteadiness when walking (parkinsonism, extrapyramidal disorder, ataxia)
- Muscle pain and muscle weakness (rhabdomyolysis)
- Breathing difficulty and pain due to inflammation of the envelop of the lungs (pleural effusion)
- Kidney disease (renal failure, tubulointerstitial nephritis) which may manifest as reduced urinary output
- Passing a lot of urine and feeling thirsty (Fanconi syndrome)

Tell your doctor or pharmacist if any of the following side effects get serious or last longer than a few days; you may need medical treatment:

- decreased platelet count or decreased red blood cell count or abnormally increased red blood cell size, or bone marrow disorders (shown in blood tests)
- reduced body levels of vitamin B8 (biotin deficiency)
- headache
- rapid, uncontrollable movements of the eyes
- dizziness
- tingling or numbness of the hands or feet
- double vision
- hearing problems or deafness,
- vomiting, nausea or stomach ache, diarrhoea especially when starting the treatment
- gingival problems (mainly hypertrophia)
- sore mouth, swollen mouth, mouth ulcers and burning feeling of mouth (stomatitis)
- bedwetting or increased need to pass urine, urinary incontinence (unintentional passing of urine)
- skin reactions such as rashes
- transient hair loss, abnormal hair growth, abnormal hair texture,
- changes in hair color, nail and nail bed disorders, darker areas of skin and mucosae (hyperpigmentation).
- excessive hairiness, particularly in women, virilism, acne (hyperandrogenism)
- irregular or absence of women's period, pain during women's period, cysts in the ovaries (polycystic ovaries)
- male infertility (may be reversible after dose reduction or discontinuation)
- weight gain, obesity
- decrease in carnitine levels (shown in blood or muscular

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tests)

- inflammation of small blood vessels (vasculitis)
- decrease in body temperature
- swelling of the feet and legs (oedema)
- aggression, agitation, disturbance in attention, abnormal behavior and psychomotor hyperactivity
- learning disorder
- seeing, feeling or hearing things that are not there (hallucinations)
- memory impairment and
- cognitive disorders

There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term antiepileptic medication, have a history of osteoporosis, or take steroids.

Additional side effects in children

Some side effects of valproate occur more frequently in children or are more severe compared to adults. These include liver damage, inflammation of the pancreas (pancreatitis), aggression, agitation, disturbance in attention, abnormal behavior, hyperactivity and learning disorder

Tell your doctor if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Encorate

– Storage

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 blister after “EXP”. The expiry date refers to the last day of that month.

Store below 30°C in dry place, protected from light. Do not use this medicine if you notice any damage or signs of tampering to the pack.

– Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

– What it looks like

A pink coloured, circular, biconvex enteric coated tablet, plain on both sides.

– Ingredients

Active ingredient: Sodium Valproate

Inactive ingredients:

Colloidal Anhydrous Silica, Microcrystalline Cellulose, Starch, Polyvinyl Pyrrolidone K-30, Calcium Silicate, Magnesium Stearate, Purified Talc, Sodium Starch Glycollate, Colloidal Silicon Dioxide, Hypromellose 2910, Dibutyl Phthalate, Methacrylic Acid Copolymer, Type C, Titanium Dioxide, Sunset Yellow FCF Lake, Ponceau 4R Lake.

– MAL Number:

MAL10070549AZ

Manufacturer

Sun Pharma Laboratories Limited,
6-9, EPIP, Kartholi, Bari Brahmana,
Jammu 181 133 (J&K), India

Product Registration Holder

Ranbaxy (Malaysia) Sdn Bhd
Lot 23, Bakar Arang Industrial Estate
08000 Sungai Petani, Malaysia

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