

ENCORATE CHRONO TABLET

Sodium Valproate (200mg, 500mg)

What is in this leaflet

1. What *Encorate Chrono* is used for
2. How *Encorate Chrono* works
3. Before you use *Encorate Chrono*
4. How to use *Encorate Chrono*
5. While you are using it
6. Side effects
7. Storage and Disposal of *Encorate Chrono*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *Encorate Chrono* is used for

Encorate Chrono is a medicine used for the treatment of epilepsy in adults and children.

Epilepsy is a condition where you have repeated seizures (fits).

Encorate Chrono is also used for treatment and prevention of mania, a mental condition with episodes of overactivity, elation or irritability associated with bipolar disorder (extreme mood swings ranging from episodes of depression to mania).

How *Encorate Chrono* works

Encorate Chrono contains sodium valproate. It belongs to a group of medicines called anti-convulsants or anti-epileptic agents. These medicines are thought to work by controlling brain chemicals which send signals to nerves.

Before you use *Encorate Chrono*

– *When you must not use it*

Do not take *Encorate Chrono* if:

- You are allergic (hypersensitive) to sodium valproate or any of the other ingredients of *Encorate Chrono*.
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have liver problems such as acute or chronic hepatitis
- You or your family have a history of liver problems especially when caused by medicines
- You have porphyria which is a rare blood disease

Pregnancy and lactation

If you are a female patient of childbearing age, make sure that you talk to your doctor about the risks associated with taking *Encorate Chrono* during pregnancy.

Tell your doctor if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Sodium Valproate *Encorate Chrono* may affect your developing baby if taken in the first trimester of pregnancy, as it is suspected of causing an increased risk of malformations in the exposed foetus. However, do not stop taking your medication unless your doctor says so as there are risks to the mother and child from uncontrolled epilepsy.

Your doctor may want to adapt your treatment and/or prescribe dietary supplements of folate.

Your doctor will discuss the risks and benefits of taking it if you are pregnant.

Tell your doctor if you are breastfeeding or planning to breastfeed.

Medicines used in the treatment of epilepsy, including *Encorate Chrono*, pass into breast milk. Your doctor will discuss the risks and benefits of taking it if you are breastfeeding or planning to breastfeed.

– *Before you start use it*

Tell your doctor if you have or have had any medical conditions, including:

- liver problems (hepatic insufficiency, hepatic damage)
- pancreas problem
- bleeding disorder
- kidney problem
- systemic lupus erythematosus (a disease affecting the skin, joints and kidneys)
- urea cycle disorders (where too much ammonia builds up in the body)

There have been cases of people being treated with Sodium Valproate have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

– *Taking other medicines*

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

Encorate Chrono should be given with caution with the following medicines:

- neuroleptic agents (medicines used to treat schizophrenia)
- medicines used to treat depression e.g. monoamine oxidase inhibitors (MAOIs)
- antidepressant (medicines used for depression)
- benzodiazepines (medicines used as sedatives or to treat anxiety)
- other medicines used to treat epilepsy such as Phenobarbital, Phenytoin, Primidone, carbamazepine, Lamotrigine, Felbamate
- Zidovudine (a medicine used to treat viral infections)
- Mefloquine (a medicine used to treat malaria)
- Aspirin (medicine for blood thinning)
- medicines used to prevent clots (anticoagulants)
- Cimetidine (used to treat stomach ulcers)
- Erythromycin, medicine used to treat infection

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking medication.

How to use *Encorate Chrono*

– *How much to use*

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

In children

Usual dosage is about 30mg/kg per day. Your doctor will tell you how much to take. This may depend on your age,

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your condition and whether or not you are taking any other medicines.

Your doctor may recommend that you start with a low dose of *Encorate Chrono* and slowly increase the dose to the lowest amount needed to control your condition.

In adults

Usual dosage is within the range 20-30 mg/kg per day.

Recommended Initial Dose: 1000 mg/day.

The recommended maintenance dosage for treatment of bipolar disorder is 1000-2000 mg daily.

In elderly

Although the pharmacokinetics of Encorate are modified, they have limited clinical significance and dosage should be determined by seizure control.

– When to use it

Use as directed by your doctor or pharmacist.

Encorate Chrono tablets should be swallowed whole and not chewed or crushed.

– How long to use it

Continue taking *Encorate Chrono* for as long as your doctor recommends.

– If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

– If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken 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 tablets may cause nausea, vomiting, dizziness, diarrhoea, deep coma and death.

While you are using it

– Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking *Encorate Chrono*.

Tell your doctor immediately if you become pregnant while taking this medication.

– Things you must not do

Encorate Chrono may cause severe skin reactions. Symptoms may include skin rash, blisters and peel off. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Encorate Chrono* to anyone else, even if they have the same symptoms or condition as you.

– Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, *Encorate Chrono* can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

The side effect include:

- Rare cases of liver dysfunction
- Congenital abnormalities
- Neurological disorder such as stupor, lethargy, coma.

- Confusion
- Very rare cases of reversible dementia
- Hair loss
- Fine postural tremor
- Somnolence
- Haematologic side effects
- Vasculitis (inflammation of a blood vessel or blood vessels)
- Hyperammonemia (excess of ammonia in the blood)
- Weight gain
- Hearing loss
- Reversible Fanconi's syndrome (kidney disease)
- Digestive disorders (nausea, gastralgia)
- Nausea, dizziness
- Bleeding disorder
- Pancreatitis
- Cutaneous reactions such as toxic epidermal necrolysis, steven johnson syndrome, erythema multiforme

Tell your Doctor immediately or go to the Accident and Emergency department of your nearest hospital if you have any thoughts of harming yourself or committing suicide.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following side effects.

The following side effects may be signs of problems with your liver or pancreas such as:

- Asthenia (weakness)
- Anorexia (eating disorder)
- Lethargy
- Drowsiness
- Vomiting
- Abdominal pain
- Nausea

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website

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portal.bpfk.gov.my

(Consumers

→Reporting).

– *MAL number(s):*

Encorate Chrono 200mg Tablet

MAL20040827A

Storage and Disposal of *Encorate Chrono*

– *Storage*

Keep out of the reach and sight of children.

Store below 25°C.

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

– *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*

Encorate Chrono 200mg Tablet

An orange coloured, circular, double radius, biconvex film coated tablet with no marking on both sides.

Encorate Chrono 500mg Tablet

An orange coloured, caplet shaped film coated tablet with no marking on both sides.

– *Ingredients*

Active ingredients

Sodium Valproate

Valproic Acid

Inactive ingredients

Colloidal Silicon Dioxide, Polyethylene Glycol, Purified Talc, Titanium Dioxide, Starch, Isopropyl Alcohol, Sunset yellow lake FCF, Eudragit E100, Hydroxypropyl Methyl Cellulose 2208, Acetone, Sodium Lauryl Sulphate and Magnesium Stearate.

Encorate Chrono 500mg Tablet

MAL20040828A

Manufacturer

Sun Pharmaceutical Industries Limited

Survey No. 214,

Government Industrial Area, Phase II,

Silvassa-396 230.

INDIA

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.

Lot 5979, Jalan Teratai,

5 ½ Mile Off Jalan Meru,

41050 Klang, Selangor

MALAYSIA

Date of revision

28/01/2016

Serial Number

BPFK(R4/1)260116/00017