PATIENT INFORMATION LEAFLET
VALPIN-200 MG) SODIUM VALPROATE TABLETS BP 200 MG
(Sodium Valproate)

Read all of this leaflet carefully before you start using this medicine.
Keep this leaflet. You may need to read it again.
If you have any further questions, ask your doctor, health care provider or pharmacist.
This medicine has been prescribed for you. 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

WHAT IS IN THIS LEAFLET:

1. WHAT VALPIN-200 MG TABLETS IS AND WHAT IT IS USED FOR

It contains the active substance sodium valproate. It belongs to a group of medicines called anti-convulsants or anti-epileptic agents. It works by helping to calm the brain down. It is indicated for the treatment of generalized, partial or other epilepsy.

2. BEFORE YOU USE VALPIN-200 MG

If you are allergic to sodium valproate or any of the other ingredients. It is contraindicated in the following situations: In pregnancy unless there is no suitable alternative treatment, in women of childbearing potential unless the conditions of the pregnancy prevention programme are fulfilled, active liver disease. Personal or family history of severe hepatic dysfunction, especially drug related. Patients with known urea cycle disorders hypersensitivity to sodium valproate, porphyria, and valproate is contraindicated in patients. Alpers-Huttenlocher Syndrome known to have mitochondrial disorders.

Warnings and precautions

Tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration. In particular, tell your doctor: Although there is no specific evidence of sudden recurrence of underlying symptoms for withdrawal of sodium valproate. This is due to the possibility of sudden alterations in plasma concentrations giving rise to a recurrence of symptoms. It advised by health professionals, the generic switching of valproate preparations is not normally recommended due to the implications of possible variations in plasma concentrations.

Patient should take special cautions:

Sodium valproate has widespread metabolic effects and monitoring of liver function tests and full blood count is essential.

Female children, women of childbearing potential and pregnant women: pregnancy prevention programme: It is contraindicated in the pregnancy and in women of childbearing potential. Conditions: The prescriber must ensure that: Female children: The parents/caregivers of female

children understand the need to contact the specialist once. Pregnancy planning: Pregnancy must be excluded before start of treatment with sodium valproate with the result of a pregnancy test confirmed by your physician.

Contraception: patients must use an effective method of birth control during your entire treatment. Oestrogen-containing products may lower valproate levels in your blood. Aggravated convulsions: An increase in the number and severity of convulsions. The patients should be advised to consult their physician immediately. Patients should be monitored for signs of suicidal ideation and behaviors and appropriate treatment should be considered. Caregivers of patients should be advised to physician, should signs of suicidal ideation or behaviour emerge. The concomitant use of valproate and carbapenem agents is not recommended. Patients with known or suspected mitochondrial disease.

Patient should take precautions: Hematological tests, renal insufficiency: Blood tests may wish to do blood tests before you start the treatment and during your treatment. Renal function test should be performed. Patients with systemic lupus erythematosus. Urea cycle disorders where too much ammonia builds up in the body hyperammonaemia with sodium valproate. Weight gain: very commonly causes weight gain, which may be marked and progressive. Patients should be warned of the risk of weight gain at the initiation of therapy and appropriate strategies should be adopted to minimise it. Diabetic patients: It is eliminated mainly through the kidneys, partly in the form of ketone bodies this may give false positives in the urine testing of possible diabetics. Patients with an underlying carnitine palmitoyl transferase type II deficiency should be warned of the greater risk of rhabdomyolysis when taking Sodium valproate.

Taking other medicines:

Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines. Tell your doctor if you are taking any of the following medicines: antipsychotics, MAO inhibitors, antidepressants and benzodiazepines may potentiate the effect (olanzapine, primidone, lamotrigine, propofol, zidovudine, nimodipine, temozolomide) Phenytoin, anti-malarial agents: mefloquine and chloroquine, vitamin K-dependent factor anticoagulants, carbapenem antibiotics, rifampicin may decrease the valproic acid blood levels resulting in a lack of therapeutic effect. Therefore, valproate dosage adjustment may be necessary when it is co-administered with rifampicin. Protease inhibitors: such as lopinavir and ritonavir decrease valproate plasma level when co-administered. Cholestyramine may lead to a decrease in plasma level of valproate when co-administered. Oestrogen-containing products, including hormonal contraceptives, concomitant use of valproate and topiramate or acetazolamide associated with encephalopathy and hyperammonaemia. Co-administration of sodium valproate and quetiapine may increase the risk of neutropenia/leucopenia. If you have any further questions about this you should speak to your doctor.

Taking Valpin-200 mg with food and drink: This medicine can be taken with food or after food or as directed by physician. Alcohol intake is not recommended during treatment.

Pregnancy and Lactation:

Pregnancy: It is contraindicated as treatment for epilepsy during pregnancy unless there is no suitable alternative to treat epilepsy. It should not be used during pregnancy and women of childbearing potential unless the conditions of the pregnancy prevention programme are fulfilled.

Lactation: It is excreted in breast milk in small amount 1-10% serum concentration. It is not known what effect this would have on a nursing infant. Therefore, it should not recommended while lactation.

Driving and using machines: Patients should be counselled when taking this medicine. If this happens to you, do not drive or use any tools or machines. Taking other medicines used to treat fits or calm emotional and mental health problems may increase sleepiness.

3. HOW TO USE VALPIN-200 MG

Always use Valpin-200 mg exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

The tablets should be swallowed whole by mouth. Do not crush or chew the tablets. If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself but ask your doctor. It can be taken administered orally twice daily with or without meals or as directed by physician. Daily dosage requirements vary according to child, age and child's body weight.

Adults (including the elderly): The starting dose is 600 mg daily. Your doctor should gradually increase this dose by 200mg every 3 days depending on your condition. The usual dose is 1000-2000mg (20-30mg per kilogram of body weight) each day. This may be increased to 2500mg each day depending on your illness.

Children over 20 kilograms: The starting dose should be 400mg daily. Your doctor should increase this dose depending on your child's illness. The usual dose is then 20-30mg for each kilogram of body weight each day. This may be further increased to 35mg for each kilogram of body weight each day depending on your child's illness.

Children under 20 kilograms: The usual dose is 20 mg for each kilogram of body weight each day. Depending on the child's condition your child's doctor may decide to increase this dose.

Patients with kidney problems: It may be necessary to decrease the dosage. Dosage should be adjusted according to clinical monitoring since monitoring of plasma concentrations may be misleading. Your doctor may decide to adjust your or your child's dose.

In patients with hepatic insufficiency: salicylates should not be used concomitantly.

Patients taking other medicines for fits (epilepsy): You or your child may be taking other medicines for epilepsy at the same time as sodium valproate. If so, your doctor should gradually initiate treatment depending on your or your child's condition. Your doctor may increase the dose of sodium valproate by 5-10mg for each kilogram of body weight each day depending on which other medicines you are taking.

Female children and women of child bearing potential: It must be initiated and supervised by a specialist experienced in the management of epilepsy. It should not be used in female children and women of childbearing potential unless other treatments are ineffective or not tolerated. It is prescribed and dispensed according to the valproate pregnancy prevention programme the benefits and risks should be carefully reconsidered at regular treatment reviews. It should preferably be prescribed as monotherapy and at the lowest effective dose, if possible as a prolonged release formulation. The daily dose should be divided into at least two single doses. Combined Therapy: When starting sodium valproate in patients already on other anti-consultant, these should be tapered slowly initiation of sodium valproate therapy should then be gradual, with target dose being reached after about 2 weeks.

Newborn: In children requiring doses higher than 40 mg/kg/day clinical chemistry and hematological parameters should be monitored. Optimum dosage is mainly determined by seizure control and routine measurement of plasma levels is unnecessary.

Salicylates should not be used in children under 16 years on (Reye's syndrome). In addition in conjunction with sodium valproate, concomitant use in children under 3 years can increase the risk of liver toxicity.

If you take more Valpin-200 mg than you should: If you take more than the prescribed dose of Valpin-200 mg tablets, contact your doctor or nearest hospital emergency department immediately. Some of the signs of an overdose could be feeling sick or being sick, pupils of the eye become smaller, dizziness, loss of consciousness, weak muscles and poor reflexes, breathing problems, headaches, fits, confusion, memory loss and unusual or inappropriate behavior. Take the Valpin-200 mg tablets box / container with you when you go to the doctor or hospital.

If you forget to take Valpin-200 mg: If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Valpin-200 mg: Do not stop until your doctor tells you to do so. Do not stop taking Valpin-200 mg just because you feel better. If you stop your fits may come back. Although there is no specific evidence of sudden recurrence of underlying symptoms following withdrawal of valproate, discontinuation should normally only be done under the supervision of a specialist in a gradual manner. This is due to the possibility of sudden alterations in plasma concentrations giving rise to a recurrence of symptoms. NICE has advised that generic switching of valproate preparations is not normally recommended due to the clinical implications of possible variations in plasma concentrations. Tests: Make sure you or your child keep your regular appointments for a check-up. They are very important as your or your child's dose may need to be changed. Sodium valproate can change the levels of liver enzymes shown up in blood tests. This can mean that your or your child's liver is not working properly. If you or your child go into hospital or visit another doctor or a dentist, tell them you are taking Sodium valproate.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Valpin-200 mg can cause side effects, although not everybody gets them. Abdominal pain, agitation, alopecia, anaemia, behaviour abnormal, concentration impaired, confusion, deafness, diarrhea, drowsiness, haemorrhage, hallucination, headache, hepatic disorders, hyponatraemia, memory loss, menstrual cycle irregularities movement disorders, nail disorder, nausea, nystagmus, oral disorders, seizures, stupor ,thrombocytopenia, tremor urinary disorders, vomiting, weight increased. Androgenetic alopecia , angioedema, bone disorders, bone fracture and marrow disorders, coma, encephalopathy, hair changes, hypothermia, leucopenia, pancreatitis, paraesthesia, parkinsonism, peripheral oedema, pleural effusion, renal failure, vasculitis virilism, agranulocytosis, cerebral atrophy, cognitive disorder, dementia, diplopia, gynaecomastia, hyperammonaemia, hypothyroidism, infertility male, learning disability, myelodysplastic syndrome, nephritis, tubulointerstitial, polycystic ovaries, red blood cell abnormalities, rhabdomyolysis, severe cutaneous adverse reactions, systemic lupus erythematosus urine abnormalities. If any of above the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

5. HOW TO STORE VALPIN-200 MG

Keep out of the reach and sight of children. Do not store above 30°C. Protect form light and moisture. Store in the original carton. Do not use after the expiry date which is stated on the label carton after abbreviation used for expiry date. The expiry date refers to the last day of that month. Do not use if you notice description of the visible signs of deterioration any unused medicinal product or waste material should be disposed of in accordance with local requirements. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

The tablets containing the active ingredient, Sodium Valproate.

Each Enteric coated tablet contains: Sodium Valproate BP 200 mg.

The other ingredient(s) are: Colloidal Anhydrous Silica (Aerosil) BP, Microcrystalline Cellulose (PH 102) BP, Croscarmellose Sodium USP-NF, Hydroxy Propyl Cellulose (KLUCEL-LF) HIS, Methanol BP, Purified Talc BP, Magnesium Stearate BP, Isopropyl Alcohol (IPA) BP, Dichloromethane (Methylene Chloride) BP, Insta Moistshield (A21R01256), HPMC

2910/Hypromellose (USP, BP, IP, Ph. Eur.), Diethyl Phthalate (USP, BP, IP, Ph. Eur.), Ethyl Cellulose (USP, BP, IP, Ph. Eur.), Talc (USP, BP, IP, Ph. Eur.), Titanium Dioxide (USP, BP, IP, Ph. Eur.), Instacoat EN HPMC P (A34D00006), Hypromellose Phthalate (USP NF, BP, IP, Ph. Eur.)

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