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EPILIM® Chronosphere®

Sodium Valproate and Valproic Acid

Prolonged Release[1]

Helps make treating Epilepsy in children easier*

New controlled-release formulation[1]

***A pharmaceutical form particularly suitable for children and adults with swallowing difficulties[1,2]**

Epilim Chronosphere®
ABBREVIATED PRESCRIBING INFORMATION

PRESENTATION
Epilim Chronosphere Prolonged Release Granules: Sachets contain: 66.60mg sodium valproate and 29.03mg valproic acid equivalent to **100mg** sodium valproate; 166.76mg sodium valproate and 72.61mg valproic acid equivalent to **250mg** sodium valproate; 333.30mg sodium valproate and 145.14mg valproic acid equivalent to **500mg** sodium valproate; 500.06mg sodium valproate and 217.75mg valproic acid equivalent to **750mg** sodium valproate; 666.60mg sodium valproate and 290.27mg valproic acid equivalent to **1000mg** sodium valproate.

INDICATIONS
Treatment of generalised, partial or other epilepsy. Treatment and prevention of mania associated with bipolar disorders.

DOSAGE AND ADMINISTRATION
Dosage in Epilepsy: Initially 10-15 mg/kg/day. Titrate to 30mg/kg/day (children) or 20-30mg/kg/day (adults).
Dosage in Bipolar Disorder: Initially 20 mg/kg/day. Adjust according to individual response. Recommended daily dose 1,000 – 2,000mg (max 3,000mg).
May be given once or twice daily. Adjust dose in renal impairment and in the elderly.
Administration: Granules should be sprinkled on a small amount of **cold or room temperature** soft food or liquid. If taken in liquid, the glass should be rinsed afterwards with a small amount of water and this should be taken as well. Granules should not be crushed or chewed. A mixture of granules with soft food or liquid should not be stored for future use. Granules should **not be sprinkled on warm or hot foods or liquids**. Granules can be poured directly into the mouth and washed down with a cold liquid. Granules should not be given in babies' bottles as they can block the nipple. Valproic acid plasma levels should be considered when adequate seizure control is not achieved, or when adverse effects are suspected, [reported therapeutic level is 40-100 mg/L (300-700 µmol/L)].

CONTRAINDICATIONS
Active liver disease, family or personal history of severe hepatic dysfunction, especially drug related. Porphyria.

PRECAUTIONS
Hepatic dysfunction: liver function tests advised before therapy and during the first six months, especially in patients at risk or with a history of liver disease. Blood cell count, bleeding time and coagulation tests advised before therapy to avoid bleeding complications. Pancreatitis, especially in young children. Hyperammonaemia: metabolic tests advised before therapy in those at risk. Systemic lupus erythematosus. Risk of weight gain. Discontinuation should be done under the supervision of a specialist. Monotherapy is recommended in children under 3 years but risks should be considered. May cause false positives in urine testing for diabetes. Women of childbearing potential. Suicidal ideation and behaviour have been reported in patients treated with antiepileptic agents in several indications. Therefore patients should be monitored for signs of suicidal ideation and behaviours and advised to seek medical advice should signs emerge.

INTERACTIONS
Epilim affects the following drugs: antipsychotics, MAOIs, antidepressants, benzodiazepines, phenobarbital, primidone, phenytoin, carbamazepine, lamotrigine, zidovudine, vitamin K-dependent anticoagulants.
Drugs which affect Epilim: phenytoin, phenobarbital, carbamazepine, felbamate, mefloquine, chloroquine, highly protein bound agents (e.g. aspirin), cimetidine, erythromycin, carbapenem antibiotics, colestyramine.
Other interactions: Caution advised when using Epilim with newer anti-epileptics.

USE IN PREGNANCY AND LACTATION
Women of childbearing potential: should receive specialist neurological advice of the risks and benefits of continuing anti-epileptic medication throughout pregnancy. Anticonvulsant monotherapy is preferable in divided doses at lowest effective dose. Epilim should not be discontinued during pregnancy without assessment of the benefits versus risks.
Risk in the neonate: Rare reports of haemorrhagic syndrome (related to hypofibrinaemia) in neonates whose mothers received sodium valproate during their pregnancy. Afibrinaemia has also been reported and may be fatal. Neonatal platelet counts, fibrinogen plasma levels and coagulation status should be fully investigated.
Lactation: Epilim is excreted in breast milk in concentrations between 1 to 10%.

SIDE EFFECTS:
Occassional: congenital and familial/genetic disorders, transient GI disorders, sedation, dose-related ataxia, fine postural tremor, increased alertness, aggression, hyperactivity, hyperammonaemia, thrombocytopenia, transient hair loss, amenorrhoea, dysmenorrhoea, vasculitis, allergic reactions, increased weight.
Rare: hepato-biliary disorders, lethargy, confusion, stupor, hallucinations, convulsions, anaemia, leucopenia, pancytopenia, cutaneous reactions, hearing loss. Very rare: pancreatitis, encephalopathy, coma, reversible parkinsonism/dementia/cerebral atrophy, hyponatraemia, reduction in fibrinogen, reversible increase in bleeding time, spontaneous bruising or bleeding, toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme, gynaecomastia, reversible Fanconi's syndrome, enuresis, non-severe peripheral oedema.

PHARMACEUTICAL PRECAUTIONS: Do not store above 25°C.
PACK QUANTITY: 30 sachets
LEGAL CATEGORY: POM
MARKETING AUTHORISATION HOLDER: sanofi-aventis Ireland Ltd., Citywest Business Campus, Dublin 24.
MARKETING AUTHORISATION NUMBERS: PA 540/150/5 (100mg), PA 540/150/6 (250mg), PA 540/150/7 (500mg), PA 540/150/8 (750mg), PA 540/150/9 (1,000mg).
Further information is available from: sanofi-aventis Ireland Ltd., 18 Riverwalk, Citywest Business Campus, Dublin 24 or contact IEmedinfo@sanofi-aventis.com, Tel.: (01) 4035600. Please refer to the Summary of Product Characteristics which can be found on IPHA @ http://www.medicines.ie/ before prescribing. **Information about adverse event reporting can be found at www.imb.ie. Adverse events should be reported to the sanofi-aventis Drug Safety Department.**
Date of preparation: January 2009.

IE.EPI.09.03.03. **Date of preparation:** March 2009.

References
1. Epilim Chronosphere Summary of Product Characteristics December 2008 Available in Ireland in the strengths 100mg, 250mg, 500mg, 750mg & 1000mg
2. Motte J. et al. Arch Pediatr. 2005 Oct; 12(10):1533-9. Acceptability and safety of sodium valproate, a new prolonged-release granule formulation, in monotherapy for epileptic children from 3 years of age.

sanofi aventis
Because health matters

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Serdolect® now available in Ireland for the treatment of Schizophrenia*

Switch on power

Turn down weight gain, EPS & sedation [1-5]

Lundbeck

Serdolect®
sertindole

Abbreviated Prescribing Information: Please refer to the Summary of Product Characteristics before prescribing. **Name**: Serdolect® sertindole. **Presentation**: Film-coated Tablets of 4, 12, 16 or 20 mg. **Indication**: Treatment of schizophrenia. Due to cardiovascular safety concerns, sertindole should only be used for patients intolerant to at least one other antipsychotic agent. Not for urgent relief of symptoms in acutely disturbed patients. **Switching from other antipsychotics**: Treatment can be initiated according to the recommended titration schedule concomitantly with cessation of other oral antipsychotics, or in place of the next depot injection. **ECG monitoring**: Mandatory prior to and during treatment with Serdolect®. ECG monitoring should be conducted at baseline, upon reaching steady state after approximately 3 weeks or when reaching 16 mg and again after 3 months of treatment. An ECG is required every 3 months during maintenance therapy and if increasing the dose of Serdolect. **Dosage and administration**: Once daily with or without meals. In patients where sedation is required, a benzodiazepine may be co-administered. *Adults*: All patients should be started on sertindole 4 mg/day. The dose should be increased by increments of 4 mg after 4-5 days on each dose until the optimal daily maintenance dose within the range of 12-20 mg is reached. Only in exceptional cases should the maximum dose of 24mg be considered. Blood pressure should be monitored during titration and early maintenance treatment. *Elderly (> 65 years)*: Treatment should only be initiated after a thorough cardiovascular examination. Slower titration and lower maintenance doses may be appropriate. *Children and adolescents (< 18 years)*: Not recommended. *Reduced renal function*: Usual dosage. *Reduced hepatic function*: Patients with mild/moderate hepatic impairment require slower titration and a lower maintenance dose. **Re-titration**: Not required if patients have been without Serdolect® for less than a week. Otherwise the recommended titration schedule should be followed which includes taking of ECGs. **Contraindications**: Prescribing physicians should comply fully with the required safety measures. Hypersensitivity to sertindole or any of the excipients. Known uncorrected hypokalaemia or hypomagnesaemia. History of clinically significant cardiovascular disease, congestive heart failure, cardiac hypertrophy, arrhythmia, or bradycardia (<50 beats per minute). Congenital long QT syndrome (or family history of this disease), or known acquired QT interval prolongation. Severe hepatic impairment. *Drugs known to significantly prolong the QT interval*: e.g. class Ia and III antiarrhythmics, cisapride, lithium, some antipsychotics, macrolides, antihistamines and quinolone antibiotics. *Drugs known to potently inhibit hepatic cytochrome P450 3A enzymes*: e.g. 'azole' antifungal agents (systemic treatment), macrolide antibiotics, HIV protease inhibitors, calcium channel blockers and cimetidine. **Pregnancy & Lactation**: Not recommended **Driving and Operating machinery**: Avoid until individual susceptibility is known. Serdolect is not sedative. **Special precautions**: Caution may be required in patients who develop postural hypotension (monitoring), Neuroleptic malignant syndrome (drug discontinuation) and tardive dyskinesia (dose reduction or drug discontinuation). Mild/moderate hepatic dysfunction. Risk of significant electrolyte disturbances: e.g. electrolyte monitoring recommended in patients experiencing vomiting or diarrhoea, potassium depleting diuretic use. Parkinson's disease. Caution in elderly (>65 years) and those with risk factors for stroke. Known poor metabolisers of CYP2D6. History of seizures. Breast-feeding. Dopamine agonists. Caution with concomitant use of some SSRIs: e.g. fluoxetine, paroxetine (potent CYP2D6 inhibitors). Agents known to induce CYP isozymes: e.g. rifampicin, carbamazepine, phenytoin, phenobarbital. Gradual withdrawal is advisable. Caution is recommended in patients with intolerance to certain milk sugars. Clinical monitoring is advisable in diabetic patients or those with risk factors for diabetes. **Drug Interactions**: Caution required with concomitant use of drugs that prolong the QTc interval, CYP2D6 inhibitors, CYP3A inhibitors contraindicated. Concomitant use of CYP inducers may require dose adjustment. **Adverse events**: Very Common (≥1/10). Rhinitis/nasal congestion. Common (≥1/100, ≤1/10): Decreased ejaculatory volume, dizziness, dry mouth, postural hypotension, weight gain, peripheral oedema, dyspnoea, paraesthesia, and prolonged QT interval. **Overdose**: Symptoms have included somnolence, slurred speech, tachycardia, hypotension, and transient prolongation of the QTc interval. Cases of Torsade de Pointes (TdP) have been observed, often in combination with other drugs known to induce TdP. *Treatment*: There is no specific antidote to sertindole, and it is not dialysable, therefore appropriate supportive measures should be instituted. Adrenaline and dopamine should be used with caution (may worsen hypotension). Close medical supervision and monitoring should continue until patient recovers. **Legal Category**: POM. **Product Licence holder**: H. Lundbeck A/S, Ottiliavej 9, DK-2500, Copenhagen – Valby, Denmark. **PA Numbers**: 4 mg PA805/1/1; 12 mg PA805/1/3; 16 mg PA805/1/4; 20 mg PA805/1/5. Further information is available upon request from Lundbeck (Ireland) Ltd., 7 Riverwalk, Citywest Business Campus, Citywest, Dublin 24. 'Serdolect' is a trademark ™ Lundbeck Ltd. **Date of preparation**: October 2007.

References: 1. Azorin et al. Int Clin Psychopharmacol 2006; 21 49-56, 2. Hale et al. Int J Psych Pract 2000; 4:47-54, 3. Lublin et al. Int Clin Psychopharmacol 2005; 20: 183-98, 4. Perquin & Steinert. CNS Drugs 2004; 18 (Suppl 2) 19-30, 5. Lis et al. Eur Neuropsychopharmacol 2003; 13(Suppl 4): S323-54

SE3/05/07

*Serdolect should only be used for the treatment of patients who are intolerant to at least one other antipsychotic agent.