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Well being with bipolar disorder

NEW
Treatment and prevention of
mania associated with bipolar
disorders (Epilim Chrono only)



Epilim[®]
Sodium Valproate/Valproic Acid

Epilim[®] **ABBREVIATED PRESCRIBING INFORMATION. PRESENTATION** Epilim Enteric 200mg Gastro-resistant Coated Tablets and Epilim Enteric 500mg Gastro-resistant Coated Tablets: Enteric coated tablets containing 200 mg, and 500 mg sodium valproate, respectively. Epilim 100mg Crushable Tablets containing 100 mg sodium valproate. Epilim Syrup 200mg/5ml Oral Solution and Epilim Liquid 200mg/5ml Oral Solution (sugar free) both containing 200 mg sodium valproate per 5 ml. Epilim Chrono 200mg, Epilim Chrono 300mg, and Epilim Chrono 500mg Prolonged Release Tablets: Prolonged release tablets containing a mixture of sodium valproate and valproic acid equivalent to 200 mg, 300 mg and 500 mg sodium valproate respectively. Epilim Intravenous 400mg powder and solvent for solution for injection or infusion: 400mg sodium valproate freeze-dried powder per vial. **INDICATIONS** Treatment of generalised, partial or other epilepsy. Treatment and prevention of mania associated with bipolar disorders (Chrono only). Epilim IV – For short-term therapy, where oral treatment is not possible. **DOSE AND ADMINISTRATION Adults:** titrate until seizure control is achieved. Initially 600 mg/day increasing in steps of 200 mg at 3 day intervals to a maximum dose of 2500 mg/day (target dose range 20-30 mg/kg/day). **Children over 20 kg:** initially 400 mg/day increasing in steps to a maximum dose of 35 mg/kg/day (target dose range 20-30 mg/kg/day). **Children under 20 kg:** initially 20 mg/kg/day - the dose may be increased in severe cases provided that plasma levels are monitored; above 40mg/kg/day chemistry and haematology should be monitored. Epilim Chrono should not be used in this group of patients, due to the tablet size and need for dose titration. **Dosage in Bipolar Disorder (Epilim Chrono):** Initially 20 mg/kg/day. Adjust according to individual response. Recommended daily dose 1,000 – 2,000mg (max 3,000mg). **Epilim IV -** Patients already satisfactorily treated with Epilim may be continued at their current dosage using continuous or repeated infusion. Other patients may be given a slow intravenous injection over 3-5 minutes, usually 400-800mg depending on body weight (up to 10mg/kg) followed by continuous or repeated infusion up to a maximum of 2500 mg/day. Epilim IV should be replaced by oral Epilim therapy as soon as practicable. **Combination therapy:** levels of Epilim and co-administered anticonvulsants may be affected and optimum dosage is determined by seizure control. Adjust dose in renal impairment and in the elderly. **CONTRAINDICATIONS** Active liver disease, family or personal history of severe hepatic dysfunction, especially drug related. Porphyria. **PRECAUTIONS** Hepatic dysfunction: liver function tests are 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 are 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 benefits and risks should be considered. May cause false positives in urine testing for diabetes. Women of childbearing potential. **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** Occasional: 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:** Epilim is hygroscopic – keep tablets in blister pack until use and avoid cutting blister strips. Epilim Liquid should not be diluted. **PACK QUANTITY** Epilim Crushable, Enteric and Chrono Tablets: 100 Tablets. Epilim Syrup & Liquid: 300ml. Epilim Intravenous: 1 vial & 1 ampoule. **LEGAL CATEGORY:** POM. **MARKETING AUTHORISATION HOLDER** sanofi-aventis Ireland Ltd., Citywest Business Campus, Dublin 24. **MARKETING AUTHORISATION NUMBERS** Epilim 100mg Crushable Tablets – PA 540/150/1 Epilim 200 Enteric Tablets – PA 540/150/2 Epilim 500 Enteric Tablets – PA 540/150/3 Epilim Chrono 200mg – PA 540/150/10 Epilim Chrono 300mg – PA 540/150/11 Epilim Chrono 500mg – PA 540/150/12 Epilim Intravenous – PA 540/150/13 Epilim Liquid – PA 540/150/14 Epilim Syrup – PA 540/150/15 **Further information is available from** sanofi-aventis Ireland Ltd., 18 Riverwalk, Citywest Business Campus, Dublin 24 or contact Imedinfo@sanofi-aventis.com, Tel: (01) 4035600. Please refer to 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:** July 2008

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Reference: 1. Refer to Summary of Product Characteristics.



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References 1. Fawcett J, Barkin RL. *J Affect Disord* 1998;51(3):267-85.
2. Baker RA and Schutte AJ. Poster presented at American Psychiatric Association 156th Annual Meeting, May 17-22, 2003, San Francisco, USA.
3. Montejo AL *et al.* *J Clin Psychiatry*. 2001;62(Suppl 3):10-21.

Zispin SolTab 15mg, 30mg, 45mg (See SmPCs before Prescribing)
Presentation: Zispin SolTab 15mg, 30mg, 45mg Peel-to-open strips of 6 orodispersible tablets each containing 15, 30 or 45mg of mirtazapine, available in packs of 30 tablets. Zispin SolTabs also contain both sucrose and aspartame. **Uses:** Episode of major depression **Administration:** Zispin SolTab should be taken out of the strip with dry hands and should be placed on the tongue. The SolTab will rapidly disintegrate and can be swallowed with or without water. **Dosage: Adults and elderly:** The effective daily dose is usually between 15 and 45mg; the starting dose is 15 or 30 mg (the higher dose should be taken at night). Effects are usually seen after 1-2 weeks and, with an adequate dose, a positive response should result within 2-4 weeks. **Children:** Do not use in children or adolescents under 18 years (See Precautions and Warnings). The clearance of mirtazapine may be decreased in patients with renal or hepatic insufficiency. Zispin is suitable for once-a-day administration, preferably as a single night-time dose. Treatment should be continued until the patient has been completely symptom-free for 4-6 months after which treatment can be gradually discontinued. **Contraindications:** Hypersensitivity to mirtazapine or any ingredients of Zispin. **Precautions and warnings:** Bone marrow depression, usually presenting as agranulocytosis or granulocytopenia has been reported with Zispin. This mostly appears after 4-6 weeks and is generally reversible once treatment stops although, in very rare cases, agranulocytosis can be fatal. Reversible agranulocytosis has also been reported as a rare occurrence in clinical studies with Zispin. During post marketing with Zispin, very rare cases of agranulocytosis were reported, mostly reversible, but in some cases fatal. All fatal cases were over age 65. The physician should be alert to symptoms such as fever, sore throat, stomatitis or other signs of infection; if these occur, treatment should be stopped and blood counts taken. Patients should also be advised of the importance of these symptoms. Careful dosing, as well as regular and close monitoring, is necessary in patients with: epilepsy and organic brain syndrome; hepatic or renal insufficiency; cardiac diseases; low blood pressure. As with other antidepressants, care should be taken in

patients with: micturition disturbances, like prostate hypertrophy; acute narrow-angle glaucoma and increased intra-ocular pressure; diabetes mellitus. Treatment should be discontinued if jaundice occurs. As with other antidepressants, the following should be taken into account: worsening of psychotic symptoms can occur when antidepressants are administered to patients with schizophrenia or other psychotic disturbances; when the depressive phase of manic-depressive psychosis is being treated, it can transform into the manic phase. As for all therapies for depression, risk of suicide, suicidal thoughts and self harm may increase in the first few weeks of treatment. Zispin is not addictive, but abruptly stopping treatment may sometimes cause withdrawal symptoms such as dizziness, agitation, anxiety, nausea and headache. It is recommended that mirtazapine is stopped gradually. Elderly patients may be more sensitive to the undesirable effects of anti-depressants. Serotonin syndrome occurs very rarely. See SmPC for full details. Zispin may impair concentration and alertness. **Zispin should not be used in the treatment of children and adolescents under 18 years.** Suicide-related behaviours (suicide attempt and suicidal thoughts), and hostility (predominantly aggression, oppositional behaviour and anger) were more frequently observed in clinical trials among children and adolescents treated with antidepressants compared to those treated with placebo. If, based on clinical need, a decision to treat is nevertheless taken, the patient should be carefully monitored for the appearance of suicidal symptoms. In addition, long-term safety data in children and adolescents concerning growth, maturation and cognitive and behavioural development are lacking. **Interactions:** Caution is advised with potent CYP3A4 inhibitors, HIV protease inhibitors, azole antifungals, erythromycin or nefazodone. Higher doses may be needed with carbamazepine (or other inducers of hepatic metabolism (such as rifampicin)) and lower doses with cimetidine. Interactions may also occur with alcohol, benzodiazepines, other serotonergic drugs, warfarin and MAO inhibitors. **Pregnancy & Lactation:** Safety in human pregnancy has not been established. Use during pregnancy only if clearly needed. Use in nursing mothers, not recommended. **Adverse reactions:** The following

common adverse effects have been reported: Increase in appetite and weight gain. Oedema. Drowsiness/sedation, generally occurring during the first few weeks of treatment. (N.B. dose reduction generally does not lead to less sedation but can jeopardize antidepressant efficacy). Dizziness. Headache. Other less common and rarely reported side effects are listed in the SmPC. **Overdosage:** Present experience with Zispin alone indicates that symptoms are usually mild. Depression of the CNS with disorientation and prolonged sedation together with tachycardia and mild hyper- or hypotension have been reported. There is a possibility of more serious outcomes (including fatalities) at dosages much higher than the therapeutic dose, especially with mixed overdoses. Treat overdose with appropriate symptomatic and supportive therapy for vital functions. Consider activated charcoal or gastric lavage. **Legal Category:** Prescription Medicine. **Product Authorisation Numbers:** Zispin SolTab 15mg orodispersible tablet: PA 61/26/5, Zispin SolTab 30mg orodispersible tablet: PA 61/26/6, Zispin SolTab 45mg orodispersible tablet: PA 61/26/7. **Product Authorisation holder:** Zispin SolTab 15mg, 30mg and 45mg orodispersible tablet: Organon Ireland Limited, a part of Schering-Plough, P.O. Box 2857, Dnyam Road, Swords, Co. Dublin, Ireland. **Further information is available from:** Schering-Plough Ltd, Shire Park, Welwyn Garden City, Hertfordshire, AL7 1TW, UK. Telephone +44 (0)1707 363636. Date of revision of API: November 2008 Zispin API/IRL/11-08/1

Please refer to the full SPC text before prescribing this product. Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk (UK) and www.imb.ie (Ireland). Adverse events with this product should also be reported to Schering-Plough Drug Safety Department on +44 (0)1707 363773

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