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'Flower' Acrylics on board (21"x16")

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. **DOSAGE 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, gynecomastia, 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.

sanofi-aventis

Because health matters

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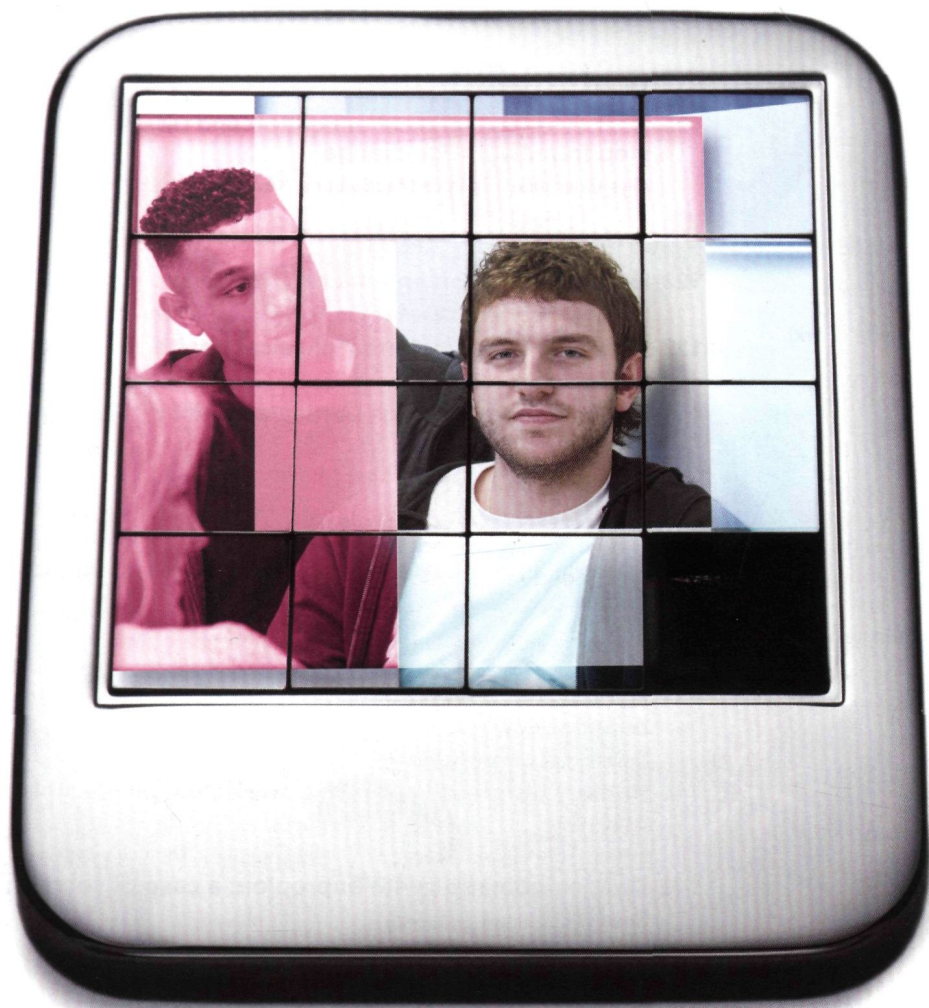
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NEW

Once Daily
Seroquel XR™
quetiapine



Putting the pieces in place

Reach recommended dose of **600mg** by **day 2***

- Simple once-daily dosing
- Proven efficacy and broad symptom improvement in schizophrenia¹

Seroquel XR™

*Refer to SPC. Elderly patients and patients with hepatic impairment should be started on 50mg/day. The dose can be increased in increments of 50mg/day to an effective dose depending on the clinical response and tolerability. 1. Kahn RS et al. Efficacy and tolerability of once daily extended release quetiapine fumarate in acute schizophrenia: A randomized, double-blind, placebo-controlled study. J Clin Psych 2007; 68: 832-842.

Seroquel XR® Abridged prescribing information

(For full details see summary of product characteristics) **Presentations:** Prolonged-release tablets containing 50mg, 200mg, 300mg and 400mg of quetiapine (as quetiapine fumarate). **Uses:** Treatment of schizophrenia and is effective in preventing relapse in stable schizophrenic patients who have been maintained on Seroquel XR. **Dosage and Administration:** Tablets should be administered once daily, without food (at least one hour before a meal) and should be swallowed whole. **Adults:** The daily dose at the start of therapy is 300mg on Day 1 and 600mg on Day 2 and up to 800mg after Day 2. The dose should be adjusted within the effective dose range of 400mg to 800mg per day depending on clinical response and tolerability. Recommended daily dose is 600mg daily. For maintenance therapy no dosage adjustment is necessary. **Elderly:** Rate of dose titration may need to be slower and daily therapeutic dose lower than in younger patients. Patients should be started on 50mg/day and can be increased in increments of 50mg/day to an effective dose. **Children & Adolescents:** Not evaluated. **Renal Impairment:** No dose adjustment required. **Hepatic Impairment:** Use with caution. Patients should be started on 50mg/day and can be increased in increments of 50mg/day to an effective dose. **Contraindications:** Hypersensitivity to quetiapine fumarate or excipients. Concomitant administration of cytochrome P450 3A4 inhibitors, such as HIV-protease inhibitors, azole-antifungal agents, erythromycin, clarithromycin and nefazodone. **Precautions and warnings:** Known cardiovascular disease (consider slower titration), cerebrovascular disease, or other conditions predisposing to hypotension. Possible initial orthostatic hypotension during the dose titration period. Caution is recommended in patients with a history of seizures. If signs and symptoms of tardive dyskinesia appear dose reduction or discontinuation should be considered. In the event of neuroleptic malignant syndrome discontinue treatment and appropriate medical treatment given. Hyperglycaemia or exacerbation of pre-existing diabetes has been reported in very rare cases – monitoring advised. QT prolongation was observed with overdose. As with other antipsychotics, caution should be exercised when quetiapine is prescribed in patients with cardiovascular disease or family history of QT prolongation, and when quetiapine is prescribed with medicines known to increase QTc interval and concomitant neuroleptics, especially in the elderly, in patients with congenital long QT syndrome, congestive heart failure, heart hypertrophy, hypokalaemia or hypomagnesaemia. Acute withdrawal symptoms such as nausea, vomiting and insomnia have been described after abrupt cessation of antipsychotic drugs including Seroquel. Gradual withdrawal is advisable. Not approved for the treatment of patients with dementia – related psychosis. Contains lactose, patients with rare hereditary problems of galactose intolerance, the lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Undesirable effects:** The most commonly reported Adverse Drug Reactions with quetiapine are somnolence, dizziness, dry mouth, mild asthenia, constipation, tachycardia, orthostatic hypotension and dyspepsia. As with other antipsychotics, weight gain, syncope, neuroleptic malignant syndrome, leucopenia, neutropenia and peripheral oedema, have been associated with quetiapine. For full list of undesirable effects refer to SPC. **Interactions:** Use with caution with other centrally acting drugs and alcohol. CYP3A4 inhibitors such as ketoconazole are contraindicated. Grapefruit juice, phenytoin, carbamazepine, thioridazine. Observe caution when used concomitantly with drugs known to cause electrolyte imbalance or to increase QTc interval. **Pregnancy & lactation:** Safety and efficacy not established. Effects on ability to drive: Patients should be advised not to drive or operate machinery until individual susceptibility is known. **Pharmaceutical precautions:** No special requirements. **Legal category:** POM. **S1A Marketing Authorisation Numbers:** Seroquel XR 50mg, 200mg, 300mg and 400mg PA 970/18/8-11 **Marketing Authorisation Holder(s):** AstraZeneca Pharmaceuticals (Ireland) Limited, College Park House, 20 Nassau Street, Dublin 2. Tel: 01 609 7100; Fax: 01 679 6650. **Further information on request from:** AstraZeneca Pharmaceuticals (Ireland) Limited, College Park House, 20 Nassau Street, Dublin 2. Tel: 01 609 7100; Fax: 01 679 6650. Abridged Prescribing Information prepared: February 2008. Date prepared: March 2008

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