Seroquel® Abridged Prescribing Information (for full details see summary of product characteristics)
Presentations: Film coated tablets containing 25mg, 100mg, 200mg and 300mg of quetiapine (as quetiapine fumarate). **Uses:** Treatment of schizophrenia and moderate to severe manic episode. **Dosage and Administration: Schizophrenia: Adults:** Initial titration from 50mg to 300mg over first 4 days. From day 4 onwards the dose should be titrated to the usual effective dose of 300-450 mg/day. Dose range 150 to 750 mg/day. **Bipolar disorder: Adults:** Initial titration from 100mg to 400mg over first 4 days. Dose range: 200-800 mg/day. **Elderly:** Rate of dose titration may need to be slower and daily therapeutic dose lower than in younger patients. **Children & Adolescents:** Not evaluated. **Renal Impairment:** No dose adjustment required. **Hepatic Impairment:** Use with caution. Patients should be started on 25 mg/day and increased by 25 – 50 mg/day until an effective dosage is achieved. **Contra-indications:** 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, 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. Hyperglycaemia or exacerbation of pre-existing diabetes has been reported in very rare cases. **Undesirable effects:** Mild asthenia, dizziness, somnolence, peripheral oedema,syncope, dry mouth, rhinitis, dyspepsia, constipation, leucopenia and tachycardia. Elevations in gamma-GT levels, non-fasting serum triglyceride levels and total cholesterol. Seroquel was associated with dose related decreases in thyroid hormone levels particularly total T_4 and free T_4. **Interactions:** Use with caution with other centrally acting drugs and alcohol. CYP3A4 inhibitors such as ketoconazole are contraindicated. Grapefruit juice, phenytoin, carbamazepine, thioridazine. **Pregnancy & lactation:** Safety and efficacy not established. **Effects on ability to drive:** Patients should be advised not to drive or operate machinery **Legal Category:** POM **Basic NHS Cost:** **Marketing Authorisation Numbers:** Seroquel 25 PA970/18/1, Seroquel 100 PA970/18/2, Seroquel 200 PA970/18/3, Seroquel 300 PA970/18/7) 4 Day starter pack (Schizophrenia) PA 970/18/5. **Product authorisation holder:** AstraZeneca Ltd., Horizon Place, 600 Capability Green, Luton Bedfordshire, LU1 3LU **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. **Date of Preparation:** January 2004

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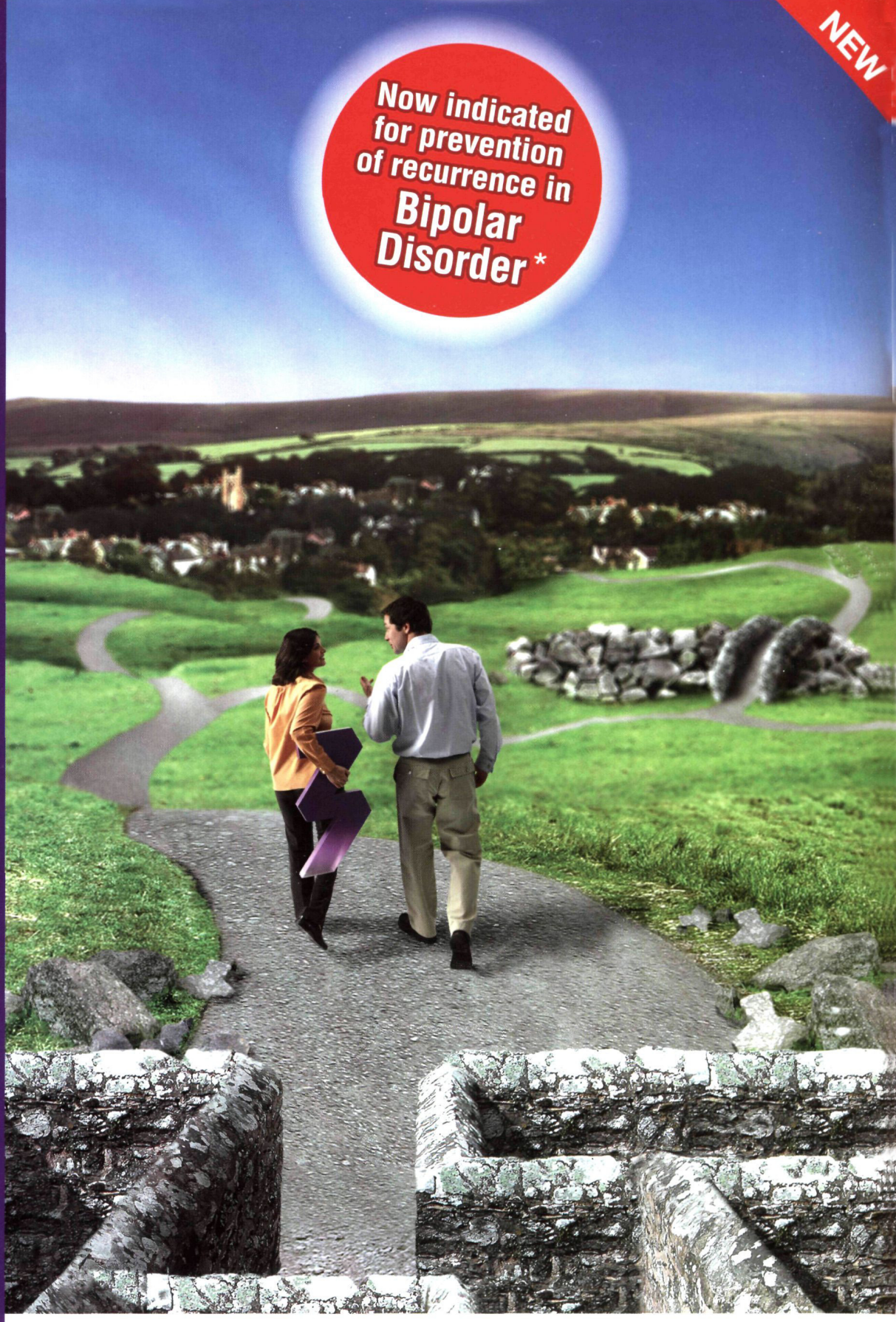

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