Prescribing Notes.
Consult Summary of Product Characteristics before prescribing.
Special reporting to the CSM required.

Use: Treatment of schizophrenia.

Presentation: Tablets containing 25 mg, 100 mg and 200 mg of quetiapine.

Dosage and Administration: 'Seroquel' should be administered twice daily. Adults: The total daily dose for the first 4 days of therapy is 50 mg (Day 1), 100 mg (Day 2), 200 mg (Day 3) and 300 mg (Day 4). From day 4 onwards, titrate to usual effective range of 300 to 450 mg/day. Dose may be adjusted within the range 150 to 750 mg/day according to clinical response and tolerability. Elderly patients: Use with caution, starting with 25 mg/day and increasing daily by 25 to 50 mg to an effective dose. Children and adolescents: Safety and efficacy not evaluated. Renal and hepatic impairment: Start with 25 mg/day increasing daily by 25 to 50 mg to an effective dose. Use with caution in patients with hepatic impairment.

Contra-indications: Hypersensitivity to any component of the product.

Precautions: Caution in patients with cardiovascular disease, cerebrovascular disease or other conditions predisposing to hypotension and patients with a history of seizures. Caution in combination with drugs known to prolong the QTc interval, especially in the elderly. Caution in combination with other centrally acting drugs and alcohol, and on co-administration with thioridazine, phenytoin or other hepatic enzyme inducers, potent inhibitors of CYP3A4 such as systemic ketoconazole or erythromycin. If signs and symptoms of tardive dyskinesia appear, consider dosage reduction or discontinuation of 'Seroquel'. In cases of neuroleptic malignant syndrome, discontinue 'Seroquel' and give appropriate medical treatment. 'Seroquel' should only be used during pregnancy if benefits justify the potential risks. Avoid breastfeeding whilst taking 'Seroquel'. Patients should be cautioned about operating hazardous machines, including motor vehicles.

Undesirable events: Somnolence, dizziness, constipation, postural hypotension, dry mouth, asthenia, rhinitis, dyspepsia, limited weight gain, orthostatic hypotension (associated with dizziness), tachycardia and in some patients syncope. Occasional seizures and rarely possible neuroleptic malignant syndrome. Transient leucopenia and/or neutropenia and occasionally eosinophilia. Asymptomatic, usually reversible elevations in serum transaminase or gamma - GT levels. Small elevations in non-fasting serum triglyceride levels and total cholesterol. Decreases in thyroid hormone levels, particularly total T4 and free T4 usually reversible on cessation. Prolongation of the QTc interval (in clinical trials this was not associated with a persistent increase).

Legal category: POM

Product licence numbers:

25 mg tablet: 12619/0112
100 mg tablet: 12619/0113
200 mg tablet: 12619/0114

Basic NHS cost:

Starter pack £6.59;
60 x 25 mg tablets £28.20;
60 x 100 mg tablets £113.10;
90 x 100 mg tablets £169.65;
60 x 200 mg tablets £113.10;
90 x 200 mg tablets £169.65.

'Seroquel' is a trademark, the property of **Zeneca Limited.**

ZENECA

Further information is available from: **ZENECA Pharma** on 0800 200 123 please ask for Medical Information, or write to King's Court, Water Lane, Wilmslow, Cheshire SK9 5AZ.

Email Address: Medical.Information@PharmaUK.Zeneca.com

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J0950 98/9860 Issued September 1998

Seroquel
quetiapine

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John has schizophrenia

Effective in negative and positive symptoms[1-4] and mood*[5] in patients with schizophrenia

EPS no different from placebo across the full dose range (150 - 750 mg/day)[1-4]

Plasma prolactin levels no different from placebo across the full dose range (150 - 750 mg/day)[6]

Low level of sexual dysfunction (3 patients out of 1085) in long term use (3-5 months)[6]

* Defined as the BPRS item score of depressive mood, anxiety, guilt feelings and tension.

Seroquel

'PROZAC' ABBREVIATED PRESCRIBING INFORMATION (FLUOXETINE HYDROCHLORIDE)

Presentation Capsules containing 20mg or 60mg fluoxetine, as the hydrochloride. Liquid containing 20mg fluoxetine, as the hydrochloride, per 5ml syrup. **Uses** *Depression:* TREATMENT OF THE SYMPTOMS OF DEPRESSIVE ILLNESS, WITH OR WITHOUT ASSOCIATED ANXIETY SYMPTOMS. *Obsessive-compulsive disorder. Bulimia nervosa:* For the reduction of binge-eating and purging activity. **Dosage and Administration** (For full information, see data sheet.) For oral administration toadults only. *Depression, with or without associated anxiety symptoms - adults and the elderly:* A dose of 20mg/day is recommended. *Obsessive-compulsive disorder:* 20mg/day to 60mg/day. A dose of 20mg/day is recommended as the initial dose. *Bulimia - adults and the elderly:* A dose of 60mg/day is recommended. Because of the long elimination half-lives of the parent drug (1-3 days after acute administration; may be prolonged to 4-6 days after chronic administration) and its major metabolite (average 9.3 days), active drug substance will persist in the body for several weeks after dosing is stopped. The capsule and liquid dosage forms are bioequivalent. *Children:* Not recommended. *Patients with renal and/or hepatic dysfunction:* See 'Contra-indications' and 'Precautions' sections. **Contra-indications** Hypersensitivity to fluoxetine. Prozac should not be administered to patients with severe renal failure (GFR <10ml/min). *Usage in nursing mothers:* Prozac should not be prescribed to nursing mothers. *Monoamine oxidase inhibitors:* At least 14 days should elapse between discontinuation of an MAOI and initiation of treatment with Prozac. At least five weeks should elapse between discontinuation of Prozac and initiation of therapy with an MAOI. Serious, sometimes fatal reactions (including hyperthermia, rigidity, myoclonus, autonomic instability and mental status changes that include extreme agitation, progressing to delirium and coma) have been reported with concomitant use or when fluoxetine had been recently discontinued and an MAOI started. Some cases presented with features resembling neuroleptic malignant syndrome. **Warnings** *Rash and allergic reactions:* Angioneurotic oedema, urticaria and other allergic reactions have been reported. Upon appearance of rash, or of other allergic phenomena for which an alternative aetiology cannot be identified, Prozac should be discontinued. *Pregnancy:* Use of Prozac should be avoided unless there is no safer alternative. **Precautions** Prozac should be discontinued in any patient who develops seizures. Prozac should be avoided in patients with unstable epilepsy; patients with controlled epilepsy should be carefully monitored. There have been rare reports of prolonged seizures in patients on fluoxetine receiving ECT treatment. A lower dose of Prozac, eg, alternate day dosing, is recommended in patients with significant hepatic dysfunction or mild to moderate renal failure (GFR 10-50ml/min). Caution is advisable when Prozac is used in patients with acute cardiac disease. Prozac may cause weight loss which may be undesirable in underweight depressed patients. In diabetics, fluoxetine may alter glycaemic control. There have been reports of abnormal bleeding in several patients, but causal relationship to fluoxetine and clinical importance are unclear. *Drug interactions:* Increased (with lithium toxicity) or decreased lithium levels have been reported. Lithium levels should be monitored. Because fluoxetine's metabolism involves the hepatic cytochrome P450IID6 isoenzyme system, concomitant therapy with other drugs also metabolised by this system, and which have a narrow therapeutic index (eg, carbamazepine, tricyclic antidepressants), should be initiated at or adjusted to the low end of their dose range. Greater than 2-fold increases of previously stable plasma levels of cyclic antidepressants have been observed when Prozac has been administered in combination. Agitation, restlessness and gastro-intestinal symptoms have been reported in a small number of patients receiving fluoxetine in combination with tryptophan. Patients on stable phenytoin doses have developed elevated plasma concentrations and clinical phenytoin toxicity after starting fluoxetine. *For further information, see data sheet.* **Adverse Effects** Asthenia, fever, nausea, diarrhoea, dry mouth, appetite loss, dyspepsia, vomiting, rarely abnormal LFTs, headache, nervousness, insomnia, drowsiness, anxiety, tremor, dizziness, fatigue, decreased libido, seizures, hypomania or mania, dyskinesia, movement disorders, neuroleptic malignant syndrome-like events, pharyngitis, dyspnoea, pulmonary events (including inflammatory processes and/or fibrosis), rash, urticaria, vasculitis, excessive sweating, arthralgia, myalgia, serum sickness, anaphylactoid reactions, hair loss, sexual dysfunction. The following have been reported in association with fluoxetine but no causal relationship has been established: aplastic anaemia, cerebral vascular accident, confusion, ecchymoses, eosinophilic pneumonia, gastro-intestinal haemorrhage, hyperprolactinaemia, immune-related haemolytic anaemia, pancreatitis, pancytopenia, suicidal ideation, thrombocytopenia, thrombocytopenic purpura, vaginal bleeding after drug withdrawal and violent behaviour. Hyponatraemia (including serum sodium below 110mmol/l) has been rarely reported. This appears to be reversible upon discontinuation. **Overdosage** On the evidence available, fluoxetine has a wide margin of safety in overdose. Since introduction, reports of death, attributed to overdosage of fluoxetine alone, have been extremely rare. One patient who reportedly took 3000mg of fluoxetine experienced 2 grand mal seizures that remitted spontaneously. **Legal Category** POM **Product Licence Numbers** 0006/0195, 0006/0198, 0006/0272. **Basic NHS Cost** £20.77 per pack of 30 capsules (20mg). £67.85 per pack of 98 capsules (20mg). £62.31 per pack of 30 capsules (60mg). £19.39 per 70ml bottle. **Date of Preparation or Last Review** October 1996 (internal review June 1998). **Full Prescribing Information is Available From** Dista Products Limited, Dextra Court, Chapel Hill, Basingstoke, Hampshire, RG21 5SY. Telephone: Basingstoke (01256) 353011.

PROZAC is a Dista trademark.

Date of preparation: July 1998

PROZAC DELIVERS

PROZAC *fluoxetine*

TREATING DEPRESSION WITH ASSOCIATED ANXIETY

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