

PRESCRIBING INFORMATION

'Seroxat'
paroxetine

Presentation: 'Seroxat' Tablets, PA 49/50/1-2, each containing either 20 mg or 30 mg paroxetine as the hydrochloride.

Uses: Treatment of symptoms of depressive illness of all types including depression accompanied by anxiety. Prevention of relapse and also recurrence of further depressive episodes. Treatment of symptoms and prevention of relapse of obsessive compulsive disorder (OCD). Treatment of symptoms of panic disorder with or without agoraphobia.

Dosage: Adults: Depression: 20 mg a day. Review response within two to three weeks and if necessary increase dose by 10 mg increments to a maximum of 50 mg according to response. Obsessive compulsive disorder and panic disorder: 40 mg daily. Start on 20 mg and increase weekly in 10 mg increments to a maximum of 60 mg daily according to response.

Possible worsening of panic symptoms during early treatment of panic disorder is recognised generally, thus low initial starting dose is recommended. Give once a day in the morning with food. The tablets should not be chewed. Continue treatment for a sufficient period, which may be several months for depression and possibly longer for OCD and panic disorder. **Elderly:** 20 mg a day increasing by increments of 10 mg up to 40 mg a day according to response. **Children:** Not recommended. Severe renal impairment (creatinine clearance <30 ml/min) or severe hepatic impairment: 20 mg a day. Restrict incremental dosage if required to lower end of range.

Contra-indications: Hypersensitivity to paroxetine and related drugs; use with MAO inhibitors; unstable epilepsy or convulsive disorders; severe renal failure.

Precautions: History of mania.

Cardiac conditions: caution. Caution in patients with controlled epilepsy (monitor carefully); stop treatment if seizures develop. Caution patients about driving and operating machinery.

Drug interactions: Do not use with or within two weeks after MAO inhibitors; leave a two-week gap before starting MAO inhibitor treatment. Possibility of interaction with tryptophan. Great caution with warfarin and other oral anticoagulants. Use lower doses if given with drug metabolising enzyme inhibitors; adjust dosage if necessary with drug metabolising enzyme inducers.

Combination with other highly protein bound drugs may alter plasma levels of either. Alcohol is not advised. Care with other CNS active drugs. Keep dosage of concomitant benzodiazepines low. Use lithium with caution and monitor lithium levels. Increased adverse events with phenytoin; similar possibility with anticonvulsants.

Pregnancy and lactation: Use in pregnancy only if essential and avoid during lactation.

Adverse reactions: Most commonly nausea, somnolence, sweating, tremor, asthenia, dry mouth, insomnia, sexual dysfunction, dizziness, constipation, diarrhoea, decreased appetite.

Spontaneous reports of dizziness, headache, vomiting, diarrhoea, restlessness, hallucinations, hypomania, rash. As with other SSRIs, postural hypotension, hypotension, hypertension, tachycardia, arrhythmias (rare). Rarely extrapyramidal reactions, hyponatraemia (possible SIADH), transient liver function abnormality. Abrupt discontinuation may cause dizziness, sensory disturbance, agitation, anxiety, nausea and sweating.

Product authorisation holder:

SmithKline Beecham Pharmaceuticals Ltd. Corrig Avenue, Dun Laoghaire, Co. Dublin.

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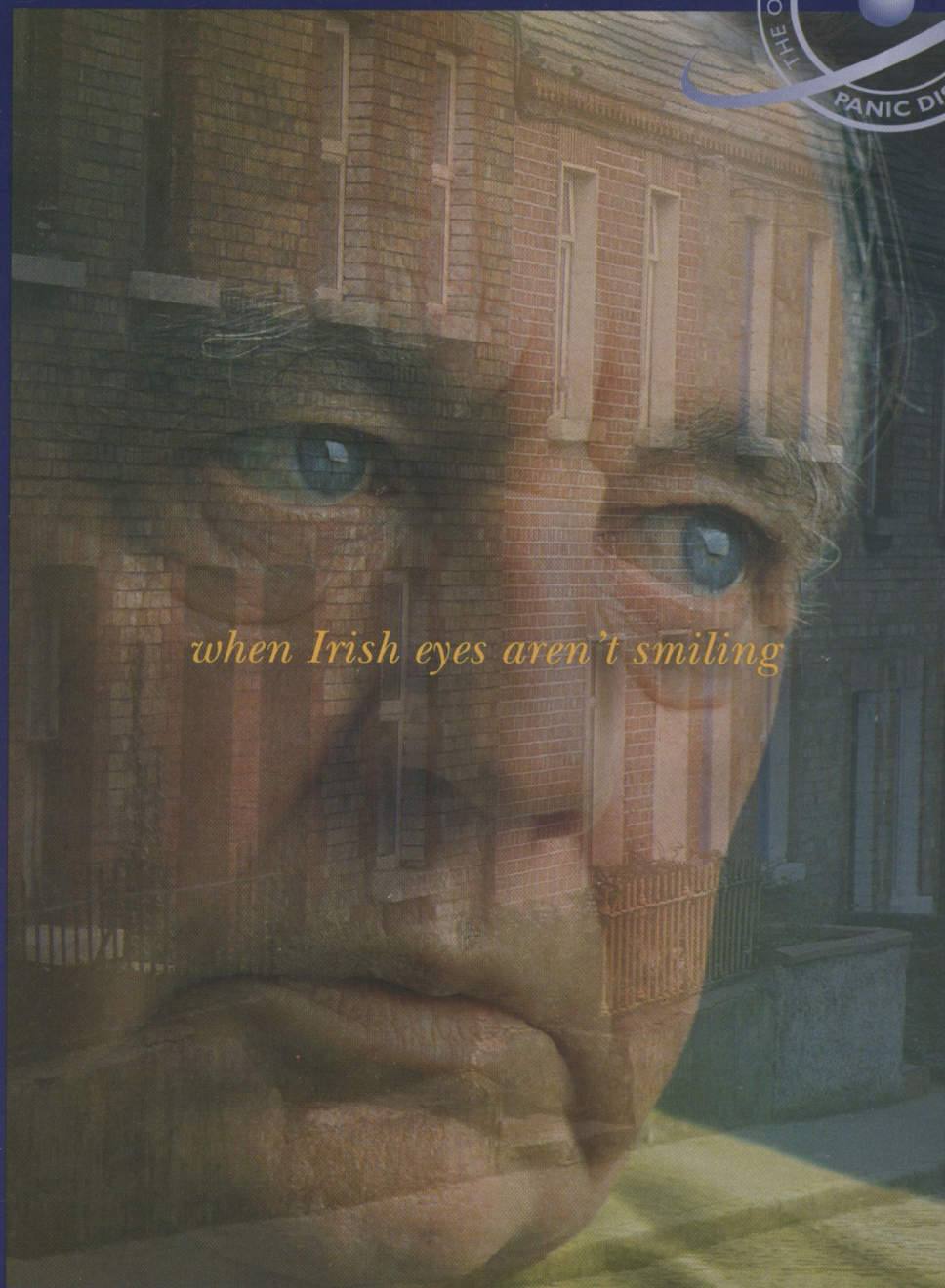
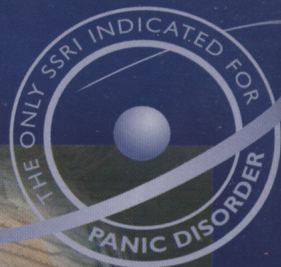
References

1. Paykel ES, Priest RG. *BMJ* 1992;305:1198-202.
2. Medicines Resource Centre. *Int Pharm J* 1992;6(1):6-9.
3. Dunbar GC, Fuell DL. *Int Clin Psychopharmacol* 1992;6(Suppl 4):81-90.

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when Irish eyes aren't smiling

*anxious. agitated. can't sleep.
 he's depressed.*

SEROXAT
 paroxetine

Effectively treats depression and relieves associated anxiety