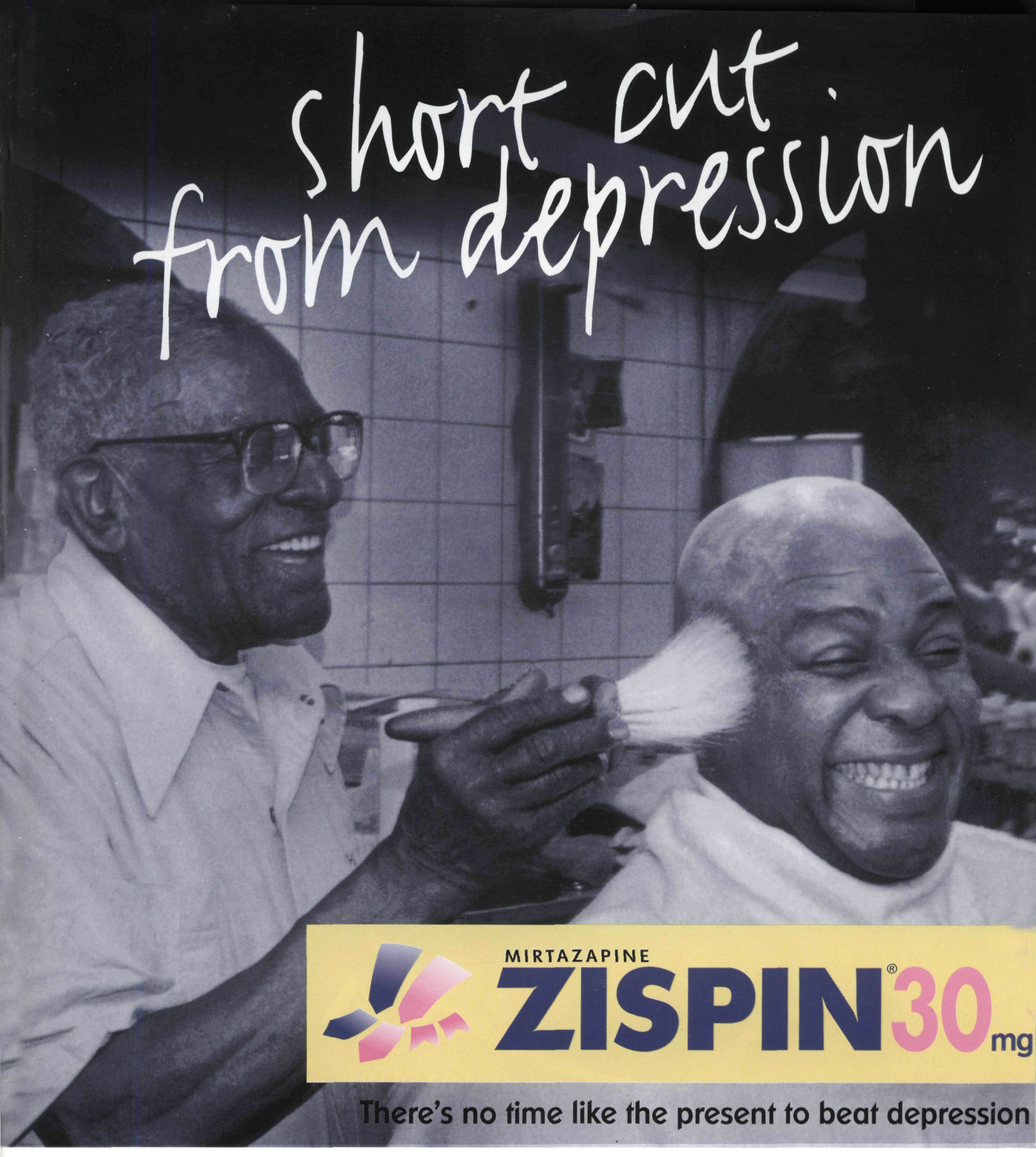





**ZISPIN Prescribing Information**

**Presentation** Blister strips of 28 tablets each containing 30mg of mirtazapine. **Uses** Episode of major depression. **Dosage and administration** The tablets should be taken orally, if necessary with fluid, and swallowed without chewing. **Adults and elderly** The effective daily dose is usually between 15 and 45mg. **Children** Not recommended. 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. **Contraindications** Hypersensitivity to mirtazapine. **Precautions and warnings** Bone marrow depression, usually presenting as granulocytopenia or agranulocytosis, has been reported during treatment with most antidepressants. The physician should be alert to symptoms like fever, sore throat, stomatitis or other signs of infection; when such symptoms occur, treatment should be stopped and blood counts taken. Careful dosing as well as regular and close monitoring is necessary in patients with: epilepsy and organic brain syndrome; hepatic or renal insufficiency; cardiac disease; low blood pressure. Like with other antidepressants care should be taken in patients with: micturition disturbances like prostate hypertrophy, acute narrow-angle glaucoma and increased intra-ocular pressure and diabetes mellitus. Treatment should be discontinued if jaundice occurs. Moreover, like 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. Zispin has sedative properties and may impair concentration and alertness. **Interactions** In vitro data suggest that clinically significant interactions are unlikely with mirtazapine. Mirtazapine may potentiate the central nervous dampening action of alcohol; patients should therefore be advised to avoid alcohol during treatment with Zispin; Zispin should not be administered concomitantly with MAO inhibitors or within two weeks of cessation of therapy with these agents; Mirtazapine may potentiate the sedative effects of benzodiazepines. **Pregnancy and lactation** The safety of Zispin in human pregnancy has not been established. Use during pregnancy is not recommended. Women of child bearing potential should employ an adequate method of contraception. Use in nursing mothers is not recommended. **Adverse reactions** The following adverse effects have been reported: **Common:** Increase in appetite and weight gain. 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). **Rare:** (Orthostatic) hypotension. Mania. Convulsions (insults), tremor, myoclonus. Oedema and accompanying weight gain. Acute bone marrow depression (eosinophilia, granulocytopenia, agranulocytosis, aplastic anemia an thrombocytopenia). Elevations in serum transaminase activitie Exanthema. **Overdosage** Toxicity studies in animals suggest tha clinically relevant cardiotoxic effects will not occur after overdosin with Zispin. Experience in clinical trials and from the market has show that no serious adverse effects have been associated with Zispin i overdose. Symptoms of acute overdosage are confined to prolonge sedation. Cases of overdose should be treated by gastric lavage wit appropriate symptomatic and supportive therapy for vital function **Marketing authorisation number** PA 261/43/2. **Legal categor** Prescription Medicine. **Marketing authorisation holder:** Organo Laboratories Limited, Cambridge Science Park, Milton Road, Cambridg CB4 0FL Telephone: 00 44 1223 423445

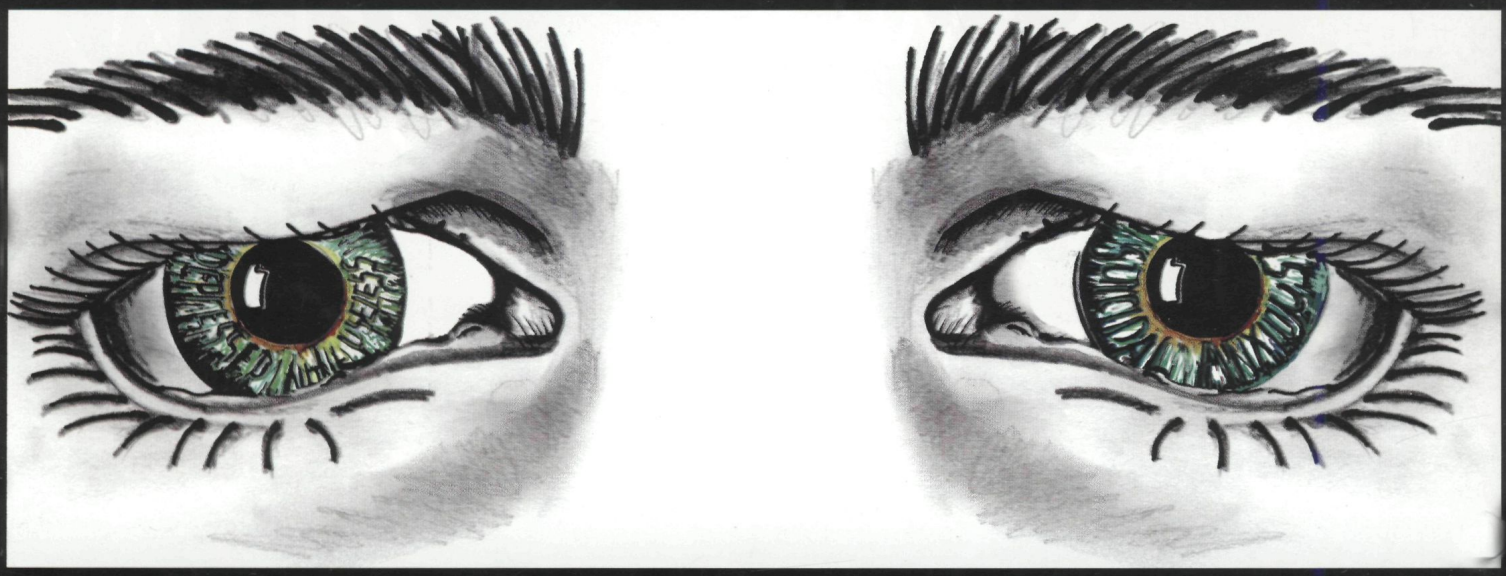
Further information is available from:

Organon

Organon Laboratories Ireland,
c/o United Drug Plc, Belgard Road, Tallaght, Dublin 24
Telephone: (01) 459 8877

Date of Preparation: November 1998 Ref No: 01756F/

# . . . when it's more than just depression



- **Superior Efficacy in the Treatment of Depression with Anxiety[1]**
- **Benign Side Effect Profile in Adults and Elderly[2]**
- **Highly Flexible, Once Daily Dosage[3,4]**

**SEROXAT**

**paroxetine**

**...takes the anxiety out of treating depression**

**'SEROXAT' Abbreviated Irish Prescribing Information. Presentation:** 'Seroxat' Tablets, PA 49/50/1-2, each containing either 20 mg or 30 mg paroxetine as the hydrochloride and 'Seroxat' Liquid, PA 49/50/3 containing 20 mg/10ml 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 daily 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 generally recognised, thus low initial starting dose is recommended. Dosage should be reviewed and adjusted if necessary within two to three weeks of initiation of therapy and thereafter as judged clinically appropriate. Continue treatment for a sufficient period, which may be several months for depression and possibly longer for OCD and panic disorder. Abrupt discontinuation should be avoided. Elderly: 20 mg daily increasing by increments of 10 mg up to 40 mg daily according to response. Children: Not recommended. Severe renal impairment (creatinine clearance <30 ml/min) or severe hepatic impairment: 20 mg daily. 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 convulsant disorders; severe renal failure. **Precautions:** History of mania. Cardiac conditions, use with ECT: 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 within two weeks after stopping MAO inhibitors; leave a two-week gap between stopping 'Seroxat' and before starting MAO inhibitor treatment. Possibility of interaction with tryptophan. Great caution with warfarin and other oral anticoagulants. Consider using lower doses if given with drug metabolising enzyme inhibitors; adjust 'Seroxat' dosage if necessary when given with drug metabolising enzyme inducers. Combination with other highly bound protein drugs may alter plasma levels of either. Alcohol is not advised. Caution with other CNS active drugs. Keep dosage of concomitant benzodiazepines low. Use concurrent lithium administration with caution and monitor lithium levels. Increased adverse events with phenytoin; similar possibility with other 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 (impotence and abnormal ejaculation), dizziness, constipation, diarrhoea, decreased appetite. Spontaneous reports of dizziness, headache, vomiting, diarrhoea, restlessness, hallucinations, hypomania, rash. As with other SSRIs, symptoms suggestive of postural hypotension, hypotension, hypertension, tachycardia. Also other arrhythmias (rare). Extrapyramidal reactions, rarely hyponatraemia (possible SIADH), liver function abnormality. Abrupt discontinuation may cause dizziness, sensory disturbance, agitation or anxiety, nausea and sweating. **Product authorisation holder:** SmithKline Beecham Pharmaceuticals Ltd, Corrig Avenue, Dun Laoghaire, Co Dublin. **Further information is available from this address.** Telephone: 01-284 5555. October 1998. 'Seroxat' is a trade mark.

**References 1.** Dunbar GC and Feull DL. Int Clin Psychopharmacol. 1992. 6(S4):81-90. **2.** Dunner D and Kumar R. Pharmacopsychiat. 1998. No.3, 31:89-101. **3.** Seroxat - Summary of Product Characteristics **4.** MIMS, September 1998.