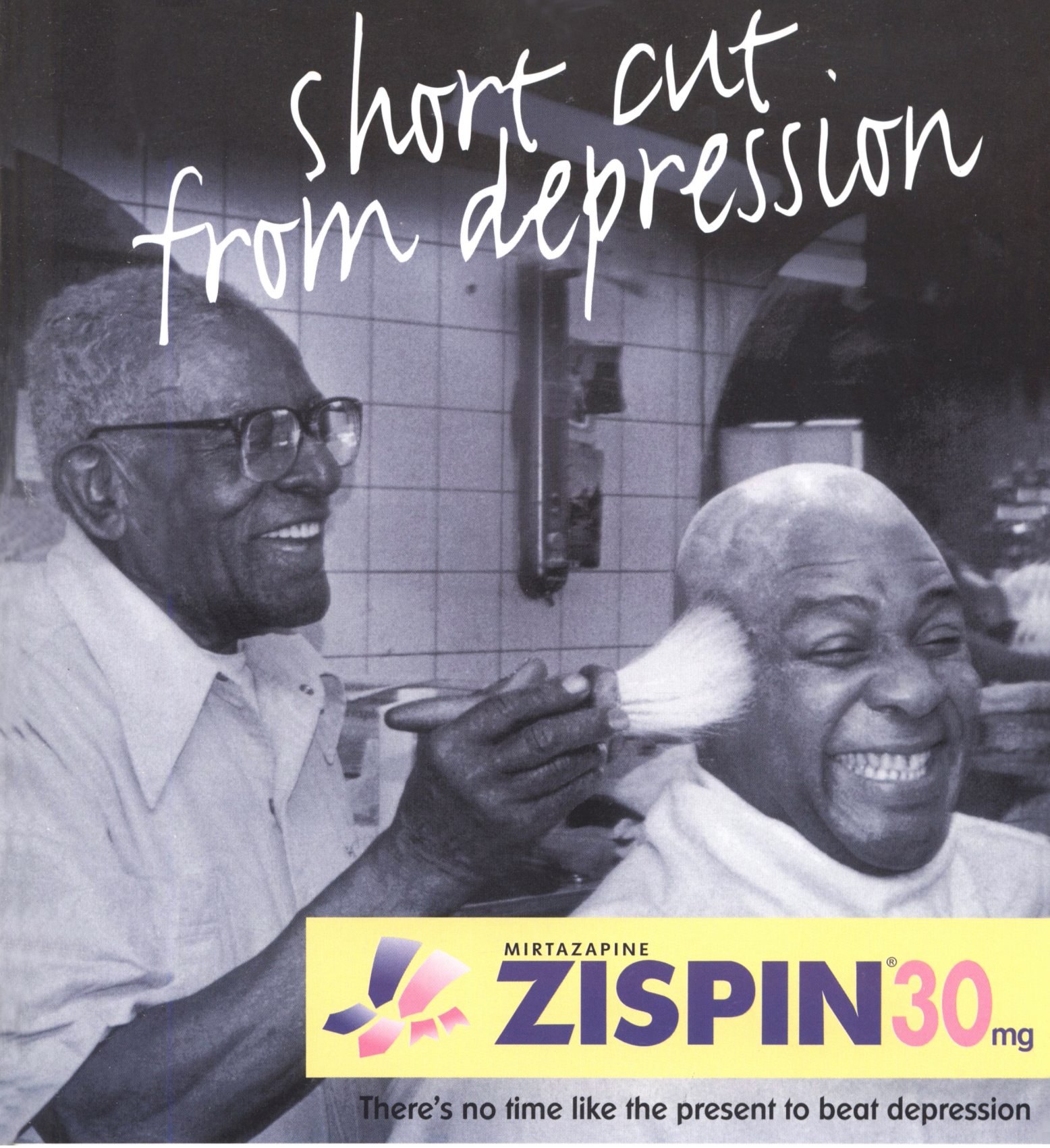

ZISPIN Prescribing Information

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 and thrombocytopenia). Elevations in serum transaminase activities. Exanthema. **Overdosage** Toxicity studies in animals suggest that clinically relevant cardiotoxic effects will not occur after overdosing with Zispin. Experience in clinical trials and from the market has shown that no serious adverse effects have been associated with Zispin in overdose. Symptoms of acute overdosage are confined to prolonged sedation. Cases of overdose should be treated by gastric lavage with appropriate symptomatic and supportive therapy for vital functions. **Marketing authorisation number** PA 261/43/2. **Legal category** Prescription Medicine. **Marketing authorisation holder:** Organon Laboratories Limited, Cambridge Science Park, Milton Road, Cambridge, CB4 0FL Telephone: 00 44 1223 423445

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