

ZISPIN Prescribing Information
Presentation Blister strips of 28 tablets each containing 30mg of mitrazapine. 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 mitrazapine may be decreased in patients with renal or hepatic insufficiency. Zispin is suitable for onceaday administration, preferably as a single night-time dose. Treatment should be continued to the patient has been completely symptomities for 4-6 months. Controllections Hypersensitivity to mitrazapine mitrazapine. 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:

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. sedative properties and may impair concentration and alertness. Interactions in vitro data suggest that clinically significant interactions are unlikely with mitrazapine. Mitrazapine 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; Mitrazapine may potentiate the sedative effects of benzodiazepines. Pregnancy and lactation The setter of Zispin in human pregner has any them estilished Use. 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) micturition disturbances like prostate hypertrophy, acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy acute narrow-angle sedation but can jeopardize antidepressant efficacy). Rare: (Orthostatic) hypertrophy

(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
Laboratoris Limited. Cambridge. Signes Park Milton Pand Cambridge. Laboratories Limited, Cambridge Science Park, Milton Road, Cambridge, CB4 OFL Telephone: 00 44 1223 423445

Further information is available from



Organon Laboratories Ireland, c/o United Drug Plc, Belgard Road, Tallaght, Dublin 24 Telephone: (01) 459 8877 Date of Preparation: November 1998 Ref No: 0 Ref No: 01756F/3





