

Summary of prescribing information for BUSPIN tablets

Active Ingredient: each tablet of BUSPIN contains: buspirone 5,10mg. **Indication:** Anxiolytic- Indicated in the treatment of anxiety and tension states. **Dosage:** recommended initial dose is 15 mg daily (7.5 mg b.i.d.). To achieve an optimal therapeutic response, at intervals of 2 to 3 days the dosage may be increased 5 mg per day, as needed. The maximum daily dosage should not exceed 60 mg per day. **Contraindications:** hypersensitive to buspirone hydrochloride and any ingredient. **Warning and precautions:** concomitantly with monoamine oxidase inhibitor (MAOIs): elevated blood pressure. Interference with Cognitive and Motor Performance; Potential for Withdrawal Reactions in Sedative/Hypnotic/Anxiolytic Drug Dependent Patients. **Pregnancy & Lactation:** No fertility impairment or fetal damage was observed in reproduction studies performed in animals. In humans, however, adequate and well-controlled studies during pregnancy have not been performed. The extent of the excretion in human milk of buspirone or its metabolites is not known. Administration to nursing women should be avoided if clinically possible. **Interaction:** potent inhibitor of CYP3A4 (Diltiazem, Verapamil, nefazodone, Erythromycin, Grapefruit Juice, itraconazole): increased plasma buspirone concentrations. **Adverse reactions:** common dizziness, nausea, headache, nervousness, lightheadedness, and excitement. **Overdose:** symptoms: nausea, vomiting, dizziness, drowsiness, miosis, and gastric distress. Few cases of overdosage have been reported, with complete recovery as the usual outcome. No deaths have been reported. Management: General symptomatic and supportive measures should be used along with immediate gastric lavage. Respiration, pulse, and blood pressure should be monitored as in all cases of drug overdosage. No specific antidote is known to buspirone, and dialyzability of buspirone has not been determined.

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It is recommended to refer full prescribing information before prescription.

For further medical information, please write to: Intas Pharmaceuticals Ltd., Corporate House, Near Sola Bridge, SG highway, Thaltej, Ahmedabad-380054, Gujarat, India. productqueries@intaspharma.com