Summary of prescribing information for TRIVON tablets

Active Ingredient: each film-coated tablet of TRIVON contains Tranylcypromine Sulfate equivalent to 10 mg tranylcypromine. **Indication:** treatment of major depressive disorder (MDD). **Dosage:** Recommended initial dose is 30 mg per day (in divided doses). If no adequate response, increase dosage in increments of 10 mg per day every 1 to 3 weeks to a maximum dosage of 30 mg twice daily (60 mg per day). Consider more gradual dosage increases in patients at risk for hypotension. **Contraindications:** Concomitant use or use in rapid succession with other MAOIs; selective serotonin reuptake inhibitors; serotonin and norepinephrine reuptake inhibitors; tricyclic antidepressants; sympathomimetic drugs; and numerous other drugs. Pheochromocytoma, other catecholamine-releasing paraganglioma. **Warning and precautions:** Activation of Mania/Hypomania: May be precipitated by antidepressant treatment in patients with bipolar disorder. Screen patients for a history of mania. Hypotension (including syncope): Monitor patients and adjust tranylcypromine dosage or concomitant medication as necessary. Hypotension and Hypertension during Anesthesia and Perioperative Care: If possible, discontinue tranylcypromine prior to elective surgery. Hepatitis and Elevated Liver Enzymes: Monitor accordingly. Discontinuing Treatment: Withdrawal effects, including delirium, have been reported with abrupt discontinuation of therapy. **Pregnancy & Lactation:** No adequate data for use of tranylcypromine for use in pregnant women. Tranylcypromine is present in human milk. There is no available information on the effects of tranylcypromine on milk production. No available information on the effects of tranylcypromine on a breastfed child; because of the potential for serious adverse reactions in a breastfed infant, advise nursing women to discontinue breastfeeding during treatment. **Interaction:** The MAO inhibitory action of tranylcypromine may last longer than concentration of drug in plasma, and clinically is considered to have reversed within 14 days. Switching to or from Other Antidepressants to TRIVON: after stopping treatment with other antidepressants, a time period of 4 to 5 half-lives of the other antidepressant or any active metabolite should elapse before starting treatment with Tranylcypromine. After stopping treatment with an MAO inhibitor antidepressant, a time period of at least one week or 4 to 5 half-lives of the other MAO inhibitor (whichever is longer) should elapse before starting treatment with Tranylcypromine to reduce the risk of additive effects. Switching from TRIVON (Tranylcypromine) to Other MAOIs or Antidepressants: After stopping Tranylcypromine treatment, at least one week should elapse before starting another MAOI (intended to treat MDD) or other contraindicated antidepressants. **Adverse reactions:** Most common: dry mouth, dizziness, insomnia, sedation, headache, overexcitement, constipation, blurred vision, and tremor. **Overdose:** symptoms**:** Insomnia, restlessness, and anxiety, progressing in severe cases to agitation, mental confusion, and incoherence; delirium; seizures; Hypotension, dizziness, weakness, and drowsiness, progressing in severe cases to extreme dizziness and shock; Hypertension with severe headache and other symptoms/complications; twitching or myoclonic fibrillation of skeletal muscles, with hyperpyrexia, sometimes progressing to generalized rigidity and coma. Management: no specific antidotes available. Medical management should normally consist of general supportive measures, close observation of vital signs, and steps to counteract specific manifestations as they occur. Patient should be closely observed for at least 1 week. Data on the dialyzability of tranylcypromine are lacking.

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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