Summary of prescribing information for SPINFREE

Active Ingredient: Each uncoated mouth dissolving tablet of SPINFREE contains: Cinnarizine IP 20 mg and Dimenhydrinate BP 40 mg. **Indication:** Treatment of vertigo symptoms of various origins. **Dosage:** Adults & elderly: 1 tablet three times a day after meals. Renal impairment: used with caution in patients with mild to moderate renal impairment; should not be used in patients with a CrCl of < 25mL/min (severe renal impairment). Hepatic impairment: should not be used in patients with severe hepatic impairment. The duration of treatment should not exceed four weeks. **Contraindications:** patients with known hypersensitivity to the active substances, i.e., cinnarizine, diphenhydramine or other antihistamines of similar structure or to any of the excipients; patients with angle-closure glaucoma, convulsions, suspicion of raised intracranial pressure, and alcohol abuse or urine retention due to urethroprostatic disorders. **Warning and precautions:** hypotensive patients; patients with conditions that might be aggravated by anticholinergic therapy, e.g. raised intra-ocular pressure, pyloro-duodenal obstruction, prostatic hypertrophy, hypertension, hyperthyroidism or severe coronary heart disease; patients with parkinson's disease. It should be taken after meals to minimize any gastric irritation. It may cause drowsiness, especially at the start of treatment. Patients affected in this way should not drive or operate machinery. **Pregnancy & Lactation:** The safety in human pregnancy has not been established. Dimenhydrinate and cinnarizine are excreted in human breast milk. It should not be taken by women who are breast feeding. **Interaction:** The anticholinergic and sedative effects of cinnarazine and dimenhydrinate may be potentiated by monoamine oxidase inhibitors. Procarbazine may enhance the effect of the product. Cinnarazine and dimenhydrinate may potentiate the sedative effects of CNS depressants including alcohol, barbiturates, narcotic analgesics and tranquillisers. Patients should be advised to avoid alcoholic drinks. Cinnarazine and dimenhydrinate may also enhance the effects of antihypertensives, ephedrine and anticholinergics such as atropine and tricyclic antidepressants. It may mask ototoxic symptoms associated with amino glycosidic antibiotics and mask the response of the skin to allergic skin tests. The concomitant administration of medicines that prolong the QT interval of the ECG (such as Class Ia and Class III anti-arrhythmics) should be avoided. Diphenhydramine inhibits CYP2D6 mediated metabolism and caution is advised if it is combined with substrates of this enzyme, especially those with narrow therapeutic range. **Adverse reactions:** The most frequently occurring ADRs are somnolence (including drowsiness, tiredness, fatigue, daze) occurring in about 8% of patients and dry mouth occurring in about 5% of patients. **Overdose:** Symptoms: drowsiness, dizziness and ataxia with anticholinergic effects such as dry mouth, flushing of the face, dilated pupils, tachycardia, pyrexia, headache and urinary retention. Convulsions, hallucinations, excitement, respiratory depression, hypertension, tremor and coma may occur, in cases of massive overdosage. Management: General supportive measures to treat respiratory insufficiency or circulatory failure. Gastric lavage with isotonic sodium chloride solution. Body temperature should be closely monitored. Cramp-like symptoms may be controlled by careful application of a short-acting barbiturate. In cases of marked central-anticholinergic effects, physostigmine (after physostigmine test) should be administered slowly intravenously (or, if necessary, intramuscularly): 0.03 mg/kg body weight (adults max. 2 mg, children max. 0.5 mg). Dimenhydrinate is dialyzable, however treatment of overdosage by this measure is considered as unsatisfactory. Sufficient elimination can be achieved by means of haemoperfusion using activated charcoal. No data are available concerning the dialysability of cinnarizine.

Prepared on 4th Feb 2020; Source SPINFREE PIL version dated 2013 February.

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