Summary of prescribing information for NICLONZ Pastilles

Active Ingredient: Each pastille of NICLONZ contains: Nicotine Polacrilex USP eq. to Nicotine 2 mg/ 4 mg. **Indication:** for the relief of nicotine withdrawal symptoms including cravings. Permanent cessation of tobacco use is the eventual objective. NIClonz Pastilles can be used: For smoking cessation (abrupt and gradual); As an aid for smokers during temporary abstinence. Pastilles should preferably be used in conjunction with a behavioural support programme. **Dosage:** 2 mg pastilles are suitable for smokers who have their first cigarette of the day >30 minutes after waking up; 4 mg pastilles suitable for smokers having their first cigarette of the day within 30 minutes after waking up. One pastille should be placed in the mouth and allowed to dissolve. Periodically, the pastille should be moved from one side of the mouth to the other, and repeated, until the pastille is completely dissolved, which may take approximately 20-30 minutes. The pastille should not be chewed or swallowed whole. Should not eat or drink while a pastille is in the mouth. Should not exceed 15 pastilles/day and nor more than 12 weeks. **Contraindications:** hypersensitivity to nicotine or any of the excipients, allergic to soya protein, Children under the age of 12 years, Non-smokers. **Warning and precautions:** The risks associated with the use of NRT are substantially outweighed invirtually all circumstances by the well established dangers of continued smoking. Patients hospitalised for MI, severe dysrhythmia or CVA: data on safety in this patient group are limited, initiation should only be under medical supervision. Diabetes: Blood glucose levels may be more variable when stopping smoking, with or without. Allergic reactions: Susceptibility to angioedema and urticaria. Phaeochromocytoma and uncontrolled hyperthyroidism, GI disease: may exacerbate symptoms. Danger in small children: Doses of nicotine tolerated by adult and adolescent smokers can produce severe toxicity in small children that may be fatal. Phenylketonuria: each pastilles contain a source of phenylalanine equivalent to 3mg/dose. Sodium content: Each pastille contains 15 mg of sodium. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Pregnancy & Lactation:** Smoking during pregnancy is associated with risks such as intra-uterine growth retardation, premature birth or stillbirth. Stopping smoking is the single most effective intervention. For women unable to quit on their own, NRT may be recommended to assist a quit attempt. Intermittent dosing products may be preferable as these usually provide a lower daily dose of nicotine than patches. Using intermittent dose NRT preparation may minimize the amount of nicotine in the breast milk as the time between administrations of NRT and feeding can be more easily prolonged. **Interaction:** No clinically relevant interactions between NRT and other drugs have definitely been established; nicotine may possibly enhance the haemodynamic effects of adenosine. Smoking cessation itself may require the adjustment of some drug therapy. **Adverse reactions:** common insomnia; dizziness; headache; coughing; pharyngitis; sore throat; nausea; hiccup, flatulence; vomiting; constipation, diarrheoa; dysphagia; dyspepsia; heartburn; indigestion; belching; mouth irritation, mouth ulceration; tongue ulceration; dry mouth; bloating. **Overdose: Symptoms:** expected to be the same as those of acute nicotine poisoning, including pallor, cold sweat, salivation, nausea, vomiting, abdominal pain, diarrhoea, headache, dizziness, disturbed hearing and vision, tremor, mental confusion and weakness. Prostration, hypotension, respiratory failure, rapid or weak or irregular pulse, circulatory collapse and convulsions (including terminal convulsions) may ensue with large overdoses. Management: user should seek medical attention immediately. All nicotine intake should cease immediately and the patient be treated symptomatically. Artificial respiration with oxygen should be instituted if necessary. Activated charcoal reduces the gastrointestinal absorption of nicotine.

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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