

## Indications

Desloratadine Sandoz tablet is indicated for the rapid relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) such as sneezing, nasal discharge and itching, congestion/stuffiness, as well as ocular itching, tearing and redness, itching of palate and coughing.

Desloratadine Sandoz tablet is also indicated for the relief of symptoms associated with urticaria such as the relief of itching and the size and number of hives.

## Posology and method of administration

Adults and adolescents (12 years of age and over): For oral use. One 5 mg tablet once a day, regardless of mealtimes, and as and when necessary, for the relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and urticaria.



### Desloratadine Sandoz Film Coated Tablet 5mg Basic Succinct Statement

**Composition:** DESLORATADINE SANDOZ FILM COATED TABLET 5 MG. **Indications:** Desloratadine Sandoz tablet is indicated for the rapid relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) such as sneezing, nasal discharge and itching, congestion/stuffiness, as well as ocular itching, tearing and redness, itching of palate and coughing. Desloratadine Sandoz tablet is also indicated for the relief of symptoms associated with urticaria such as the relief of itching and the size and number of hives. **Dose and Method of Administration:** Adults and adolescents (12 years of age and over): For oral use. One 5 mg tablet once a day, regardless of mealtimes, and as and when necessary, for the relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and urticaria. Desloratadine is not recommended for long-term use. Intermittent allergic rhinitis (presence of symptoms for less than 4 days per week or for less than 4 weeks) should be managed in accordance with the evaluation of patient's disease history and the treatment could be discontinued after symptoms are resolved and reinitiated upon their reappearance. In persistent allergic rhinitis (presence of symptoms for 4 days or more per week and for more than 4 weeks), continued treatment may be proposed to the patients during allergen exposure periods. **Contraindications:** Hypersensitivity to the active substance (desloratadine), loratadine or to any of the excipients listed in section 6.1. **Special warnings and precautions for use:** Efficacy and safety of desloratadine tablets in children under 12 years of age have not been established. Therefore, use of desloratadine tablets in children is not recommended. Desloratadine should be administered with caution in patients with a medical or family history of seizures. In particular, young children may be more susceptible to developing new seizures under desloratadine treatment. Healthcare providers may consider discontinuing desloratadine in patients who experience a seizure while on treatment. **Interactions with other medicinal products and other forms of interaction:** Desloratadine was shown to have no clinically relevant effects on ECG parameters with ketoconazole and erythromycin. There was no effect of food or grapefruit juice on the disposition of desloratadine. Desloratadine taken concomitantly with alcohol did not potentiate the performance impairing effects of alcohol. **FERTILITY, PREGNANCY AND LACTATION:** No teratogenic or mutagenic effects were observed in animal trials with desloratadine. Since no clinical data on exposed pregnancies are available with desloratadine, the use of desloratadine during pregnancy has not been established. Therefore use only if the potential benefit justifies the potential risk to the fetus. Desloratadine is excreted into breast milk; therefore breast-feeding is not recommended in lactating women taking desloratadine tablets. There are no data available on male and female fertility. **Effects on ability to drive and use machines:** Based on assessments using the Standard Highway Driving Test, the Car Following Test, and a full battery of psychometric evaluations, no undesirable effects on the ability to drive and use machines have been observed. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines. Desloratadine should be administered with caution in patients with a medical or family history of seizures. In particular, young children may be more susceptible to developing new seizures under desloratadine treatment. Healthcare providers may consider discontinuing desloratadine in patients who experience a seizure while on treatment. **Undesirable effects:** Headache, Fatigue, Dry Mouth

**Reference 1:** Desloratadine 5mg comparative bioavailability project report, Kiran Chauhan and Prakash Patel, 2010 (BE study)

**For Healthcare Professionals Only. Before prescribing, consult full prescribing information in the package insert.**



Novartis (Singapore) Pte Ltd  
20 Pasir Panjang Road, #10-25/28 Mapletree Business City, Singapore 117439  
Phone: +65 6722 6010 | Fax: +65 6323 4335

