

# LEAVE ALLERGY SYMPTOMS BEHIND



 **Haydine**  
Desloratadine Film-coated tablet 5 mg

# Desloratadine

- ❖ Active & potent metabolite of Loratadine
- ❖ No CNS suppression (selective H1 receptor antagonist)
- ❖ Limited penetration of BBB (no anticholinergic effects)
- ❖ Absorption is unaffected by food
- ❖ Not metabolized by CYP450
- ❖ No tolerance/tachyphylaxis
- ❖ Convenient once daily dosing
- ❖ Excellent compliance

## SmPC:

### Name of the medicinal product

Haydine®, Desloratadine 5 mg film-coated tablet

### Therapeutic indications

Desloratadine is an H1 receptor antagonist indicated for:

- Seasonal allergic rhinitis: relief of nasal and non-nasal symptoms in patients 2 years of age and older.
- Perennial allergic rhinitis: relief of nasal and non-nasal symptoms in patients 6 months of age and older.
- Chronic idiopathic urticaria: symptomatic relief of pruritus, reduction in the number of hives, and size of hives in patients 6 months of age and older.

### Posology and method of administration

#### Posology

Adults and adolescents (12 years of age and over):

The recommended dose is one tablet once a day.

#### Method of administration

Oral use. The tablets can be taken with or without food.

### Contraindications

Hypersensitivity to desloratadine, loratadine, or any component of the formulation.

### Warnings/Precautions

#### Concerns related to adverse effects

- Hypersensitivity reactions including rash, pruritus, urticaria, edema, dyspnea, and anaphylaxis have been reported. In such cases, stop Haydine® at once and consider alternative treatments.

#### Disease-related concerns

- Hepatic impairment: Use with caution in patients with severe hepatic impairment.
- Renal impairment: Use with caution in patients with severe renal impairment.

#### Concurrent drug therapy issues

- Sedatives: Effects may be potentiated when used with other sedative drugs or ethanol.

#### Special populations

- Slow metabolizers: Use with caution in patients known to be slow metabolizers of desloratadine (incidence of side effects may be increased).

### Adverse Reactions

The most common adverse reactions (reported in  $\geq 2\%$  of adult and adolescent patients with allergic rhinitis and greater than placebo) were pharyngitis, dry mouth, myalgia, fatigue, somnolence, dysmenorrhea.

### Use in specific populations

#### Moderate to severe renal impairment

No dosage adjustment necessary; use with caution in severe impairment. Although the US manufacturer's labeling recommends a dose reduction to 5 mg every other day in patients with mild to severe renal impairment, the increased exposure (C<sub>max</sub> and AUC) observed in single- and multiple-dose pharmacokinetic studies is not considered clinically relevant.

#### Hepatic impairment

No dosage adjustment necessary; use with caution in severe impairment. Although the US manufacturer's labeling recommends a dose reduction to 5 mg every other day in patients with mild to severe hepatic impairment, the increased exposure (C<sub>max</sub> and AUC) observed in single- and multiple-dose pharmacokinetic studies is not considered clinically relevant.

### Fertility, pregnancy and lactation

#### Pregnancy

Guidelines for the use of antihistamines in the treatment of allergic rhinitis or urticaria in pregnancy are generally the same as in nonpregnant females. Second generation antihistamines may be used for the treatment of allergic rhinitis and urticaria during pregnancy; however, information related to the use of desloratadine in pregnancy is limited and other medications may be preferred.

#### Breast-Feeding

Desloratadine is present in breast milk.

According to the manufacturer, the decision to continue or discontinue breastfeeding during therapy should consider the risk of exposure to the infant and the benefits of treatment to the mother. When treatment with an antihistamine is needed in breastfeeding women, second generation antihistamines are recommended; however, agents other than desloratadine may be preferred.

#### Fertility

There are no data available on male and female fertility.

#### References:

1. Clarines (desloratadine) [prescribing information], Whitehouse Station, NJ: Merck Sharp & Dohme Corp; May 2020.2. Zuberbier T, Aberer W, Asero R, et al. The EAACI/GA<sup>2</sup>LEN/EDF/WAO guideline for the definition, classification, diagnosis and management of urticaria. *Allergy*. 2018;73(7):1393-1414. [PubMed 29336054] 3. Brożek J, Bosquet J, Agache I, et al. Allergic rhinitis and its impact on asthma (ARIA) guidelines 2016 revision. *J Allergy Clin Immunol*. 2017;140(4):S26-S58. [PubMed 28602343]