

	A A A O
Product Name:	AKEROL SYRUP (Desloratadine syrup 2.5mg/5ml)

1.3 PRODUCT INFORMATION

1.3.1 Summary of Product characteristics (SmPC)

1. Name of the Medicinal Product:

1.1 Name of the Medicinal Product

- **Brand Name / Generic Name:** AKEROL SYRUP (Desloratadine syrup 2.5mg/5ml)

- **International Non-Proprietary Name (INN):** Desloratadine syrup 2.5mg/5ml

1.2 **Strength:** Desloratadine 2.5mg/5ml

1.3 **Pharmaceutical Form:** Syrup

2. Qualitative and Quantitative Composition :

Each 5ml contains:

Desloratadine USP 2.5 mg

Flavoured syrup base Q.S

Color: Sunset yellow FCF

3. Pharmaceutical Form:

Orange to light orange colored syrup.

4. Clinical Particulars

4.1 Therapeutic indications

Desloratadine is indicated in adults, adolescents and children over the age of 1 year for the relief of symptoms associated with:

- allergic rhinitis
- urticaria

4.2 Posology and method of administration

Posology

Adults and adolescents (12 years of age and over)

The recommended dose of Desloratadine is 10 ml (5 mg) oral solution once a day.

Paediatric population

AKEROL SYRUP (Desloratadine syrup 2.5mg/5ml)

The prescriber should be aware that most cases of rhinitis below 2 years of age are of infectious origin and there are no data supporting the treatment of infectious rhinitis with Desloratadine.

Children 1 through 5 years of age: 2.5 ml (1.25 mg) Desloratadine oral solution once a day.

Children 6 through 11 years of age: 5 ml (2.5 mg) Desloratadine oral solution once a day.

The safety and efficacy of Desloratadine 0.5 mg/ml oral solution in children below the age of 1 year have not been established.

There is limited clinical trial efficacy experience with the use of desloratadine in children 1 through 11 years of age and adolescents 12 through 17 years of age.

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 the allergen exposure periods.

Method of administration

Oral use.

The dose can be taken with or without food.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients used in this formulation or to Loratadine.

4.4 Special warnings and precautions for use

Convulsions

Desloratadine should be administered with caution in patients with medical or familial history of seizures, and mainly young children, being more susceptible to develop new seizures under desloratadine treatment. Healthcare providers may consider discontinuing desloratadine in patients who experience a seizure while on treatment.

Paediatric population

In children below 2 years of age, the diagnosis of allergic rhinitis is particularly ~~difficult to distinguish from other forms of rhinitis. The absence of upper respiratory~~
AK tract infection or structural abnormalities, as well as patient history, physical examinations, and appropriate laboratory and skin tests should be considered.

Approximately 6 % of adults and children 2- to 11-year-old are phenotypic poor metabolisers of desloratadine and exhibit a higher exposure. The safety of desloratadine in children 2-to 11-years of age who are poor metabolisers is the same as in children who are normal metabolisers.

The effects of desloratadine in poor metabolisers < 2 years of age have not been studied.

In the case of severe renal insufficiency, Desloratadine should be used with caution.

Desloratadine oral solution contains sorbitol (E420)

Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product.

4.5 Interaction with others medicinal products and other forms of Interactions

Desloratadine taken concomitantly with alcohol did not potentiate the performance impairing effects of alcohol. However, cases of alcohol intolerance and intoxication have been reported during post-marketing use. Therefore, caution is recommended if alcohol is taken concomitantly.

4.6 Pregnancy and Lactation

Pregnancy

A large amount of data on pregnant women (more than 1,000 pregnancy outcomes) indicates no malformative nor foeto/ neonatal toxicity of desloratadine. As a precautionary measure, it is preferable to avoid the use of desloratadine during pregnancy.

Breast-feeding

Desloratadine has been identified in breastfed newborns/infants of treated women. The effect of desloratadine on newborns/infants is unknown. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from desloratadine therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility

There are no data available on male and female fertility.

4.7 Effects on ability to drive and use machines

Desloratadine has no or negligible influence on the ability to drive and use machines. Patients should be informed that most people do not experience drowsiness. Nevertheless, as there is individual variation in response to all medicinal products, it is recommended that patients are advised not to engage in activities requiring mental

AKEROL SYRUP (Desloratadine syrup 2.5mg/5ml) alertness, such as driving a car or using machines, until they have established their own response to the medicinal product.

4.8 Undesirable Effects

The frequency of the clinical trial adverse reactions reported in excess of placebo and other undesirable effects reported during the post-marketing period are listed in the following table. Frequencies are defined as very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$) and not known (cannot be estimated from the available data).

System organ class	Frequency	Adverse reactions seen with Desloratadine
Metabolism and nutrition disorders	Not known	Increased appetite
Psychiatric disorders	Very rare	Hallucinations
	Not known	Abnormal behaviour, aggression
Nervous system disorders	Common	Headache
	Common (children less than 2 years)	Insomnia
	Very rare	Dizziness, somnolence, insomnia, psychomotor hyperactivity, seizures
Cardiac disorders	Very rare	Tachycardia, palpitations
	Not known	QT prolongation
Gastrointestinal disorders	Common	Dry mouth
	Common (children less than 2 years)	Diarrhoea
	Very rare	Abdominal pain, nausea, vomiting, dyspepsia, diarrhoea
Hepatobiliary disorders	Very rare	Elevations of liver enzymes, increased bilirubin, hepatitis
	Not known	Jaundice
AKEROL SYRUP (Desloratadine syrup, 2.5mg/5ml) Skin and subcutaneous Not known		Photosensitivity

tissue disorders		
Musculoskeletal and connective tissue disorders	Very rare	Myalgia
General disorder and administration site conditions	Common Common (children less than 2 years of age) Very rare Not known	Fatigue Hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash and urticaria) Asthenia
Investigations	Not known	Weight increased

4.9 Overdose

The adverse event profile associated with overdosage, as seen during post-marketing use, is similar to that seen with therapeutic doses, but the magnitude of the effects can be higher.

Treatment

In the event of overdose, consider standard measures to remove unabsorbed active substance. Symptomatic and supportive treatment is recommended.

Desloratadine is not eliminated by haemodialysis; it is not known if it is eliminated by peritoneal dialysis.

Symptoms

Based on a multiple dose clinical trial in adults and adolescents, in which up to 45 mg of desloratadine was administered (nine times the clinical dose), no clinically relevant effects were observed.

Paediatric population

The adverse event profile associated with overdosage, as seen during post-marketing use, is similar to that seen with therapeutic doses, but the magnitude of the effects can be higher.

5. Pharmacological properties

5.1 Pharmacodynamics

Pharmacotherapeutic group: Antihistamines – H₁ antagonist
ATC code: R06AX27

Mechanism of action

Desloratadine is a non-sedating, long-acting histamine antagonist with selective peripheral H₁-receptor antagonist activity. After oral administration, desloratadine selectively blocks peripheral histamine H₁-receptors because the substance is excluded from entry to the central nervous system.

Desloratadine has demonstrated antiallergic properties from *in vitro* studies. These include inhibiting the release of proinflammatory cytokines such as IL-4, IL-6, IL-8, and IL-13 from human mast cells/basophils, as well as inhibition of the expression of the adhesion molecule P-selectin on endothelial cells. The clinical relevance of these observations remains to be confirmed.

5.2 Pharmacokinetics

Absorption

Desloratadine plasma concentrations can be detected within 30 minutes of desloratadine administration in adults and adolescents. Desloratadine is well absorbed with maximum concentration achieved after approximately 3 hours; the terminal phase half-life is approximately 27 hours. The degree of accumulation of desloratadine was consistent with its half-life (approximately 27 hours) and a once daily dosing frequency.

Distribution

Desloratadine is moderately bound (83 % - 87 %) to plasma proteins. There is no evidence of clinically relevant active substance accumulation following once daily adult and adolescent dosing of desloratadine for 14 days.

Biotransformation

The enzyme responsible for the metabolism of desloratadine has not been identified yet, and therefore, some interactions with other medicinal products cannot be fully excluded. Desloratadine does not inhibit CYP3A4 *in vivo*, and *in vitro* studies have shown that the medicinal product does not inhibit CYP2D6 and is neither a substrate nor an inhibitor of P-glycoprotein.

5.3 Preclinical safety data

Desloratadine is the primary active metabolite of loratadine. Non-clinical studies conducted with desloratadine and loratadine demonstrated that there are no qualitative or quantitative differences in the toxicity profile of desloratadine and loratadine at comparable levels of exposure to desloratadine.

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development. The lack of carcinogenic potential was demonstrated in studies conducted with desloratadine and loratadine.

6. Pharmaceutical particulars

6.1 List of excipients

- Sugar
- Sorbitol solution 70%
- Propylene glycol
- Citric acid
- Sodium citrate
- Sodium benzoate
- Di sodium Edetate
- Sunset yellow
- Mix fruit
- Cherry
- Purified water

6.2 Incompatibilities

None.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store in cool dry place below 30° C, Protect from light.

1

MODULE-1

REGIONAL ADMINISTRATIVE INFORMATION

Product Name: **AKEROL SYRUP**(Desloratadine syrup 2.5mg/5ml)

7. Marketing Authorisation holder

BEKRAPHARMA UKLTD.
13/091, Lavington Road,
Beddington,
LONDON.
UNITED KINGDOM

8. Marketing Authorization Number

9. Date of first authorization/renewal of the authorization

10. Date of revision of the text

January 15th, 2019