**SUMMARY OF PRODUCT CHARACTERISTICS**

**1. Name of the Medicinal Product:**

AKEROL TABLETS

**2. Qualitative and Quantitative Composition**

Each 5ml contains:
Desloratadine USP 5 mg

For full list of excipients, see section 6.1.

**3. Pharmaceutical Form:**☒

White to off white, round shaped, flat faced, uncoated tablet having break line on one side & plain on other side

**4.0 Clinical Particulars**

**4.1 Therapeutic indications**

Desloratadine orally disintegrating tablets 5 mg Tablets are indicated in adults and adolescents aged 12 years and older for the relief of symptoms associated with Seasonal Allergic Rhinitis: Desloratadine orally disintegrating tablets are indicated for the relief of the nasal and non-nasal symptoms of seasonal allergic rhinitis in patients 12 years of age and older.
Perennial Allergic Rhinitis: Desloratadine orally disintegrating tablets are indicated for the relief of the nasal and non-nasal symptoms of perennial allergic rhinitis in patients 12 months of age and older.

**4.2 Posology and method of administration**

Posology

- Adults and Adolescents 12 Years of Age and Over☒The recommended dose of desloratadine orally disintegrating tablets is one 5 mg tablet
- Children 6 to 11 Years of Age☒The recommended dose of desloratadine orally disintegrating tablet is one 2.5 mg
- tablet once daily.☒NOTE: Desloratadine orally disintegrating tablets are not recommended for use in pediatric patients under 6 years of age as desloratadine syrup is better suited for these
- Adults with Hepatic or Renal Impairment☒In adult patients with liver or renal impairment, a starting dose of one 5 mg tablets every other day is recommended based on pharmacokinetic data. Dosing recommendation for children with liver or renal impairment cannot be made do the lack of data.

Method of administration
loratadine orally disintegrating tablets may be taken without regard to meals. Pl loratadines orally disintegrating tablets on the tongue and allow to disintegrate before swallowing. Tablet disintegration occurs rapidly. Administer with or without water. Take tablet immediately after opening the blister.

**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**

Hypersensitivity reactions
cactions including rash, pruritus, urticaria, edema, dyspnea, an
anaphylaxis have been reported after administration of desloratadine. If such a reaction cur, therapy with desloratadine should be stopped and alternative treatment should be considered.

**4.5 Interaction with others medicinal products and other forms of Interactions**

Desloratadine with ketoconazole,
erythromycin, or azithromycin resulted in increased
plasma concentrations of desloratadine and 3 hydroxy desloratadine, but there were no clinically relevant changes in the safety profile of desloratadine.
Fluoxetine
Desloratadine with fluoxetine, a selective serotonin reuptake inhibitor (SSRI), resulted in increased plasma concentrations of desloratadine and 3 hydroxy desloratadine, but there were no clinically relevant changes in the safety profile of desloratadine.
Cimetidine
Desloratadine with cimetidine, a histamine H2-receptor antagonist, resulted in increased plasma concentrations of desloratadine and 3 hydroxy desloratadine, but there were no clinically relevant changes in the safety profile of desloratadine.

**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
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to discontinue breast-feeding or to discontinue/abstain from desloratadine therapy takin into account the benefit of breast feeding for the child and the benefit of therapy for th 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 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 (2 1/10), common (2 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 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 |
|---|---|---|
| Psychiatric disorders | Very rare | Hallucinations |
| | Not known | Abnormal behaviour, aggression |
| Nervous system disorders | Common | Headache |
| | Can 2 yearchitren less | Insomnia |
| | Very rare | Dizziness, somnolence insomnia, psychomoto hyperactivity, seizures |
| Cardiac disorders | Very rare | Tachycardia, |
| | Not known | palpitations 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 |
| | Not known | enzymes, increased bilirubin, hepatitis Jaundice |
| Skin and subcutaneous Not known tissue disorders | | Photosensitivity |

| | | |
|---|---|---|
| Musculoskeletal connective tissue disorders | and Very rare | Myalgia |
| General disorder administration conditions site | and Common<br>'ommon (children les han 2 years of age<br>Very rare<br>Not known | Fatigue<br>Hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoca, pruritus, rash and urticaria)<br>Asthenia |
| Investigations | Not known | Weight increased |
| Metabolism and nutrition Notknown disorders | | Increased appetite |

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after Authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Pharmacovigilance Electronic Reporting System (PvERS) **https://pv.pharmacyboardkenya.org/**

**4.9 Overdose**

Treatment

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Desloratadine is not eliminated by hemodialysis; 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 c ere obtained as administered (nine times the clinical dose, no clinically relevant effect.

Paediatric population

The adverse event profile associated with overdosage, as seen during post-marketing use, milar 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 long-acting tricyclic histamine antagonist with selective H1-receptor histamine antagonist activity. Receptor binding data indicates that at a concentration of 2 to 3 ng/mL (7 nanomolar), desloratadine shows significant interaction with the human
histamine H1-receptor. Desloratadine inhibited histamine release from human mast cells in vitro. Results of a radiolabeled tissue distribution study in rats and a radioligand HI-receptor binding study in guinea pigs showed that desloratadine did not readily cross the blood brain barrier. The clinical significance of this finding is unknown.

**5.2 Pharmacokinetics**

Absorption

A single desloratadine orally disintegrating tablets containing 5 mg of desloratadine was biocquivalent to a single 5 mg
desloratadine
orally disintegrating tablets (original
formulation) for both desloratadine and 3-hydroxydesloratadine. Food and water had no effect on the bioavailability (AUC and Cmax) of desloratadine orally disintegrating tablets.

Distribution

Desloratadine and 3-hydroxydesloratadine are approximately 82% to 87% and 85% to 89% bound
to plasma proteins, respectively.
Protein
binding of desloratadine and 3-
hydroxydesloratadine was unaltered in subjects with impaired renal function.

Metabolism

Desloratadine (a
major metabolite
of loratadine) is extensively metabolized to 3
ydroxydesloratadine, an active metabolite, which is subsequently glucuronidated. Th enzyme(s) responsible for the identified.
formation of 3-hydroxydesloratadine have not been

Elimination

The mean plasma elimination half-life of desloratadine was approximately 27 hours. Cmax andAUC values increased in a dose proportional manner following single oral doses between 5 and 20 mg.
The degree of accumulation after 14 days of dosing was consistent
with the half-life and dosing frequency. A human mass balance study documented a recovery of approximately
87% of the 14C-desloratadine dose,
which
distributed in urine and feces as metabolic products.

Analysis

hydroxydesloratadine showed similar Tmax and half-life values compared to desloratadine.

**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**

- Microcrystalline cellulose granules☒Mannitol 200 DC
- Polacrilin potassium (KYRON T-314)
- Crospovidone (kollidon)
- Aspartame
- Citric acid anhydrous silica
- Colloidal anhydrous silica
- Sodium stearyl fumarate
- Purified talc

**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.

**6.5 Nature and contents of container**
2 X 10 Alu-Alu Blister pack

**7. Marketing Authorisation holder**
BEKRAPHARMA UKLTD.
13/091, Lavington Road, Boddington, LONDON.
UNITED KINGDOM

**8.0 Marketing Authorization Number**
H2022/CTD10162/21335

**9.0 Date of first authorization/renewal of the authorization**
10/12/2023

**10. Date of revision of the text**
24/08/2026