Summary of Product Characteristics

1. Name of the medicinal product

DESONAL SYRUP (Desloratadine Syrup 2.5 ml/5 mL)

2. Qualitative and Quantitative composition

Composition:
Each ml contains:
Desloratadine 0.5mg

For the full list of excipients, See Section 6.1

3. Pharmaceutical form

Oral Liquid
Reddish-brown colored, sweet flavored syrup.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications

Treating allergy symptoms and chronic hives. It may also be used for other conditions as determined by your doctor.
Desloratadine syrup is an antihistamine. It works by blocking the action of histamine to relieve allergy symptoms, such as sneezing, runny nose, and itchy or watery eyes, and to relieve itching and rash due to chronic hives

4.2 Posology and method of administration

Desloratadine Syrup may be taken without regard to mealtime for the relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and chronic idiopathic urticaria. 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 Aerius. Children 1 through 5 years of age: 2.5 ml (1.25 mg) Aerius syrup once a day. Children 6 through 11 years of age: 5 ml (2.5 mg) Aerius syrup once a day. In adults and adolescents (12 years of age and over): 10 ml (5 mg) Aerius syrup once a day. 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

4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients, or to loratadine.

4.4 Special warnings and precautions for use
Efficacy and safety of Aerius syrup in children under 1 year of age have not been established. 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 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 Aerius syrup 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 Aerius syrup in poor metabolisers < 2 years of age have not been studied. In the case of severe renal insufficiency, Aerius should be used with caution. This medicinal product contains sucrose and sorbitol; thus, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. This medicinal product contains the colouring agent E110 which may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction
No clinically relevant interactions were observed in clinical trials with Aerius tablets in which erythromycin or ketoconazole were co-administered. In a clinical pharmacology trial, Aerius tablets taken concomitantly with alcohol did not potentiate the performance impairing effects of alcohol.

4.6 Fertility, Pregnancy and Lactation
Desloratadine was not teratogenic in animal studies. The safe use of the medicinal product during pregnancy has not been established. The use of Aerius during pregnancy is therefore not recommended. Desloratadine is excreted into breast milk, therefore the use of Aerius is not recommended in breastfeeding women

4.7 Effects on ability to drive and use machines
In clinical trials that assessed the driving ability, no impairment occurred in patients receiving desloratadine. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

4.8 Undesirable effects
In clinical trials in a paediatric population, Aerius syrup was administered to a total of 246 children aged 6 months through 11 years. The overall incidence of adverse events in children 2 through 11 years of age was similar for the Aerius syrup and the placebo groups. In infants and toddlers aged 6 to 23 months, the most frequent adverse events reported in excess of placebo were diarrhoea (3.7 %), fever (2.3 %) and insomnia (2.3 %). At the recommended dose, in clinical trials involving adults and adolescents in a range of indications including allergic rhinitis and chronic idiopathic urticaria, undesirable effects with Aerius were reported in 3 % of patients in excess of those treated with placebo. The most frequent of

adverse events reported in excess of placebo were fatigue (1.2 %), dry mouth (0.8 %) and headache (0.6 %). Other undesirable effects reported very rarely during the post-marketing period are listed in the following table.

Psychiatric disorders	Hallucinations
Nervous system disorders	Dizziness, somnolence, insomnia, psychomotor hyperactivity, seizures
Cardiac disorders	Tachycardia, palpitations
Gastrointestinal disorders	Abdominal pain, nausea, vomiting, dyspepsia, diarrhoea
Hepato-biliary disorders	Elevations of liver enzymes, increased bilirubin, hepatitis
Musculoskeletal and connective tissue disorders	Myalgia
General disorders	Hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash, and urticaria)

Reporting of suspected adverse reactions
Healthcare professional are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9 Overdose
In the event of overdose, consider standard measures to remove unabsorbed active substance. Symptomatic and supportive treatment is recommended. 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. Desloratadine is not eliminated by haemodialysis; it is not known if it is eliminated by peritoneal dialysis.

5. Pharmacological properties
5.1 Pharmacodynamic properties
PHARMACOLOGICAL PROPERTIES
Pharmacodynamic Properties
Pharmacotherapeutic group: antihistamines – H1 antagonist, ATC code: R06A X27
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.

Efficacy of Aerius syrup has not been investigated in separate paediatric trials. Safety of Aerius syrup was demonstrated in three paediatric trials. Children, 1-11 years of age, who were candidates for antihistamine therapy received a daily desloratadine dose of 1.25 mg (1 through 5 years of age) or 2.5 mg (6 through 11 years of age). Treatment was well tolerated as documented by clinical laboratory tests, vital signs, and ECG interval data, including QTc. When given at the recommended doses, the plasma concentrations of desloratadine were comparable in the paediatric and adult populations. Thus, since the course of allergic rhinitis/chronic idiopathic urticaria and the profile of desloratadine are similar in adults and paediatric patients, desloratadine efficacy data in adults can be extrapolated to the paediatric population.

In a multiple dose clinical trial, in adults and adolescents, in which up to 20 mg of desloratadine was administered daily for 14 days, no statistically or clinically relevant cardiovascular effect was observed. In a clinical pharmacology trial, in adults and adolescents, in which desloratadine was administered to adults at a dose of 45 mg daily (nine times the clinical dose) for ten days, no prolongation of QTc interval was seen.

Desloratadine does not readily penetrate the central nervous system. In controlled clinical trials, at the recommended dose of 5 mg daily for adults and adolescents, there was no excess incidence of somnolence as compared to placebo. Aerius tablets given at a single daily dose of 7.5 mg to adults and adolescents did not affect psychomotor performance in clinical trials. In a single dose study performed in adults, desloratadine 5 mg did not affect standard measures of flight performance including exacerbation of subjective sleepiness or tasks related to flying.

In clinical pharmacology trials in adults, co-administration with alcohol did not increase the alcoholinduced impairment in performance or increase in sleepiness. No significant differences were found in the psychomotor test results between desloratadine and placebo groups, whether administered alone or with alcohol.

No clinically relevant changes in desloratadine plasma concentrations were observed in multiple-dose ketoconazole and erythromycin interaction trials.

In adult and adolescent patients with allergic rhinitis, Aerius tablets were effective in relieving symptoms such as sneezing, nasal discharge and itching, as well as ocular itching, tearing and redness, and itching of palate. Aerius effectively controlled symptoms for 24 hours. Efficacy has not been clearly demonstrated in patients 1 through 17 years of age.

In addition to the established classifications of seasonal and perennial, allergic rhinitis can alternatively be classified as intermittent allergic rhinitis and persistent allergic rhinitis according to the duration of symptoms. Intermittent allergic rhinitis is defined as the presence of symptoms for less than 4 days per week or for less than 4 weeks. Persistent allergic rhinitis is defined as the presence of symptoms for 4 days or more per week and for more than 4 weeks.

Desloratadine were effective in alleviating the burden of seasonal allergic rhinitis as shown by the total score of the rhino-conjunctivitis quality of life questionnaire. The greatest amelioration was seen in the domains of practical problems and daily activities limited by symptoms. In two placebo-controlled six week trials in patients

with chronic idiopathic urticaria, Aerius was effective in relieving pruritus and decreasing the size and number of hives by the end of the first dosing interval. In each trial, the effects were sustained over the 24 hour dosing interval. As with other antihistamine trials in chronic idiopathic urticaria, the minority of patients who were identified as nonresponsive to antihistamines was excluded. An improvement in pruritus of more than 50 % was observed in 55 % of patients treated with desloratadine compared with 19 % of patients treated with placebo. Treatment with Aerius also significantly reduced interference with sleep and daytime function, as measured by a four-point scale used to assess these variables.

5.2 Pharmacokinetic properties

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. The bioavailability of desloratadine was dose proportional over the range of 5 mg to 20 mg.

In a series of pharmacokinetic and clinical trials, 6 % of the subjects reached a higher concentration of desloratadine. The prevalence of this poor metaboliser phenotype was comparable for adult (6 %) and paediatric subjects 2- to 11-year old (6 %), and greater among Blacks (18 % adult, 16 % paediatric) than Caucasians (2 % adult, 3 % paediatric) in both populations.

In a multiple-dose pharmacokinetic study conducted with the tablet formulation in healthy adult subjects, four subjects were found to be poor metabolisers of desloratadine. These subjects had a Cmax concentration about 3-fold higher at approximately 7 hours with a terminal phase half-life of approximately 89 hours. Similar pharmacokinetic parameters were observed in a multiple-dose pharmacokinetic study conducted with the syrup formulation in paediatric poor metaboliser subjects 2- to 11-year old diagnosed with allergic rhinitis. The exposure (AUC) to desloratadine was about 6-fold higher and the Cmax was about 3 to 4 fold higher at 3-6 hours with a terminal half-life of approximately 120 hours. Exposure was the same in adult and paediatric poor metabolisers when treated with age-appropriate doses. The overall safety profile of these subjects was not different from that of the general population. The effects of Aerius syrup in poor metabolizers < 2 years of age have not been studied.

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 (5 mg to 20 mg) for 14 days.

In a single dose, crossover study of desloratadine, the tablet and the syrup formulations were found to be bioequivalent.

In separate single dose studies, at the recommended doses, paediatric patients had comparable AUC and Cmax values of desloratadine to those in adults who received a 5 mg dose of desloratadine syrup.

The enzyme responsible for the metabolism of desloratadine has not been identified yet, and therefore, some interactions with other medicinal products can not 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.

In a single dose trial using a 7.5 mg dose of desloratadine, there was no effect of food (high-fat, high caloric breakfast) on the disposition of desloratadine. In another study, grapefruit juice had no effect on the disposition of 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 with desloratadine reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, and toxicity to reproduction. The lack of carcinogenic potential was demonstrated in studies conducted with loratadine.

6. Pharmaceutical particulars
6.1 List of excipients

Sr. No.	Material Name	Specification
1.	Sucrose	BP
2.	Glycerol	BP
3.	Sodium Benzoate	BP
4.	Sodium Chloride	BP
5.	Citric Acid Monohydrate	BP
6.	Sodium Methyl Paraben	BP
7.	Sodium Propyl Paraben	BP
8.	Disodium edetate	BP
9.	Sodium Saccharin	BP
10.	Propylene glycol	BP
11.	Erythrosine Supra	IH
12.	Strawbery crush Liquid	IH
13.	Hydrochloric Acid	BP
14.	Purified Water	BP

6.2 Incompatibilities
None known

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store below 30°C in a dry place. Protect from light

6.5 Nature and contents of container
60 ml amber coloured glass bottle to be packed in carton along with pack insert.

6.6 Special precautions for disposal and other handling
No special requirements

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURER
Marketing Authorisation Holder:
NATIONAL PHARMACY LTD.,
P O BOX: 17843-00500,
Nairobi, Kenya

MANUFACTURER:
ZAIN PHARMA LTD.
Plot No: 209/13741, Colchester Park,
Go-Down No.1, 2, 3, Off Mombasa Road,
Behind Nice And Lovely House,
P.O. Box: 100167-00101, Nairobi, Kenya

8. Marketing Authorization Number:
H2025/CTD12761/27577

9. Date of First <Registration> / Renewal of the <Registration>
Not Applicable

10. Date of Revision of the Text: ---
20/08/2026