SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

ALLERBAN
Loratadine Tablets USP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains:
Loratadine USP……..…..….. 25 mg
Excipients…….... Q.S
Colour: Erythrosine
For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Tablet
For oral administration

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ALLERBAN is indicated for the symptomatic treatment of Allergic Rhinitis and Chronic Idiopathic Urticaria.

4.2 Posology and method of administration

Adults
One tablet once daily.
Paediatric population:
Children 6 years of age and older with a body weight greater than 30 kg:
One tablet once daily
For appropriate dosing in children younger than 6 years or with body weight of 30 kg or less, there are other formulations more suitable.
Children under 2 years of age:
Safety and efficacy of Loratadine 10 mg Tablets have not been established. No data are available.

Hepatic impairment

Patient with severe liver impairment should be administered a lower intial dose because they may have reduced clearance of loratadine. An initial dose of 10 mg every other day is recommended for adults and children weighing more than 30 kg.

Renal impairment

No dosage adjustments are required in patients with renal insufficiency.

Elderly

No dosage adjustments are required in the elderly.

Method of Administration

Oral

4.3 Contraindications

Hypersensitive to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

ALLERBAN should be administered with caution in patients with severe liver impairment. This medicinal product contains lactose; thus patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

The administration of ALLERBAN should be discontinued at least 48 hours before skin tests since antihistamines may prevent or reduce otherwise positive reactions to dermal reactivity index.

4.5 Interaction with other medicinal products and other forms of interaction

When administered concomitantly with alcohol, ALLERBAN has no potentiating effects as measured by psychomotor performance studies.

Potential interaction may occur with all known inhibitors of CYP3A4 or CYP2D6 resulting in elevated levels of Loratadine, which may cause an increase in adverse events.

Increase in plasma concentrations of Loratadine has been reported after concomitant use with ketoconazole, erythromycin, and cimetidine in controlled trials, but without clinically significant changes (including electrocardiographic).

Paediatric population

Interaction studies have only been performed in adults.

4.6 Pregnancy and lactation

Pregnancy

A large amount of data on pregnant women (more than 1000 exposed outcomes) indicate no malformative nor feto/ neonatal toxicity of loratadine. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

As a precautionary measure, it is preferable to avoid the use of ALLERBAN during pregnancy.

Breast-feeding
Loratadine is excreted in breast milk. Therefore, the use of Loratadine is not recommended in breast-feeding women.

Fertility
There are no data available on male and female fertility.

4.7 Effects on ability to drive and use machines

In clinical studies that assessed driving ability, no impairment was observed in patients receiving loratadine. Loratadine 10 mg Tablets has no or negligible influence on the ability to drive and use machines. 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

Summary of the safety profile
In clinical trials involving adults and adolescents in a range of indications including allergic rhinitis (AR) and chronic idiopathic urticarial (CIU), at the recommended dose of 10 mg daily, adverse reactions with loratadine were reported in 2% of patients in excess of those treated with placebo. The most frequent adverse reactions reported in excess of placebo were somnolence (1.2%), headache (0.6%), increased appetite (0.5%) and insomnia (0.1%).

Tabulated list of adverse reactions
The following adverse reactions reported during the post-marketing period are listed in the following table by System Organ Class. Frequencies are defined as very common (≥ 1/10), common (≥ 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).
Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Experience Term
Immune system disorders	Very rare	Hypersensitivity reactions (including angioedema and anaphylaxis)
Nervous system disorders	Very rare	Dizziness, convulsion
Cardiac disorders	Very rare	Tachycardia, palpitation

Gastrointestinal disorders	Very rare	Nausea, dry mouth, gastritis
Hepatobiliary disorders	Very rare	Abnormal hepatic function
Skin and subcutaneous tissue disorders	Very rare	Rash, alopecia
General disorders and administration site conditions	Very rare	Fatigue
Investigations	Not known	Weight increased

4.9 Overdose

Overdosage with Loratadine increased the occurrence of anticholinergic symptoms. Somnolence, tachycardia and headache have been reported with overdoses.
In the event of overdose, general symptomatic and supportive measures are to be instituted and maintained for as long as necessary. Administration of activated charcoal as a slurry with water may be attempted. Gastric lavage may be considered. Loratadine is not removed by haemodialysis and it is not known if Loratadine is removed by peritoneal dialysis. Medical monitoring of the patient is to be continued after emergency treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: H1 Antagonist
ATC code: R06A X13

Mechanism of action
Loratadine the active ingredient in ALLERBAN is a tricyclic antihistamine with selective, peripheral H1 receptor activity.

Pharmacodynamic effects
Loratadine has no clinically significant sedative or anticholinergic properties in the majority of the population and when used at the recommended dosage.
During long-term treatment there were no clinically significant changes in vital signs, laboratory test values, physical examinations or electrocardiograms.
Loratadine has no significant H2-receptor activity. It does not inhibit norepinephrine uptake and has practically no influence on cardiovascular function or on intrinsic cardiac pacemaker activity.
Human histamine skin wheal studies following a single 10 mg dose has shown that the antihistamine effects are seen within 1-3 hours reaching a peak at 8-12 hours and lasting in

excess of 24 hours. There was no evidence of tolerance to this effect after 28 days of dosing with loratadine.

5.2 Pharmacokinetic properties

Absorption
Loratadine is rapidly and well-absorbed. Concomitant ingestion of food can delay slightly the absorption of Loratadine but without influencing the clinical effect. The bioavailability parameters of loratadine and of the active metabolite are dose proportional.

Distribution
Loratadine is highly bound (97% to 99%) and its active major metabolite desloratadine (DL) moderately bound (73% to 76%) to plasma proteins.
In healthy subjects, plasma distribution half-lives of loratadine and its active metabolite are approximately 1 and 2 hours, respectively.

Biotransformation
After oral administration, loratadine is rapidly and well absorbed and undergoes an extensive first pass metabolism, mainly by CYP 3A4 and CYP 2D6. The major metabolite – desloratadine (DL) – is pharmacologically active and responsible for a large part of clinical effect. Loratadine and DL achieve maximum plasma concentrations (Tmax) between 1 – 1.5 hours and 1.5 – 3.7 hours after administration, respectively.

Elimination
Approximately 40% of the dose is excreted in the urine and 42% in the faeces over a 10-day period and mainly in the form of conjugated metabolites. Approximately 27% of the dose is eliminated in the urine during the first 24 hours. Less than 1% of the active substance is excreted unchanged in active form, as loratadine or DL.
The mean elimination half-lives in healthy adult subjects were 8.4 hours (range = 3 to 20 hours) for loratadine and 28 hours (range = 8.8 to 92 hours) for the major active metabolite.

Renal impairment
In patients with chronic renal impairment, both the AUC and the peak plasma levels (Cmax) increased for loratadine and its metabolite as compared to the AUCs and peak plasma levels (Cmax) of patients with normal renal function. The mean elimination half-lives of loratadine and its active metabolite were not significantly different from that observed in normal subjects. Haemodialysis does not have an effect on the pharmacokinetics of loratadine or its active metabolite in subjects with chronic renal impairment.

Hepatic impairment
In patients with chronic alcoholic liver disease, the AUC and peak plasma levels (Cmax) of loratadine were double while the pharmacokinetic profile of the active metabolite was not significantly changed from that in patients with normal liver function. The elimination half-

lives for loratadine and its active metabolite were 24 hours and 37 hours, respectively, and increased with increasing severity of liver disease.

Elderly
The pharmacokinetic profile of loratadine and its active metabolite is comparable in healthy volunteers and in healthy geriatric volunteers.

5.3 Preclinical Safety Data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential.
In reproductive toxicity studies, no teratogenic effects were observed. However, prolonged parturition and reduced viability of offspring were observed in rats at plasma levels (AUC) 10 times higher than those achieved with clinical doses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name of Material	Specification
Maize Starch	BP
Dibasic Calcium Phosphate	BP
Sodium Benzoate	BP
Color Erythrosine Supra	IHS
Purified water	BP
Magnesium stearate	BP
Purified Talc	BP

6.2 Incompatibilities
NA

6.3 Shelf life
36 Months

6.4 Special precautions for storage
Store below 30°C. Protected from light.
KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container
10 x 10 Tablets in Alu-PVC pack is packed in a printed carton along with a package insert.

6.6 Instructions for use and handling
No special requirements.

7. MARKETING AUTHORISATION HOLDER

Ahmedabad
Gujarat, India.
E-mail: info@sagalabs.com
URL: www.sagalabs.com

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

07803/07973/NMR/2019

9. DATE OF FIRSHT AUTHORISATION/RENEWAL OF THE AUTHORISATION

Sep 23, 2022

10. DATE OF REVISION OF THE TEXT

01 April 2026