1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

1.1 (Invented) Name of the medicinal product

NEURODAY (Loratadine Tablets USP 10 mg)

1.2 Composition

Each Uncoated Tablet Contains:
Loratadine USP …….10 mg
Excipients……..Q.S.

1.3 Pharmaceutical Form
Tablets

2. Qualitative and Quantitative Formula

Sr. No.	Ingredient	Specification	Qty/ Tab (mg)	Qty/Batch (Kg)	Functions
1.	Lactose	BP	91.00	91.910	Diluent
2.	PVP K-30	BP	6.00	6.060	Binder
3.	IPA	BP	q.s	q.s	Solvent
4.	Maize Starch	BP	84.00	84.840	Diluent
Wt. Without Lubrication			**181 mg**	**182.81**	
5.	Talcum	BP	2.00	2.020	Lubricant
6.	SSG	BP	3.00	3.030	Disintegrant
7.	Magnesium Stearate	BP	4.00	4.040	Lubricant
8.	Loratadine	USP	10.00	10.100	API
9.	Dry Raspberry	IH	1.00	1.010	Flavouring agent
10.	Aerosil	BP	3.00	3.030	Adsorbent
11.	Aspartame	BP	2.00	2.020	Sweetner
12.	Maize Starch	BP	q.s	q.s	Diluent
13.	LLP	BP	1.6580	1.675	Lubricant
Wt. With Lubrication			**206.00 mg**	**208.06**	

3. Pharmaceutical form
White to off white Colour Round Shape, Biconvex Uncoated Tablet.

4. Clinical particulars:
4.1 Therapeutic Indication:
Treatment of:
Loratadine Tablet USP 10 mg is indicated for the symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria.

4.2 Dosage and Administration:
Oral use. The tablet may be taken without regard to mealtime.
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 tablets have not been established. No data are available.
Patients with hepatic impairment
Patients with severe liver impairment should be administered a lower initial dose because they may have reduced clearance of Loratadine. An initial dose of 10mg every other day is recommended for adults and children weighing more than 30kg.
Patients with renal impairment
No dosage adjustments are required in patients with renal insufficiency.
Elderly
No dosage adjustments are required in the elderly.

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients used in this formulation

4.4 Special warnings and precautions for use:
Loratadine Tablet USP 10 mg should be administered with caution in patients with severe liver impairment.
The administration of Loratadine Tablet USP 10 mg should be discontinued at least 48 hours before skin tests since antihistamines may prevent or reduce otherwise positive reactions to dermal reactivity index.
This medicinal product contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction
When administered concomitantly with alcohol, Loratadine Tablet USP 10 mg 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 Fertility, 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. As a precautionary measure, it is preferable to avoid the use of Loratadine Tablet USP 10 mg 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 trials that assessed driving ability, no impairment occurred in patients receiving Loratadine. Loratadine 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 urticaria (CIU), at the recommended dose of 10mg 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).
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
Paediatric population
In clinical trials in a paediatric population, children aged 2 through 12 years, common adverse reactions reported in excess of placebo were headache (2.7%), nervousness (2.3%), and fatigue (1%).
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.

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 overdosage, 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: H_1 antagonist
ATC Code: R06A X13.

Pharmacodynamic properties
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 H_2-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 CYP3A4 and CYP2D6. The major metabolite-desLoratadine (DL)- is pharmacologically active and responsible for a large part of the clinical effect. Loratadine and DL achieve maximum plasma concentrations (T_{max}) 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.

5.3 Preclinical safety data

Preclinical data reveal no special hazard 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
Lactose	BP
PVP K-30	BP
IPA	BP
Maize Starch	BP
Talcum	BP
SSG	BP
Magnesium Stearate	BP
Dry Raspberry	IH
Aerosil	BP
Aspartame	BP
Maize Starch	BP
LLP	BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 months from the date of manufacturing.

6.4 Special precautions for storage

Store in a dry place below 30°C. Protected from light.

6.5 Nature and contents of container

10 X 10 Alu - Alu Blisters in printed carton along with package insert.

6.6 Special precautions for disposal

No special requirements.

7. REGISTRANT

HUGO DRUGS LIMITED
62 FALOLU STREE, SURULERE LAGOS. NIGERIA

8. DATE OF REVISION OF THE TEXT

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9. NAME AND ADDRESS OF MANUFACTURER HEALTH CARE FORMULATIONS PRIVATE LIMITED C/8,

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BARODA 390 019