SUMMARY OF PRODUCT CHARACTERISTICS

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1. NAME OF THE FINISHED PRODUCT

Loratyn-10

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS	PER TABLET (MG)
Loratadine	10 mg

Kindly refer to Section 6.1 for excipient.

3. PHARMACEUTICAL FORM

White, oblong uncoated tablet, shallow convex, scored on one face and 'H 10' embossed on the same face.

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

- For relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge (rhinorrhea) and itching, and ocular itching and burning.
- Also indicated for relief of symptoms and signs of chronic urticaria and other allergic dermatological disorders.

4.2 Posology and Method of administration

Route of administration is oral.
Usual adult and adolescent dose: Oral; 10 mg once daily.
Usual geriatric dose: Oral; 10 mg once daily.
(Note: Geriatric patients may be more sensitive to the effects of the adult dose)

Patients with severe liver impairment:
Due to the possibility of a reduced clearance of loratadine, a lower dose should be administered, i.e. an initial dose of 5 mg once daily, or 10 mg on alternate days is recommended.

4.3 Contraindication

Risk-benefit should be considered when the following medical problems exist: bladder neck obstruction, prostatic hypertrophy, urinary retention, glaucoma, or sensitivity to loratadine.

4.4 Warnings and precautions

- Precaution should be exercised when administering loratadine to patients with severe hepatic impairment as reduced clearance of loratadine may occur.
- Patients sensitive to one of the antihistamines may be sensitive to others.
- Drugs known to inhibit hepatic metabolism should be co-administered with caution until definitive interaction studies can be completed. The number of subjects who

concomitantly received macrolide antibiotics, ketoconazole, cimetidine, ranitidine or theophylline along with loratadine in controlled clinical trials is too small to rule out possible drug interactions.

4.5 Drug Interactions

Concomitant therapy with drugs that inhibit or are metabolized by hepatic cytochromes P450, 3A4 and/or 2D6, may elevate plasma concentrations of either drug and adverse effects might result. Increased plasma concentrations of loratadine have been reported when used concomitantly with ketoconazole, erythromycin and cimetidine.

4.6 Pregnancy and lactation

The safe use of loratadine in pregnancy has not been established. Small amounts of loratadine are excreted in breast milk and therefore risk-benefit should be considered due to the increased risk of antihistamines on infants.

4.7 Effects on ability to drive and use machines

None known

4.8 Main Side/ Adverse Effects

Sedative and anticholinergic effects are not likely. Events of fatigue, nausea and headache were reported rarely. Spontaneous adverse events reported rarely include alopecia, anaphylaxis, and abnormal hepatic function.

4.9 Overdose

Symptoms of overdosage, i.e. somnolence, tachycardia and headache have been reported.

Treatment of overdosage:

In the event of overdosage, treatment which should be started immediately is symptomatic and supportive. The patient should be induced to vomit, even if emesis has occurred spontaneously, but not in patients with impaired consciousness. Administration of activated charcoal as a slurry with water may be attempted following emesis. If vomiting is unsuccessful or contraindicated, gastric lavage should be performed.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Loratadine, a piperidine derivative related to azatadine, is a long-acting, non-sedating tricyclic antihistamine with selective peripheral H1-receptor antagonist activity, with no significant sedative or antimuscarinic activity.

5.2 Pharmacokinetic properties

Loratadine is rapidly absorbed from the gastrointestinal tract after oral administration. Peak plasma concentrations are being attained in about one hour. Loratadine, which is 98%, bound to plasma protein, undergoes extensive metabolism, mainly to descarboethoxyloratadine, which has potent antihistamine activity. However, descarboethoxyloratadine is less extensively bound to plasma protein. Loratadine and descarboethoxyloratadine have half-lives of 8.4 hours and 28 hours respectively. Most of a dose is excreted equally in the urine and faeces, mainly in the form of metabolites.

5.3 Preclinical Safety Data

NOT APPLICABLE

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipeints

Magnesium Stearate
Sodium Starch Glycolate
Polyvinylpyrrolidone
Lactose Monohydrate
Cornstarch
Colloidal Silicon Dioxide

6.2 Incompatibilities

NOT APPLICABLE

6.3 Shelf life

3 years from date of manufacture

6.4 Special precaution for storage

Store below 30˚C. Protect from moisture.

6.5 Nature and contents of container

I. Immediate Container/Packaging

Blister Pack

Type: Push-through blister pack; the package consists of a transparent thermoformable plastic material (PVC) and aluminium foil.

PVC Film

Appearance: Clear transparent film

Aluminium foil

Description: Aluminium foil with high slip primer on bright surface and heat seal on matt surface

II. Secondary Packaging Components

a) Material description : Loratyn-10 (10 x 10) Unit Box
b) Material description : Plain carton for Loratyn-10
c) Material description : Loratyn-10 Insert

6.6 Instructions for use and handling <and disposal>

NOT APPLICABLE

7. MARKETING AUTHORISATION HOLDER

Name : HOVID Bhd.
Address : 121, Jalan Tunku Abdul Rahman,
(Jalan Kuala Kangsar)
30010 Ipoh, Perak, Malaysia

Manufacturer Name :

Name : HOVID Bhd.
Address : Lot 56442, 7 ½ Miles,
Jalan Ipoh / Chemor,
31200 Chemor,
Perak., Malaysia.

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

05720/6395/REN/2018

9. DATE OF FIRST AUTHORISATION

2018

10. DATE OF REVISION OF THE TEXT

April 2017