SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

Name of the medicinal product

Lorinase

Qualitative and quantitative composition

For Lorinase syrup:
Active ingredients: Loratadine Micronized USP 5 mg and Pseudoephedrine sulfate 60 mg.

For a full list of excipients, see section 6.1.

Pharmaceutical form

A colourless to yellowish syrup with a characteristic strawberry odour and taste, free from foreignmatter.

Clinical particulars

Therapeutic indications

Lorinase syrup is indicated for the symptomatic treatment of seasonal allergic rhinitis when accompanied by nasal congestion.

Posology and method of administration

Adults and children 6-12 years of age (body weight > 30 Kg): 5 ml syrup (one tea spoonful) twicea day (every 12 hours).

Do not give to children below 6 years of age.

Contraindications

- Hypersensitivity to the active substance or to any of the excipients.

Since Lorinase syrup containing pseudoephedrine, it is also contraindicated in patients receiving monoamine oxidase enzyme (MAO) inhibitors or within 14 days after discontinuation of MAO inhibitors in patients with narrow-angle glaucoma, urinary retention, cardiovascular diseases, such as for example. Coronary ischemia, tachyarrhythmia and severe hypertension, or hyperthyroidism.

Lorinase syrup should not be given to children under the age of 6 years.

Special warnings and precautions for use

In patients taking digitalis, patients with cardiac arrhythmias, hypertension, myocardial infarction, diabetes, stenosing peptic ulcer, pyloroduodenal obstruction, prostatic hypertrophy or bladder neck obstruction, or bronchospasm in patients with a history of caution. Special caution is required in patients aged 60 years or more, it is for people in this age group are more likely adverse reactions to sympathomimetics. In this case, the dose should be reduced. The dose should be reduced in the case of severe renal insufficiency.

Caution should be exercised in patients treated with other sympathomimetic agents, including decongestants, drugs to reduce appetite or amphetamine-type stimulant medications, antihypertensive, tricyclic antidepressants and other antihistamines.

As with any CNS stimuli are also in pseudoephedrine sulfate reported abuse. Prolonged use can lead to tolerance and therefore increases the risk of over-dosing.

The effect of the results of laboratory test results: Antihistamines should be discontinued approximately 2 days before skin tests because they can prevent or reduce otherwise positive reaction to the skin indicators.
Lorinase medicine may affect your test taking doping in athletes.

Lorinase medicine contains sucrose: Patients with rare hereditary problems of fructose intolerance, glucose / galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Lorinase medicine contains lactose: patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose / galactose malabsorption should not take this medicine.

Interaction with other medicinal products and other forms of interaction

Loratadine: Concomitant use of alcohol Loratadine does not increase its activities, which are research assessed by measurements of physical and mental fitness.

Following concomitant administration of ketoconazole, erythromycin, or cimetidine in controlled clinical trials reported an increase in plasma concentrations of Loratadine but without clinically significant changes (including changes in the ECG). Other drugs known to inhibit hepatic metabolism should only be used concurrently with caution until definitive studies are completed drug-drug interactions.

Pseudoephedrine: Sympathomimetics may reduce the antihypertensive effect of drugs affecting the sympathetic system as example. methyldopa, reserpine, and guanethidine, and partially counteract the hypotensive effects of beta blockers. Concomitant use of tablets Lorinase with sympathomimetic agents such as, for example. decongestants, drugs used to reduce appetite, amphetamines, tricyclic antidepressants or MAO inhibitors may increase blood pressure. Due to the long-term operation MAO inhibitors, this effect can also be 14 days after discontinuation of treatment (see section 4.3). Concomitant use of furazolidone should be avoided as it may cause a dose-dependent brake MAO. Concomitant use of pseudoephedrine and digitalis may result in increased ectopic activity centers in the heart. Antacids increase the rate of pseudoephedrine absorption, kaolin decreases it.

Fertility, Pregnancy and lactation

Pregnancy Category C
The safety of Lorinase during pregnancy and lactation has not been established, so the drug in themeantime should not be used.

Effects on ability to drive and use machines

At a daily dose of 10 mg of Loratadine were reported sedating the operation of the product. Attention and reaction time were not reduced. Similarly, it is not known that pseudoephedrinesulfate decreased psychophysical ability.

Undesirable effects

Reported adverse reactions by system organ class in MedDRA
Very common (≥ 1/10); Common (≥ 1/100 to <1/10); uncommon (≥ 1/1000 to <1/100); Rare (≥ 1/10, 000 to <1/1000); very rare (<1/10, 000)

Metabolism and nutrition disorders
Common: thirst.

Psychiatric disorders
Very common: anorexia, insomnia.
Common: nervousness, somnolence, depression, agitation.

Nervous system disorders Very common: dry mouth. Common: dizziness.
Uncommon: confusion, tremors, increased sweating, hot flushes, broken flavor.

Eye Disorders
Uncommon: disorders of lacrimal gland.

Ear and labyrinth disorders Uncommon: tinnitus

Heart disease Common: tachycardia Uncommon: palpitations

Respiratory, thoracic and mediastinal disorders
Common: pharyngitis, rhinitis Uncommon: epistaxis

Gastrointestinal Disorders Common: constipation, nausea

Renal and urinary disorders Uncommon: micturition disorders

Skin and subcutaneous tissue disorders
Common: pruritus

General disorders and administration site conditions
Common: headache, chills.

Other adverse reactions have been reported very rarely during post-marketing are listed below:

Immune system disorders: anaphylaxis

Nervous system disorders: vertigo **Vascular diseases:** hypertension

Respiratory, thoracic and mediastinal disorders: cough, bronchospasm

Hepato-biliary disorders: abnormal liver function

Renal and urinary disorders: urinary retention

Skin and subcutaneous tissue disorders: alopecia

Other adverse reactions reported during post-marketing only to Loratadine include increased appetite, redness and gastritis.

To report any side effect(s):

The National Pharmacovigilance and Drug Safety Centre
(NPC) o Fax: +966-11-205-7662
o Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340. o Toll free phone: 8002490000
o E-mail: npc.drug@sfda.gov.sa o Website: www.sfda.gov.sa/npc

Overdose

In case of overdose should be initiated immediately with general symptomatic treatment and supportive care measures that should last as long as necessary.

In addition to mild sedation, which might be caused by Loratadine at doses that are severaltimes higher than the recommended dose of medicine for intoxication occur even signs of overdose sympathomimetic agents. May vary from CNS depression (sedation, apnea, reduce mental attention, cyanosis, coma, cardiovascular collapse) to CNS stimulation (insomnia, hallucinations, tremors or convulsions), perhaps even death. Other signs and symptoms may include headache, anxiety, difficulty urinating, muscle weakness and tension, euphoria, agitation, tachycardia, palpitations, thirst, sweating, nausea, vomiting, precordial pain, dizziness, tinnitus, ataxia, blurred vision and hypertension or hypotension. The probability of CNS stimulation is particularly high in children, and this also applies to signs and symptoms similar to those seen after atropine (dry mouth, dilated pupils unresponsive, flushing, hyperthermia, and gastrointestinal symptoms).

Treatment: The patient vomiting, even if it is already vomited spontaneously. The best way to challenge vomiting using syrup of ipecac. In patients with disorders of consciousness, vomiting should not be induced. Precautions must be taken against aspiration of vomit, especially in children. After vomiting may try to adsorb the remaining amount of drug in the stomach, so that the patient administered the active carbon in the form of a mixture with water.

If vomiting is unsuccessful or contraindicated if it is necessary to carry out gastric lavage. The solution of choice for this purpose is a saline solution, particularly in children, while in adults may be used as drinking water. Before the next instillation should be removed as big as possible intake of medicines.

Salt laxatives pull water into the intestines on the principle of osmosis and therefore may be useful due to the rapid dilution of bowel content.

It is not known, or can be administered to remove by dialysis.

After emergency treatment, the patient continued to remain under medical supervision. Treatment of the signs and symptoms of overdose is symptomatic and supportive. Stimulants (analeptiki) should not be used. Hypertension can be controlled with alpha blockers, tachycardia with beta- blockers. Short-acting barbiturates - diazepam 10 mg i.v. or i.m. (adults) and 0.5 mg / kg intrarectally (children), or paraldehyde - can be used for the control of possible seizures. In hyperpyrexia, especially in children, may require lowering the body temperature by washing with a sponge soaked in lukewarm water, or hypothermic blanket. Apnea is treated with ventilatory support.

Pharmacological properties

Pharmacodynamic properties

Pharmacotherapeutic group: nasal decongestants for systemic use, ATC code: R01BA52

Pharmacodynamics Lorinase tablet directly follows from the pharmacokinetics of active ingredients: Loratadine is a long-acting antihistamine and pseudoephedrine sulfate, which is a nasal decongestant. Loratadine is a potent long-acting tricyclic antihistamine with selective antagonism of peripheral H1-receptors, no central sedative or anticholinergic activity.

Pharmacokinetic properties

Loratadine:

Absorption and metabolism:

After oral administration, Loratadine is rapidly and well absorbed and extensively metabolized in the first pass. On the basis of a comparison of AUC assume that the ratio of Loratadine and its active metabolites of about 0.05, starting from the C max, however, this ratio is approximately 0.29.

Distribution:

The half-life of distribution of Loratadine is approximately 1 hour and 2 hours for the activemetabolite.

Elimination:

The initial data for normal subjects showed a mean elimination half-life of 12.4 hours for Loratadine and 19.6 hours for its active metabolite. Subsequent data for normal adult subjects showed a mean elimination half-life of 8.4 hours (range, 3 to 20 hours) for Loratadine and 28 hours (range 8.8 to 92 hours) for its major active metabolite. In 10 days excreted about 40% of the dose in urine and 42% in the faeces, primarily in the form of conjugated metabolites. Approximately 27% of the dose is excreted in the urine within the first 24 hours. The urine was found unchanged Loratadine and its active metabolite trace.

The pharmacokinetic profile of Loratadine and its metabolites in healthy elderly volunteers is similar to that of healthy adult volunteers. Bioavailability parameters of Loratadine and its active metabolite are dose proportional. Loratadine and its active metabolite are excreted in the milk of lactating mothers. 48 hours after ingestion of Loratadine found in the milk of only 0.029% of the dose in the form of unchanged Loratadine and its active metabolite. Loratadine is highly bound to plasma proteins (97% to 99%), its active metabolite moderately (73% to 76%).

Pseudoephedrine sulfate:

Absorption and metabolism:

After oral administration, pseudoephedrine sulfate is absorbed quickly and completely. Its onset of action occurred within 30 minutes and the dose of 60 mg operates decongestant for 4 to 6 hours. Pseudoephedrine sulfate is incompletely metabolized in the liver by N-demethylation to an inactive metabolite.

Elimination:

Elimination half-life in humans, at a suitable pH of the urine (and 6) is between 5 and 8 hours. Drug and its metabolite are excreted in the urine, namely 55-75% of the dose in unchanged form. Secretion rate is larger and a shorter duration of action, if the urine acidic (pH 5). In the case of alkalinisation of urine there is a partial reabsorption.

Pseudoephedrine is presumed to cross the placenta and into the cerebrospinal fluid. This medicine may be excreted in the milk of lactating women.

Preclinical safety data

Studies on laboratory animals it has been shown that Loratadine has very low affinity for the membrane receptors in the cortex and does not pass quickly into the CNS. Profile sedation for Loratadine at a dose of 10 mg per day was similar to that of sedation for placebo. Long-term treatment has not been established clinically significant changes in vital signs, test results of laboratory tests, physical examination, or ECG.

List of excipients

- Fructose: 1600 mg
- Polyethylene Glycol 1500 (SP): 900 mg
- Disodium Edetate: 1.25 mg
- Citric Acid Anhydrous: 117.50 mg
- Sodium Citrate Anhydrous: 10 mg
- Sodium Benzoate: 5 mg
- Sorbitol Solution 70% Non Cryst: 765 mg
- Propylene Glycol: 500 mg
- Strawberry Flavour Liquid: 10 mg
- Sucralose: 15 mg
- Purified Water BP: q.s to 5 ml

Incompatibilities

Not Applicable.

Shelf life

24 months / 2 years
This medicine will be expired after 30 days from the first opening.

Special precautions for storage

Do not store above 30°C.

Nature and contents of container

For Lorinase syrup: 100 ml amber bottle with child resistant cap/unit carton.

Special precautions for disposal and other handling

No Special Disposal

Marketing authorisation holder

SPIMACO
Al Qassim Pharmaceutical Plant,
Saudi Pharmaceutical Industries & Medical Appliance Corporation

Marketing authorisation number(s)

TAN 21 HM 0481

Date of first authorisation/renewal of the authorisation

26/11/2021

Date of revision of the text