Claritine (loratadine)

Amendments to the Product Information

It has been agreed that the following amendments to the Product Information are required:

CSP wording

Section 4.6

The following new wording was implemented in the section 4.6 (Fertility, pregnancy and lactation) of the CSP:

"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 {tradename} during pregnancy.

Loratadine is excreted in breast milk, therefore the use of loratadine is not recommended in breast-feeding women. »

Section 4.8

The following modifications were implemented in the section 4.8 (Undesirable effects) of the CSP:

SOC IMMUNE SYSTEM DISORDERS: Hypersensitivity reactions (including angioedema and anaphylaxis)

SOC NERVOUS SYSTEM DISORDERS: Dizziness, Convulsion

Core Safety Profile

Loratadine

4.3 Contraindications

X is contraindicated in patients who are hypersensitive to the active substance or to any of the excipients in these formulations.

4.4 Special warnings and precautions for use

X should be administered with caution in patients with severe liver impairment (see section 4.2).

<Tablet
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.>

<<Syrup>
This medicinal product contains sucrose; thus patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase isomaltase insufficiency should not take this medicine.>

<<Effervescent tablet><soluble tablet>
This medicinal product contains lactose, sorbitol and sucrose; thus patients with rare hereditary problems of fructose, galactose intolerance, the Lapp lactase deficiency, glucose-galactose malabsorption or sucrose isomaltase insufficiency should not take this medicine.>

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.>

[To be completed nationally]

The administration of X 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, X 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 (see Section 5.2), which may cause an increase in adverse events.

4.6 Fertility, pregnancy and lactation

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 {tradename} during pregnancy.

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

4.7 Effects on ability to drive and use machines

In clinical trials that assessed driving ability, no impairment occurred in patients receiving loratadine.
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, children aged 2 through 12 years, common adverse reactions reported in excess of placebo were headache (2.7%), nervousness (2.3%), and fatigue (1%).

In clinical trials involving adults and adolescents in a range of indications including AR and 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%). Other adverse reactions reported very rarely during the post-marketing period are listed in the following table.

Immune system disorders	Hypersensitivity reactions (including angioedema and anaphylaxis)
Nervous system disorders	Dizziness, convulsion
Cardiac disorders	Tachycardia, palpitation
Gastrointestinal disorders	Nausea, dry mouth, gastritis
Hepatobiliary disorders	Abnormal hepatic function
Skin and subcutaneous tissue disorders	Rash, alopecia
General disorders and administration site conditions	Fatigue

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.

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