

## **Summary Public Assessment Report**

**non-generics**

**Strepfen Lemon & Honey 8.75 mg  
oromucosal spray**

**(flurbiprofen)**

**NL/H/4506/001/DC**

**Date: 17 March 2020**

## Summary Public Assessment Report

### non-generics

Streptfen Lemon & Honey 8.75 mg oromucosal spray  
Active substance: flurbiprofen

This is a summary of the public assessment report (PAR) for Streptfen Lemon & Honey. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Streptfen Lemon & Honey.

For practical information about using this medicine, patients should read the package leaflet or contact their doctor or pharmacist.

#### **What is Streptfen Lemon & Honey and what is it used for?**

Streptfen Lemon & Honey is used for the short term relief of symptoms of sore throat such as throat soreness, pain, difficulty swallowing and swelling in adults aged 18 and over.

#### **How does this medicine work?**

The active substance in this medicine is flurbiprofen. Flurbiprofen belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), which work by changing how the body responds to pain, swelling and high temperature.

#### **How is this medicine used?**

The pharmaceutical form of this medicine is an oromucosal spray. One dose of 3 sprays should be administered to the back of the throat every 3-6 hours as required, up to a maximum of 5 doses in a 24 hour period.

In the Netherlands, this medicine can be obtained without a prescription.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

#### **What benefits of this medicine have been shown in studies?**

The company provided its own data on efficacy and safety studies. In these studies Streptfen Lemon & Honey 8.75 mg oromucosal spray was more effective than placebo (dummy treatment) at improving the symptoms of sore throat.

#### **What are the possible side effects from this medicine?**

The most common side effects with Streptfen Lemon & Honey (which may affect more than 1 in 10 people) are dizziness, headache, throat irritation, mouth ulcers, pain or numbness in the mouth, throat pain, discomfort (warm or burning feeling or tingling) in the mouth, nausea and diarrhoea, prickling and itching sensation in skin.

For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

**Why is this medicine approved?**

The Medicines Evaluation Board of the Netherlands decided that the benefits of this medicine are greater than its risks and recommended that it be approved for use.

**What measures are being taken to ensure the safe and effective use of this medicine?**

A risk management plan has been developed to ensure that Strepfen Lemon & Honey is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for this medicine, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

**Other information about Strepfen Lemon & Honey**

In the Netherlands, the marketing authorisation for Strepfen Cherry Mint 8.75 mg oromucosal spray was granted on 6 November 2019.

The full PAR for this medicine can be found on the website <http://mri.cts-mrp.eu/Human/>. For more information about treatment with this medicine, read the package leaflet (<http://mri.cts-mrp.eu/Human/Product/Details/58350>) or contact your doctor or pharmacist.

This summary was last updated in March 2020.