

Summary Public Assessment Report
non-generics

**Livoden
(flurbiprofen)**

SK/H/0325/001/DC

Date: 17/12/2025

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Livoden

flurbiprofen; oromucosal spray, solution; 8,75 mg/dose

This is a summary of the public assessment report (PAR) for Livoden. It explains how Livoden 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 Livoden.

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

What is Livoden and what is it used for?

Livoden is a 'hybrid generic medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available as oromucosal spray, solution.

The company has provided additional own data to demonstrate the safety and efficacy of Livoden regarding this difference from the reference medicine.

The reference medicine for Livoden is Strepfen Sprej 8,75 mg orálna roztoková aerodisperzia. Livoden is used for the short-term relief of symptoms of sore throats such as throat soreness, pain, swelling and difficulty swallowing in adults aged 18 and over.

How does Livoden work?

The active substance 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 Livoden used?

The pharmaceutical form of Livoden is oromucosal spray, solution and the route of administration is oromucosal use.

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

The recommended dose is:

Adults aged 18 years and over

One dose of 3 actuations to the back of the throat every 3-6 hours as required, up to a maximum of 5 doses (15 actuations) in a 24-hour period.

One dose (3 actuations) contains 8.75 mg of flurbiprofen.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

The medicine can be obtained without a prescription.

What benefits of Livoden have been shown in studies?

Because Livoden is a hybrid application and is considered to be therapeutically equivalent, to the reference product Strepfen Sprej 8,75 mg orálna roztoková aerodisperzia, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Livoden?

The most common side effect with Livoden (which may affect more than 1 in 10 people) is inflammation of the mucosa of the oral cavity (stomatitis).

The most common side effects with Livoden (which may affect up to 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 Livoden, see section 4 of the package leaflet.

STOP TAKING this medicine and contact a doctor immediately if you develop:

- Severe forms of skin reaction such as bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis.
- Signs of anaphylactic shock characterised by swelling of the face, tongue or throat causing difficulty in breathing, racing heart, drop in blood pressure leading to shock.
- Signs of hypersensitivity and skin reactions such as redness, swelling, peeling, blistering, flaking or ulceration of skin and mucous membrane.
- Signs of an allergic reaction such as asthma, unexplained wheezing or shortness of breath, itching, runny nose, or skin rashes.
- Swelling of different parts of the body (angioedema).

For the full list of restrictions, see the package leaflet.

Why is Livoden approved?

The State institute of drug control in Slovakia decided that Livoden's benefits are greater than its risks and recommended that it be approved for use.

Other information about Livoden

The marketing authorisation for Livoden was granted on 24/10/2025.

The full PAR for Livoden can be found on the website www.sukl.sk. For more information about treatment with Livoden, read the [package leaflet](#) (link) or contact your doctor or pharmacist.

This summary was last updated in 12/2025.