Summary Public Assessment Report

non-generics

Flurbiprofen Naiax orálny roztokový sprej (flurbiprofen)

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Flurbiprofen orálny roztokový sprej

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

This is a summary of the public assessment report (PAR) for Flurbiprofen orálny roztokový sprej. It explains how Flurbiprofen orálny roztokový sprej 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 Flurbiprofen orálny roztokový sprej.

For practical information about using Flurbiprofen orálny roztokový sprej, patients should read the package leaflet or contact their doctor or pharmacist.

What is Flurbiprofen orálny roztokový sprej and what is it used for?

Flurbiprofen orálny roztokový sprej 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 Flurbiprofen orálny roztokový sprej regarding this difference from the reference medicine.

The reference medicine for Flurbiprofen orálny roztokový sprej is Strepfen Sprej 8,75 mg orálna roztoková aerodisperzia.
Flurbiprofen orálny roztokový sprej 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 Flurbiprofen orálny roztokový sprej 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 Flurbiprofen orálny roztokový sprej used?

The pharmaceutical form of Flurbiprofen orálny roztokový sprej 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 Flurbiprofen orálny roztokový sprej have been shown in studies?

Because Flurbiprofen orálny roztokový sprej 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 Flurbiprofen orálny roztokový sprej?

The most common side effect with Flurbiprofen orálny roztokový sprej (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 Flurbiprofen orálny roztokový sprej (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 Flurbiprofen orálny roztokový sprej, 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 orulceration 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 Flurbiprofen orálny roztokový sprej approved?

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

Other information about Flurbiprofen orálny roztokový sprej

The marketing authorisation for Flurbiprofen orálny roztokový sprej was granted on 24/10/2025.

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

This summary was last updated in 12/2025.