

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed without a doctor's prescription

Strefen Spray 8.75 mg, Oromucosal Spray Solution

Active substance composition and quantity:

Flurbiprofen 2.92 mg /Actuation

Inactive ingredients – see the list in Section 6. See also section "Important information about some of the ingredients of the medicine"

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to your doctor or pharmacist.

You must use this medicine in accordance with the instructions in the section concerning dosage in this leaflet. Consult your pharmacist if you need further information. Refer to your doctor if the symptoms worsen or do not improve after 3 days.

1. What is the medicine intended for?

Strefen Spray 8.75 mg is intended for the short-term relief of the symptoms of acute sore throat in adults.

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

2. Before using the medicine

• Do not use this medicine if:

- o You are sensitive (allergic) to flurbiprofen, other non-steroidal anti-inflammatory drugs (NSAIDs), aspirin (acetylsalicylic acid) or any of the other ingredients this medicine contains (see section 6)
- o You have previously suffered from hypersensitivity (such as: asthma, bronchospasm/wheezing, rhinitis/runny nose, hives/ skin rash (urticaria), angioedema/swelling/edema) after the use of aspirin or other NSAIDs.
- o You are suffering or have suffered in the past from recurrent peptic ulcer (2 or more episodes of proven peptic ulcer) or gastrointestinal bleeding.
- o You have suffered in the past from gastrointestinal perforation or bleeding, severe colitis (inflammation of the bowel) or from

bleeding related to treatment with other NSAIDs.

- o You are in your last trimester of pregnancy. See also the section 'Pregnancy, breastfeeding and fertility'
- o You are suffering from severe heart failure, severe liver failure or severe kidney failure.
- o You are below the age of 18 years.

• Special warnings regarding the use of this medicine:

Before treatment with Strefen Spray 8.75 mg, consult your doctor if you:

- Are taking other NSAIDs or aspirin.
- Are suffering from tonsillitis or if you think you may have a bacterial throat infection (as you may need treatment with antibiotics).
- Are suffering from an infection - since non-steroidal anti-inflammatory drugs (NSAIDs) may mask signs of infection such as fever and pain. Therefore, this medicine may delay appropriate treatment of the infection, which may lead to an increased risk of complications. If you take this medicine while you have an infection and the symptoms of your infection persist or worsen, consult a doctor without delay.
- Are over the age of 65, since there is a higher likelihood that you will suffer from the side effects mentioned in this leaflet.
- Suffer or have suffered in the past from asthma, or if you suffer from allergies.
- Suffer from a skin condition called systemic lupus erythematosus or mixed connective tissue disease.
- Suffer from high blood pressure.
- Have suffered in the past from gastrointestinal diseases such as ulcerative colitis or Crohn's disease. See also section 'Do not use this medicine if.'
- Are suffering from renal, cardiac, or liver problems. See also the section 'Do not use this medicine if.'
- Have had a stroke.
- Are in the first six months of pregnancy, or if you are breastfeeding. See also sections 'Do not use this medicine if' and 'Pregnancy, breastfeeding and fertility.'

Additional warnings while using Strefen Spray –

- At the first sign of any skin reaction (rash, peeling skin, blistering) or any other sign of an allergic reaction, stop using the medicine and seek medical advice immediately.
- Report any unusual abdominal symptoms (especially bleeding) to your doctor.
- Consult your doctor if the symptoms of the disease worsen or do not improve, or if you develop new symptoms.
- Medicines of the NSAID group, such as

flurbiprofen, may be associated with a slightly increased risk of heart attack or stroke, especially in cases of higher doses or prolonged treatment. **Do not exceed the recommended dose or duration of treatment** (See section 3).

Children and adolescents

This medicine must not be used by children or adolescents under the age of 18 years. The efficacy and safety of use have not been determined in this age group.

Drug interactions:

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist. It is especially important to notify your doctor or pharmacist if you are taking:

- Other non-steroidal anti-inflammatory drugs (NSAIDs), including cyclooxygenase-2 selective inhibitors for pain or inflammation, as these may increase the risk of bleeding from the stomach or intestines.
- Warfarin, aspirin (acetylsalicylic acid) and other blood-thinning or anti-clotting medicines.
- ACE inhibitors, angiotensin II receptor blockers (medicines which lower blood pressure).
- Diuretics (which support urination), including potassium-sparing diuretics.
- SSRIs- (selective serotonin re-uptake inhibitors) for the treatment of depression.
- Cardiac glycosides (for heart problems), such as digoxin.
- Cyclosporin (for the prevention of organ rejection after transplant)
- Corticosteroids (to reduce inflammation).
- Lithium (for mood disorders).
- Methotrexate (for the treatment of psoriasis, arthritis or cancer).
- Mifepristone (used to terminate pregnancy) - NSAIDs should not be used for 8 – 12 days after taking mifepristone, as they can reduce the effect of mifepristone.
- Oral antidiabetic medicines.
- Phenytoin (for the treatment of epilepsy).
- Probenecid, sulfapyrazone (medicines for gout and arthritis).
- Quinolone antibiotics (for the treatment of bacterial infections) such as ciprofloxacin and levofloxacin.
- Tacrolimus (used for immunosuppression to prevent organ rejection after transplant).
- Zidovudine (a medicine for the treatment of human immunodeficiency virus (HIV)).

Use of the medicine and alcohol consumption

Avoid alcohol while using this medicine, as this combination increases the risk of bleeding in the

stomach or intestines.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Do not take this medicine during the last three months of pregnancy. This medicine has a possible side effect of renal injury in the fetus and low levels of amniotic fluid as of the 20th week of pregnancy. It is recommended to avoid using medicines of the NSAIDs class as of the 20th week of pregnancy and consult a healthcare professional, if necessary.

Avoid the use of this medicine in the first six months of pregnancy or if you are breastfeeding, unless your doctor has advised you otherwise. Flurbiprofen belongs to a group of drugs that can temporarily impair fertility in women. This effect is reversible once you stop taking the medicine. It is unlikely that the medicine, taken from time to time, will affect your chances of getting pregnant. However, before taking the medicine, tell your doctor if you have any known difficulties getting pregnant.

Driving and using machines

The effect of this medicine on the ability to drive and use machines has not been investigated. However, dizziness and vision disturbances are possible side effects following the use of non-steroidal anti-inflammatory drugs (NSAIDs). Should you experience these side effects, abstain from driving and using machines.

Important information about some of the ingredients of the medicine (1)

- This medicine contains methyl parahydroxybenzoates (E218) and propyl parahydroxybenzoates (E216), which may cause an allergic reaction (possibly delayed).
- This medicine contains less than 1 millimole (23 mg) sodium per dose, which is considered 'sodium-free'
- This medicine contains fragrance with citral, d-limonene, eugenol and linalool, which may cause allergic reactions.

3. How should you use the medicine?

Always use this medicine in accordance with the instructions for use or in accordance with your doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage and treatment regimen of the medicine.

The usual dosage is generally:

Adults aged 18 years and over:
One dose (3 sprays) to the back of the throat (see the image below) every 3-6 hours as required, up

to a maximum of 5 doses in a 24-hour period. One dose (3 sprays) contains 8.75 mg of flurbiprofen.

The medicine is not intended for use in children or adolescents below the age of 18.

For oromucosal use only.

- Spray at the back of the throat only.
- Do not inhale while spraying the throat.
- Do not take more than 5 doses (15 sprays) in 24 hours.

This medicine is intended for **short-term use only**. Take the lowest possible effective dose for the shortest time necessary to relieve your symptoms. If you have an infection – consult your doctor without delay if the symptoms (such as fever and pain) worsen or do not improve. If you experience irritation in your mouth, stop use of the medicine. See also the section 'Special warnings regarding the use of this medicine'

Do not use this medicine for more than 3 days unless instructed to do so by a doctor. If there is no improvement in your condition, or if your condition worsens, or if you suffer from new symptoms, refer to your doctor.

Instructions for use:

Priming the pump

When using the pump for the first time (or after storage for a long period of time) you must first prime the pump.

Point the nozzle away from you and spray a minimum of 4 times until a fine, consistent mist is produced.

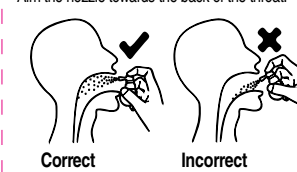
The pump is then ready for use.

If the product is not used for a period of time, point the nozzle away from you and spray at least once, until a fine, consistent mist is produced.

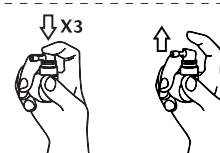
Always ensure that a fine, consistent mist is produced before spraying the product to the throat.

Using the spray

Aim the nozzle towards the back of the throat.



Using a smooth rapid motion, depress the pump **3 times**, taking care to fully depress the pump for each spray, while removing your finger from the top of the pump between each spray.



Do not inhale while spraying the throat.

If you accidentally take a higher dose, you may experience nausea, vomiting, stomach ache, and infrequently, even diarrhoea, tinnitus, headache and gastrointestinal bleeding.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer to a doctor or proceed to a hospital emergency room immediately and bring the package of medicine with you, even if you are feeling well.

If you forgot to use the medicine at the required time, do not take a double dose to make up for the forgotten dose. Take the next dose as needed and do not exceed the recommended dose.

If you have further questions regarding use of the medicine, consult your doctor or pharmacist.

4. Side effects

Like every medicine, the use of Strefen may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop taking the medicine immediately and refer to your doctor immediately if you develop:

- Severe skin reactions, such as a widespread rash with blisters, including Stevens-Johnson syndrome and toxic epidermal necrolysis (a rare medical condition due to a severe adverse reaction in the skin or mucous membrane to a medicine or to infection). The frequency of these side effects is unknown (it is not possible to determine their frequency based on the available data).
- Signs of anaphylactic shock, characterised by swelling of the face, throat or tongue, causing difficulty in breathing, rapid heart rate, and a drop in blood pressure leading to shock (these can happen even with the first use of the medicine). These side effects are rare (may affect up to 1 in 1,000 people).
- Signs of hypersensitivity and skin reactions such as redness, swelling, peeling, blistering, flaking or ulceration of the skin or mucous membrane. These side effects are uncommon (may affect up to 1 in 100 people).
- Signs of a severe allergic reaction such as asthma, unexplained wheezing or shortness of breath, itching, runny nose, or skin rashes.

These side effects are uncommon (may affect up to 1 in 100 people).

Tell your doctor if any of the following side effects occur:

Common side effects (may affect up to 1 in 10 people):

- Dizziness, headache
- Throat irritation
- Mouth ulcers, pain or numbness in the mouth
- Sore throat
- Discomfort in the mouth (such as a sensation of warmth, burning, tingling, pricking)
- Nausea and diarrhoea
- pricking and itching sensation in the skin

Uncommon side effects (may affect up to 1 in 100 people):

- Drowsiness
 - Blisters in the mouth or throat, numbness in the throat
 - Abdominal swelling, abdominal pain, flatulence, constipation, indigestion, vomiting
 - Dry mouth
 - A burning sensation in the mouth, altered sense of taste.
 - Fever, pain
 - Feeling drowsy, or difficulty falling asleep
 - Worsening of asthma, wheezing, shortness of breath
 - Reduced sensation in the throat
- Side effects of unknown frequency** (it is not possible to determine their frequency based on the available data)
- Anaemia, thrombocytopenia (a low blood platelet count, a condition that can increase the risk of bruising and bleeding).
 - Swelling (edema), high blood pressure, heart failure or heart attack.
 - Inflammation of the liver (hepatitis).

If a side effect appears, if one of the side effects worsens or if you suffer from any side effect not mentioned in this leaflet, consult a doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that appears on the homepage of the Ministry of Health's website (www.health.gov.il) which links to an online form for reporting side effects, or via the following link: <https://sideeffects.health.gov.il>

5. How should the medicine be stored?

- o **Avoid poisoning!** This medicine, and any other medicine, should be kept in a closed place out

of the reach of children and/or infants, in order to avoid poisoning. **Do not induce vomiting** unless explicitly instructed to do so by your doctor.

- o Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.
- o Do not use the medicine after the EXP. date stated on the package. The expiry date refers to the latest day of that month.
- o Store below 25°C. Do not refrigerate or freeze.
- o This medicine can be used for 6 months after the first use and not later than the expiration date of the medicine.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Purified water, Betadex, Disodium phosphate dodecahydrate, Hydroxypropyl Betadex, Cherry flavour, Sodium hydroxide, Methyl parahydroxybenzoate, Mint flavour, Citric acid monohydrate, N,2,3-Trimethyl-2-isopropylbutanamide, Saccharin sodium, Propyl parahydroxybenzoate.

What the medicine looks like and the contents of the pack: The oromucosal spray, solution is clear colourless to slightly yellow solution with a taste of cherry and mint.

This medicine consists of a white opaque plastic bottle of solution with a pump unit and protective polypropylene over cap.

Each bottle contains 15 ml of solution which provides approximately 83 sprays.

Manufacturer and address: Reckitt Benckiser Healthcare International Ltd, Nottingham, England.

Registration holder and address: Reckitt Benckiser (Near East) Ltd., 6 Hanagar St., Hod Hasharon, Israel 4527704.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 175-36-3623-00

This leaflet was checked and approved by the Ministry of Health in September 2024