

Patient Package Insert in Accordance with Pharmacists' Regulation (Preparations)-1986.

This product is sold without a doctor's prescription.

Strefen Orange Sugar Free, Lozenges

Composition of the active ingredient and its quantity/ concentration: Flurbiprofen 8.75 mg/Lozenge.

Inactive ingredients- see 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.

This medicine is intended for adults and children over 12 years of age. Under this age refer to your doctor. You must use this medicine correctly. Consult your pharmacist if you need further information. Refer to your doctor if symptoms worsen or do not improve after 3 days.

1. What is the medicine intended for?

Strefen is intended for the short-term relief of symptoms of sore throat such as throat soreness and swelling in adults and children over 12 years of age.

Therapeutic group- The active ingredient in this medicine is flurbiprofen, which belongs to the Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) group. This group of substances provides relief by changing the body's reaction to pain, swelling and high fever.

2. Before using the medicine

Do not use the preparation if:

- o you are hypersensitive (allergic) to flurbiprofen or any of the other ingredients this medicine contains (see section 6).
- o you suffer or have suffered in the past from recurrent peptic ulcer (2 or more episodes of a proved peptic ulcer), or gastrointestinal bleeding.
- o you have experienced hypersensitivity in the past (such as: asthma, bronchospasm, rhinitis, angioedema or urticaria) after using aspirin or other NSAIDs.
- o you have suffered from gastrointestinal bleeding or perforation, severe colitis (inflammation of the intestines) or bleeding while taking other NSAIDs.
- o you take other NSAIDs (such as celecoxib, ibuprofen, diclofenac sodium, etc.) or a dosage of aspirin that exceeds 75 mg per day.
- o you suffer from severe heart failure, severe liver failure or severe kidney failure.
- o you are in the last trimester of pregnancy.
- o you are under 12 years of age.

Special warnings regarding the use of this medicine:

Before treatment with Strefen, consult your doctor if:

- you suffer or have suffered in the past from asthma or you suffer from allergies.
- you suffer from tonsillitis or if you think you may have a bacterial throat infection (that can be treated with antibiotics).
- you suffer from kidney, heart, or liver problems.
- you have had a stroke.
- you have suffered in the past from gastrointestinal diseases such as ulcerative colitis, Crohn's disease.
- you suffer from a chronic autoimmune disease (such as systemic lupus or mixed connective tissue disease).
- you are over 65 years of age, since you have a higher likelihood of suffering from the side effects mentioned in the leaflet.
- you are in the first six months of pregnancy or are breastfeeding.
- you have an infection- non-steroidal anti-inflammatory drugs (NSAIDs) may hide signs of infections such as fever and pain. Therefore, this may delay appropriate treatment of infection, which may lead to an increased risk of complications. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor or pharmacist without delay.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and nutritional supplements. Especially notify your doctor or pharmacist if you are taking:

- a low dosage of aspirin (up to 75 mg per day).
- medicines for the treatment of high blood pressure or medicines for the treatment of heart failure (antihypertensives or glycosides).
- diuretics (including potassium-sparing medicines).
- medicines for blood dilution (anticoagulants or antiplatelets).
- medicines for gout (probenecid, sulfapyrazone).
- other non-steroidal anti-inflammatory medicines (NSAIDs), or corticosteroids such as: celecoxib, ibuprofen, diclofenac sodium or prednisolone.
- mifepristone (drug to terminate pregnancy).
- antibiotics from the quinolone group (such as ciprofloxacin).
- immunosuppressive medicines (such as cyclosporine, tacrolimus).

- phenytoin (for treatment of epilepsy).
- methotrexate (for treatment of autoimmune diseases or cancer).
- lithium or drugs from the group of selective serotonin reuptake inhibitors (SSRIs) (for the treatment of depression).
- oral antidiabetics (for treatment of diabetes).
- zidovudine (medicine for treatment of AIDS).

Use of this medicine and alcohol consumption

Abstain from alcohol consumption during treatment with Strefen, since alcohol increases the risk of stomach or intestinal bleeding.

Pregnancy and breastfeeding

Do not take this medicine during the last three months of pregnancy. Consult your doctor about the use of Strefen during the first six months of pregnancy or if you are breastfeeding. 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 in getting pregnant.

Driving and use of machinery

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

Important information about some of the ingredients of the medicine:

Strefen Orange Sugar Free:

- Contains isomalt 2033.29 mg/lozenge as well as liquid maltitol 509.31 mg/lozenge. May have a mild laxative effect. The caloric value of maltitol or isomalt: 2.3 kilocalories/gram. If you have been told that you suffer from an intolerance to certain sugars, consult a doctor before starting treatment with Strefen.
- Contains a flavoring component including Geraniol, d-Limonene, Citronell, Citral and Linalool that may cause allergic reactions.

3. How to use this medicine

Check with your doctor or pharmacist if you are not sure.

Adults, the elderly and children over 12 years of age:

The recommended dosage is one lozenge to be sucked on or dissolved in your mouth every 3-6 hours. Suck on the lozenge slowly, while slowly moving it around the inside of your mouth in order to prevent local irritation. **Do not use more than 5 lozenges in a 24-hour period.** Do not exceed the recommended dose.

This medicine is not intended for infants and children under 12 years of age. This medication is 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 a doctor or pharmacist without delay if symptoms (such as fever and pain) persist or worsen. If you feel irritation in your mouth, discontinue use of the medicine.

Do not take this medicine for more than 3 days, unless instructed to do so by a doctor.

If there is no improvement in your condition within 3 days, or if your condition worsens, or if you suffer from new symptoms, refer to your doctor.

If you have accidentally taken an overdose, you may feel drowsy or nauseous. If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or hospital emergency room and bring the medicine's package with you, even if you feel well.

If you forget to take this medicine at the required time, do not take a double dose, take the next dose at the usual time and do not exceed the recommended dose. If you have further questions about the use of this 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 while reading the list of side effects. You may not suffer from any of them.

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

- o **signs of a severe allergic reaction appear** such as asthma, unexplained wheezing or shortness of breath, itching, runny nose, skin rashes, etc.
- o swelling of the face, throat or tongue that causes breathing difficulty, rapid heartbeat, and a drop in blood pressure leading to shock (this can occur even with first use of the medicine).
- o severe skin reactions such as peeling of the skin or the appearance of blisters on the skin.

Refer to the doctor if the following side effects appear:

Common side effects (appear in 1 out of 10 users):

- o Dizziness, headache
- o Throat irritation
- o Mouth ulcers or mouth pain
- o Sore throat

o Discomfort or unusual sensation in the mouth (such as a sensation of warmth, burning, tingling, pricking, etc.)

- o Nausea and diarrhea
- o Prickling and itching sensation in the skin

Uncommon side effects (appear in 1 out of 100 users):

- o Drowsiness
- o Blisters in the mouth or throat, numbness in the throat, abdominal swelling, abdominal pain, flatulence, constipation, indigestion, vomiting
- o Dry mouth
- o Burning sensation in the mouth, changes in sense of taste
- o Skin rashes, itchy skin
- o Fever, pain
- o Sleepiness or difficulty in falling asleep
- o Worsening of asthma, wheezing, shortness of breath
- o Reduced sensation in the throat

Rare side effects (appear in 1 out of 1,000 users):

- o Anaphylactic reaction (acute and life-threatening allergic reaction that causes breathing difficulty and dangerously low blood pressure)

Side effects with unknown frequency (it is not possible to determine their frequency from the existing data):

- o Anemia, thrombocytopenia (a low count of blood platelets that can increase the risk of bruising and bleeding)
- o Swelling (edema), high blood pressure, heart failure or heart attack
- o Severe skin reactions including extensive rash with blisters including Stevens-Johnson syndrome, Lyell syndrome, and a more severe form causing peeling of the skin on more than 30% of the body's surface area (toxic epidermal necrolysis).
- o Liver inflammation (hepatitis)

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

o Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, in order to avoid poisoning. **Do not induce vomiting** unless explicitly instructed to do so by your doctor.

Do not take medicines in the dark! Check the label and dose **each time** you take a medicine. Wear glasses if you need them.

Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.

Store below 25°C, in the original package.

6. Additional information

In addition to the active ingredient, the medicine also contains: Macrogl 300 (Polyethylene glycol 300), Potassium Hydroxide, Orange Flavor PHL-010300, Levomenthol, Acesulfame K, Liquid Maltitol, Isomalt.

What the medicine looks like and contents of the pack:

Strefen Orange Sugar Free lozenges are round, white to pale yellow in color, with an icon imprinted on both sides of the lozenge. The lozenges are packed as 16, 24 or 36 lozenges in a package. Not all package sizes may be marketed.

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.

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153-42-34072-00

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