

**Package Leaflet: Information for the User**  
**Strepsils Intensive Sugar-Free 8.75 mg lozenges**

flurbiprofen

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

**What is in this leaflet**

- 1 What Strepsils Intensive lozenges are and what they are used for
- 2 What you need to know before you take Strepsils Intensive lozenges
- 3 How to take Strepsils Intensive lozenges
- 4 Possible side effects
- 5 How to store Strepsils Intensive lozenges
- 6 Contents of the pack and other information

**1. What Strepsils Intensive lozenges are and what they are used for**

Strepsils Intensive lozenges contains flurbiprofen. Flurbiprofen is a non-steroidal anti-inflammatory drug (NSAID) which has analgesic, antipyretic and anti-inflammatory properties. Flurbiprofen 8.75 mg lozenges are used for the short-term relief of symptoms of sore throat such as throat pain, soreness and swelling, and difficulty in swallowing in adults and adolescents over the age of 12 years.

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

**2. What you need to know before you use Strepsils Intensive lozenges**

**Do not take these lozenges if you:**

- are allergic (hypersensitive) to Flurbiprofen or to any of the other ingredients of this medicine (listed in section 6)
- have ever had asthma, unexpected wheezing or shortness of breath, a runny nose, facial swelling or itchy rash (hives) after taking acetylsalicylic acid (aspirin) or any other NSAID medicine
- currently have or have ever had two or more episodes of a stomach ulcer, intestinal ulcers, or gastrointestinal bleeding
- have had gastrointestinal bleeding or perforation, severe colitis (inflammation of the bowel) or bleeding disorders when taking NSAID medicines in the past
- are in the last 3 months of pregnancy
- have severe heart, severe kidney or severe liver failure

**Warnings and precautions**

**Talk to your doctor or pharmacist before taking Strepsils Intensive lozenges if you:**

- have ever had asthma or suffer from allergies
- have tonsillitis (inflamed tonsils) or think you may have a bacterial throat infection (as you may need antibiotics)
- have an infection – please see heading ‘Infections’ below
- have heart, kidney or liver problems
- have had a stroke
- have a history of bowel disease (ulcerative colitis, Crohn’s disease)
- suffer from chronic autoimmune disease such as systemic lupus erythematosus and mixed connective tissue disease
- are elderly, as you are more likely to experience the side effects listed in this leaflet
- are in the first 6 months of pregnancy or breastfeeding
- If you have high blood pressure
- If you have analgesic-induced headache

### **Infections**

Non-steroidal anti-inflammatory drugs (NSAIDs) may hide signs of infections such as fever and pain. 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.

### **Whilst using Strepsils Intensive lozenges**

At the first sign of any skin reaction (rash, peeling, blistering) or other sign of an allergic reaction, stop using the lozenge and consult a doctor at once.

- Report any unusual abdominal symptoms (especially bleeding) to your doctor.
- If you do not get better, you get worse, or develop new symptoms, talk to a doctor.
- The use of medicines containing flurbiprofen may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment (3 days).

### **Children**

This medicine should not be used by children under the age of 12 years.

### **Other medicines and Strepsils Intensive lozenges**

**Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine. In particular, tell them if you are taking:**

- low dose acetylsalicylic acid (aspirin) (up to 75 mg daily)
- medicines for high blood pressure or heart failure (antihypertensives, cardiac glycosides)
- water tablets (diuretics, including potassium sparing drugs)
- medicines for thinning the blood (anticoagulants, antiplatelet agents)
- medicines for gout (probenecid, sulfinpyrazone)
- other NSAIDs including cyclooxygenase-2 selective inhibitors or corticosteroids (such as celecoxib, ibuprofen, diclofenac sodium or prednisolone)
- mifepristone (a medicine used for pregnancy termination)
- quinolone antibiotics (such as ciprofloxacin)
- cyclosporine or tacrolimus (to suppress the immune system)
- phenytoin (to treat epilepsy)
- methotrexate (to treat autoimmune diseases or cancer)
- lithium or SSRIs (for depression)
- oral antidiabetics (to treat diabetes)

- zidovudine (to treat HIV)

### **Taking Strepsils Intensive lozenges with food, drink and alcohol.**

Alcohol should be avoided during treatment with this medicine as it increases the risk of bleeding in the stomach or intestines.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Do not take** this medicine if you are **in the last 3 months of pregnancy**. If you are in the first 6 months of pregnancy or are breast-feeding, speak to your doctor before taking these lozenges.

Flurbiprofen belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that the lozenges, used occasionally, will affect your chances of becoming pregnant; however, tell your doctor before taking this medicine if you have problems becoming pregnant.

### **Driving and using machines**

No studies on the effects on the ability to drive and use of machines have been performed. However, dizziness and visual disturbances are possible side effects after taking NSAIDs. If affected, do not drive or operate machinery.

### **Strepsils Intensive lozenges contains Isomalt (E953), Liquid Maltitol (E965) and fragrance with Citral, Citronellol, d-Limonene, Geraniol and Linalool.**

Strepsils Intensive lozenges contains Isomalt (E953) 2033.29 mg/lozenge and Liquid Maltitol (E965) 509.31 mg/lozenge.

May have a mild laxative effect

Calorific value 2.3 kcal/g maltitol or isomalt

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Citral, Citronellol, d-Limonene, Geraniol and Linalool may cause allergic reactions.

### **3. How to take Strepsils Intensive lozenges**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### **The recommended dose: Adults and adolescents over the age of 12 years:**

- Take one lozenge by mouth and suck slowly.
- Always move the lozenge around whilst sucking.
- The lozenges should start to work within 30 minutes.
- Then take one lozenge every 3-6 hours, if needed.
- Do not take more than 5 lozenges in 24 hours.

Do not use this product in children under 12 years.

**These lozenges are for short-term use only.** The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor or pharmacist without delay if symptoms (such as fever and pain) persist or worsen (see section 2). If mouth irritation occurs, flurbiprofen treatment should be withdrawn.

**Do not take Strepsils Intensive lozenges for more than 3 days** unless your doctor tells you to. If you do not get better, you get worse, or if you develop new symptoms, talk to a doctor or pharmacist.

#### **If you take more lozenges than you should**

Talk to a doctor or pharmacist or go to your nearest hospital straight away. Symptoms of overdose include: feeling sick or being sick, stomach ache or, more rarely, diarrhoea. Ringing in the ears, headache and gastrointestinal bleeding is also possible.

If you have any questions on the use of this product, ask your doctor or pharmacist.

#### **If you forget to take Strepsils Intensive lozenges**

Do not take a double dose to make up for a forgotten dose

### **4. Possible side effects**

Like all medicines this medicine can cause side effects, although not everybody gets them.

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

- signs of an allergic reaction such as asthma, unexplained wheezing or shortness of breath, itchiness, runny nose, skin rashes, etc.
- swelling of the face, tongue or throat causing difficulty in breathing, racing heart and drop in blood pressure leading to shock (these can happen even on the first use of the medicine.)
- severe skin reactions such as peeling, blistering or flaking skin.

#### **Tell your doctor or pharmacist if you notice any of the following effects or any effects not listed:**

##### **Common** (*may affect up to 1 in 10 people*)

- dizziness, headache
- throat irritation
- mouth ulcers or pain in the mouth
- throat pain
- discomfort or unusual sensation in the mouth (such as warmth, burning, tingling, prickling, etc.)
- nausea and diarrhoea
- prickling and itching sensation in skin

##### **Uncommon** (*may affect up to 1 in 100 people*)

- drowsiness
- blistering in the mouth or throat, numbness in the throat
- stomach bloating, abdominal pain, wind, constipation, indigestion, vomiting.
- dry mouth
- burning sensation in the mouth, altered sense of taste
- skin rashes, itchy skin
- fever, pain
- feeling sleepy or difficulty in falling asleep
- worsening of asthma, wheezing, shortness of breath
- reduced sensation in the throat

**Rare** (may affect up to 1 in 1000 people)

- anaphylactic reaction

**Frequency not known (cannot be estimated from the available data)**

- anaemia, thrombocytopenia (low platelet count in the blood that can give rise to bruising and bleeding)
- swelling (oedema), high blood pressure, heart failure or attack
- severe forms of skin reactions such as bullous reactions, including Stevens-Johnson syndrome and Lyell's syndrome and toxic epidermal necrolysis.
- hepatitis (inflammation of the liver)

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: [www.hpra.ie](http://www.hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Strepsils Intensive lozenges**

Keep this medicine out of the sight and reach of children.

- Do not use this medicine after the expiry date stated on the pack and blister pack after EXP. The expiry date refers to the last day of that month
- Store below 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

### **6. Contents of the pack and other information**

**What Strepsils Intensive lozenges contains:**

The active ingredient (the ingredient which makes the medicine work) is flurbiprofen 8.75 mg. The other ingredients are: macrogol 300, potassium hydroxide (E525), orange flavour (contains triacetin, Citral, Citronellol, d-Limonene, Geraniol and Linalool), levomenthol, acesulfame potassium (E950), maltitol liquid (E965) and isomalt (E953).

**What Strepsils Intensive lozenges looks like and contents of the pack**

The lozenges are circular in shape with an embossed brand logo and a white to pale yellow colour, in opaque, white PVC/PVdC/Aluminium blisters and packed into cardboard cartons.

The pack contains 8 or 16 lozenges. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Reckitt Benckiser Ireland Ltd, 7 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

### **Manufacturer**

RB NL Brands B.V., Schiphol Boulevard 207, 1118 BH Schiphol, Netherlands

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Ireland	[To be determined]
Netherlands	[To be determined]

This leaflet was last revised in **upon approval**