

**Strepsils Intensive 8.75mg Lozenges
Flurbiprofen**

PATIENT INFORMATION LEAFLET

Please 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 use Strepsils Intensive Lozenges
3. How to use 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?

The ingredient which makes this medicine work is called flurbiprofen. Flurbiprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which help reduce inflammation (swelling) and pain.

Strepsils Intensive Lozenges are for use in adults and children over 12 years of age to help relieve the symptoms of sore throats, such as soreness, pain and swelling.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE STREPSILS INTENSIVE LOZENGES

Do not take these lozenges if you:

- Have or have ever had a **stomach ulcer**
- Are **allergic** to flurbiprofen, aspirin or other NSAIDs or any of the other ingredients (see Section 6)
- Have previously experienced **gastrointestinal bleeding or perforation** whilst taking NSAIDs
- Have ever had **blood clotting problems or bleeding problems** after taking NSAIDs
- Have ever had **wheezing, a runny nose or an itchy rash** (hives) after taking aspirin, flurbiprofen or medicines containing NSAIDs
- Are **under 12 years** old

- Have ever had severe heart failure
- Have ever had severe kidney or liver disease
- Are in the last three months of pregnancy

Warnings and precautions

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

- have an infection – please see heading ‘Infections’ below
- Are already taking any other **Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)** or **aspirin**
- Have **tonsillitis** (inflamed tonsils) or think you may have a **bacterial throat infection** (as you may need antibiotics)
- Are **elderly** (as you may be more likely to have side effects)
- Have or have ever had **asthma** or suffer from **allergies**
- Suffer from a skin condition called **systemic lupus erythematosus** or **mixed connective tissue disease**
- Have **hypertension** (high blood pressure)
- Have a history of **bowel disease** (ulcerative colitis, Crohn’s disease)
- Have **heart, kidney or liver** problems
- Have had a **stroke**
- Are in the first **6 months of pregnancy** or **breastfeeding**

Whilst using Strepsils Intensive Lozenge

- At the first sign of any skin reaction (rash, peeling, blistering) or other signs of an allergic reaction, stop using this medicine 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
- Medicines such as flurbiprofen may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with higher doses or prolonged treatment. Do not exceed the recommended dose or duration of treatment (see section 3).

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.

Children

Do not give to children under 12 years

Other medicines and Strepsils Intensive Lozenges

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular:

- Other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) including cyclooxygenase-2 selective inhibitors for pain, 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 and Angiotensin II antagonists (medicines which lower blood pressure)

- Diuretics (water tablets) including potassium sparing diuretics
- Cardiac glycosides (for heart problems) such as digoxin
- Ciclosporin (to prevent organ rejection after transplant)
- Corticosteroids (to reduce inflammation)
- Lithium (for mood disorders)
- Methotrexate (for psoriasis, arthritis and 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 epilepsy)
- Probenecid, sulfapyrazone (for gout and arthritis)
- Quinolone antibiotics (for bacterial infections) such as ciprofloxacin & levofloxacin
- SSRIs (selective serotonin re-uptake inhibitors) for depression
- Tacrolimus (immunosuppressant used after organ transplant)
- Zidovudine (for HIV)

Taking Strepsils Intensive lozenge with food, drink and alcohol

Avoid alcohol whilst using this medicine as it may increase the risk of bleeding in the stomach or intestines.

Pregnancy, breastfeeding and fertility:

Oral forms (e.g. tablets) of flurbiprofen can cause adverse effects in your unborn baby. It is not known if the same risk applies to Strepsils Intensive Lozenges.

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 use Strepsils Intensive Lozenge if you are in the last 3 months of pregnancy.

You should not use Strepsils Intensive Lozenge during the first 6 months of pregnancy unless clearly necessary and advised by your doctor.

If you need treatment during this period, the lowest dose for the shortest time possible should be used.

Flurbiprofen belongs to a group of medicines which may impair fertility in women. This effect is reversible when the medicine is stopped being taken. It is unlikely that the occasional use of this medicine will affect your chances of becoming pregnant; however, tell your doctor before taking this medicine if you have problems becoming pregnant.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

This medicine should not affect your ability to drive or use machines. However, dizziness and visual disturbances are possible side effects after taking NSAIDs. If affected, do not drive or operate machinery.

Important information about some of the ingredients of Strepsils Intensive lozenges

This medicine contains 1.069 g glucose, 1.407 g sucrose and 50.3 mg invert sugar (honey) per lozenge which should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains only very low levels of gluten (from wheat starch). It is regarded as 'gluten-free' and is very unlikely to cause problems if you have coeliac disease. One lozenge contains no more than 21.38 micrograms of gluten. If you have wheat allergy (different from coeliac disease) you should not take this medicine.

Also contains:

Fragrance with Citral, Citronellol, d-Limonene, Farnesol, Geraniol and Linalool which may cause allergic reactions.

Sulphur Dioxide (E220) which may rarely cause severe hypersensitivity reactions and bronchospasms.

Butylated hydroxyanisole (E320) which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

3. HOW TO USE STREPSILS INTENSIVE LOZENGES

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).

Adults and adolescents over 12 years:

Suck one lozenge slowly every 3 to 6 hours, as required

Do not take more than five lozenges in any 24 hour period.

Not to be given to children under 12 years of age.

To work properly, the lozenge must dissolve slowly in your mouth. Do not chew, crunch or swallow the lozenges whole. Move the lozenge around your mouth whilst sucking it. You should get some relief from pain and soreness within half an hour of sucking the lozenge and this relief should last up to 4 hours.

If your sore throat does not get better after 3 days, it gets worse, or if you get new symptoms, talk to your pharmacist or doctor.

Do not exceed the recommended dose or duration of treatment (3 days).

If you take too many Strepsils Intensive Lozenges by mistake or if a child under 12 takes the lozenges, talk to a pharmacist or doctor straight away. Take the packet and leaflet with you. Symptoms of overdose may include: feeling sick or being sick, stomach ache or more rarely, diarrhoea, blurred vision and dizziness. Ringing in the ears, headache and gastrointestinal bleeding is also possible.

4. POSSIBLE SIDE EFFECTS

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

Stop taking this medicine and consult a doctor at once if you develop

- Signs of an allergic reaction such as asthma, unexplained wheezing or shortness of breath, itching, runny nose or skin rashes

- Swelling of the face, tongue or throat causing difficulty in breathing, racing heart, drop in blood pressure leading to shock (these can happen even on the first use of the medicine)
- Signs of hypersensitivity and skin reactions such as redness, swelling, peeling, blistering, flaking or ulceration of skin and mucous membranes.

Tell your doctor if you have any of the following side effects, they become serious or if you notice any other effects not listed

Common (may affect up to 1 in 10 people)

- 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 on 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, being sick
- 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 1,000 people)

- Anaphylactic reaction

Not known (frequency 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 reaction such as bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis (rare medical condition due to severe adverse reactions to medication or infection where skin and mucous membranes react severely)
- Hepatitis (inflammation of the liver)

Medicines such as Strepsils Intensive may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. (See Other Warnings in section 2)

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.

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.

Store below 25°C.

Do not use after the expiry date which is shown on the pack and the foil blister after EXP. This expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Strepsils Intensive Lozenges contains:

Each lozenge contains the active ingredient flurbiprofen 8.75mg. Also contains liquid sucrose (1.407g), liquid glucose (wheat starch containing gluten, sulphur dioxide (E220)), (1.069g), honey (50.3mg), macrogol 300, lemon flavour (butylated hydroxyanisole (E320), citral, citronellol, d-limonene, farnesol, geraniol & linalool), potassium hydroxide, levomenthol.

What Strepsils Intensive Lozenges look like:

These lozenges are a round, clear colour.

There are 16 lozenges in a pack

Marketing Authorisation Holder and Manufacturer

PA Holder: Reckitt Benckiser (Ireland) Ltd, Dublin 24, Ireland

Manufacturers: Reckitt Benckiser Healthcare International, Nottingham, NG90 2DB, UK and RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL

PA 979/41/1

This leaflet was last revised in upon approval