

Package Leaflet: Information for the User

Strepsils Intensive Honey and Lemon 8.75 mg/dose Oromucosal Spray

Flurbiprofen

For use in adults

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 Honey and Lemon is and what it is used for
2. What you need to know before you use Strepsils Intensive Honey and Lemon
3. How to use Strepsils Intensive Honey and Lemon
4. Possible side effects
5. How to store Strepsils Intensive Honey and Lemon
6. Contents of the pack and other information

1 What Strepsils Intensive Honey and Lemon is and what it is used for

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.

Strepsils Intensive Honey and Lemon is used for the short-term relief of symptoms of sore throats such as throat soreness, pain, difficulty swallowing and swelling in adults and adolescents aged 12 and over.

2 What you need to know before you use Strepsils Intensive Honey and Lemon

Do not use Strepsils Intensive Honey and Lemon if you:

- are **allergic to flurbiprofen, other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), aspirin** (acetylsalicylic acid), or to any of the ingredients (listed in section 6).
- have had a **previous allergic reaction after taking Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or aspirin** (acetylsalicylic acid); e.g. asthma, wheezing, itching, runny nose, skin rashes, swelling
- currently have or have ever had two or more episodes of **stomach ulcers or bleeding or intestinal ulcers.**
- have ever had **severe colitis** (inflammation of the bowel).
- have ever had **blood clotting problems or bleeding problems after taking NSAIDs**
- are in the **last three months of pregnancy.**

- have **severe heart failure, severe kidney failure or severe liver failure**.
- are a child below the age of 12 years.

Warnings and precautions

Talk to your doctor or pharmacist before using Strepsils Intensive Honey and Lemon if you:

- 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).
- have an infection – please see heading ‘Infections’ below
- 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**.

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 Honey and Lemon

- At the first sign of any skin reaction (rash, peeling, blistering) or other sign of an allergic reaction, stop using the spray 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).

Children

Do not use this medicinal product in children under the age of 12 years.

Other medicines and Strepsils Intensive Honey and Lemon

Tell your doctor or pharmacist if you are taking, have recently taken, or might take 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 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-antagonists** (medicines which lower blood pressure)
- **diuretics** (water tablets) including **potassium sparing diuretics**
- **SSRIs** (selective serotonin re-uptake inhibitors) for depression
- **cardiac glycosides** (for heart problems) such as digoxin
- **cyclosporine** (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, sulfinpyrazone** (for gout and arthritis)
- **quinolone antibiotics** (for bacterial infections) such as ciprofloxacin, levofloxacin
- **tacrolimus** (immunosuppressant used after organ transplant)
- **zidovudine** (for HIV).

Strepsils Intensive Honey and Lemon 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, 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 this medicine.

The product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the 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 Honey & Lemon:

Strepsils Intensive Honey and Lemon contains Methyl parahydroxybenzoate (E218) and Propyl parahydroxybenzoate (E216)

May cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

This medicine contains fragrance with Anisyl Alcohol, Citral, Citronellol, d-Limonene, Geraniol and Linalool.

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

3 How to use Strepsils Intensive Honey and Lemon

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.

Recommended dose

Adults and adolescents aged 12 years and over:

One dose of 3 sprays to the back of the throat 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.

Do not use this medicine in children under 12 years.

For oromucosal use only

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

Strepsils Intensive Honey and Lemon is 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 use this medicine for more than 3 days unless instructed to do so by your doctor.

If you do not get better, you get worse, or if new symptoms occur, talk to a doctor or pharmacist.

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 four times until a fine, consistent mist is produced. The pump is then primed and ready for use. If the product is not used for a period of time, point the nozzle away from you and spray a minimum of once ensuring a fine, consistent mist is produced. Always ensure a fine consistent mist is produced before dosing the product.

Using the spray

Aim the nozzle towards the back of the throat.

Correct



Incorrect



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



Do not inhale whilst spraying.

If you use more Strepsils Intensive Honey and Lemon than you should

Talk to a doctor or pharmacist or go to your nearest hospital straight away. Symptoms of overdose may 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 further questions on the use of this medicine, ask your doctor or pharmacist.

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:

- severe forms of skin reaction such as bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis (rare medical conditions due to severe adverse reactions to medication or infection where skin and mucous membrane react severely. Frequency: Not known (frequency cannot be estimated from the available data)
- 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 (these can happen even on the first use of the medicine). Frequency: Rare (may affect up to 1 in 1000 people).
- signs of hypersensitivity and skin reactions such as redness, swelling, peeling, blistering, flaking or ulceration of skin and mucous membrane. Frequency: Uncommon (may affect up to 1 in 100 people).
- signs of an allergic reaction such as asthma, unexplained wheezing or shortness of breath, itching, runny nose, or skin rashes. Frequency: Uncommon (may affect up to 1 in 100 people).

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, 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

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
- fever, pain
- feeling sleepy or difficulty in falling asleep
- worsening of asthma, wheezing, shortness of breath
- reduced sensation in the throat

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
- hepatitis (inflammation of the liver)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report any 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 Honey and Lemon

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

Do not use this medicine after the expiry date which is stated on the bottle and the carton after **EXP**. The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

Do not use this medicine for more than 6 months after the first use.

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 to protect the environment.

6 Contents of the pack and other information

What Strepsils Intensive Honey and Lemon contains:

The active substance is flurbiprofen. One dose (3 sprays) contains 8.75 mg. flurbiprofen, corresponding to 16.2 mg/ml flurbiprofen.

The other ingredients are: Betadex, Disodium phosphate dodecahydrate, Citric acid monohydrate, Methyl parahydroxybenzoate (E218), Propyl parahydroxybenzoate (E216), Sodium hydroxide, Honey flavour (contains Flavouring substance(s), Flavouring preparation(s) and Propylene Glycol (E1520)), Lemon flavour (contains Flavouring substance(s), Flavouring preparation(s) and Propylene Glycol (E1520)), N, 2,3-Trimethyl-2-isopropylbutanamide, Saccharin sodium, Hydroxypropylbetadex and Purified water.

What Strepsils Intensive Honey and Lemon looks like and contents of the pack

The oromucosal spray, solution is clear colourless to slightly yellow solution with a taste of honey and lemon.

Strepsils Intensive Honey and Lemon consists of a white opaque HDPE bottle of solution with a multi-component pump unit and protective polypropylene over cap. Each bottle contains 15 ml of solution which provides approximately 83 sprays.

Marketing Authorisation Holder

Reckitt Benckiser Ireland Ltd.,
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Manufacturer

Reckitt Benckiser Healthcare International Ltd, Thane Road, Nottingham, Nottinghamshire, NG90 2DB, United Kingdom.
RB NL Brands B.V, Schiphol Boulevard 207, 1118 BH Schiphol, The Netherlands.

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

Italy	<[To be determined]>
Poland	<[To be determined]>
Germany	<[To be determined]>
Czech	<[To be determined]>
Slovak R	<[To be determined]>
Austria	<[To be determined]>
Belgium	<[To be determined]>
Luxembourg	<[To be determined]>
Netherlands	<[To be determined]>
Hungary	<[To be determined]>
Romania	<[To be determined]>
Bulgaria	<[To be determined]>
Spain	<[To be determined]>
Portugal	<[To be determined]>
Croatia	<[To be determined]>

Cyprus	<[To be determined]>
Greece	<[To be determined]>
Denmark	<[To be determined]>
Finland	<[To be determined]>
Iceland	<[To be determined]>
Norway	<[To be determined]>
Sweden	<[To be determined]>
Latvia	<[To be determined]>
Estonia	<[To be determined]>
Lithuania	<[To be determined]>
Slovenia	<[To be determined]>

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