APPLICANT	**: Reckitt Benckiser Pharmaceuticals (Pty) Ltd**
PROPRIETARY NAME (DOSAGE FORM)	**: Strepsils Intensive Spray (Throat Spray)**
STRENGTH	**: Flurbiprofen 8,75 mg**

PATIENT INFORMATION LEAFLET (PIL)

SCHEDULING STATUS:

S1

STREPSILS INTENSIVE SPRAY

8,75 mg flurbiprofen per metered dose or 3 sprays

Contains sweetener (0,27 mg Saccharin sodium per dose)

Read all of this leaflet carefully because it contains important information for you:

STREPSILS INTENSIVE SPRAY is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use STREPSILS INTENSIVE SPRAY carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share STREPSILS INTENSIVE SPRAY with any other person
- Ask your health care provider or pharmacist if you need more information or advice
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet:

1. What STREPSILS INTENSIVE SPRAY is and what it is used for
2. What you need to know before you use STREPSILS INTENSIVE SPRAY
3. How to use STREPSILS INTENSIVE SPRAY
4. Possible side effects
5. How to store STREPSILS INTENSIVE SPRAY
6. Contents of the pack and other information

1. What STREPSILS INTENSIVE SPRAY is and what it is used for:

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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 SPRAY is used for the short-term relief of symptoms of sore throats such as throat soreness, pain, difficulty swallowing and swelling.

2. What you need to know before you use STREPSILS INTENSIVE SPRAY:

Do not use STREPSILS INTENSIVE SPRAY 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 first, second or in the **last three months of pregnancy**
- have **severe heart failure, severe kidney failure** or **severe liver failure**.

Warnings and precautions

Take special care with STREPSILS INTENSIVE SPRAY 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).
- are **elderly** (as you may be more likely to have side effects).
- have or have ever had **asthma** or suffer from **allergies.**

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- suffer from a skin condition called **systemic lupus erythematosus** or **mixed connective tissue disease.**
- DRESS syndrome: life-threatening reaction which may resemble a flu-like infection, other signs may include rash, facial swelling, abdominal pain and abnormal heartbeat. If such signs or symptoms are present, discontinue STREPSILS INTENSIVE SPRAY.
- have a history of **hypertension** (high blood pressure) or heart failure.
- have a history of **bowel disease** (ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angio-dysplasia))
- if you generally bruise easily or experience abnormal bleeding.
- have **heart, kidney or liver problems.**
- have had a **stroke**.

Whilst using STREPSILS INTENSIVE SPRAY

- 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 an 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

This medicine should not be used by children or adolescents under the age of 18 years.

Other medicines and STREPSILS INTENSIVE SPRAY

Always tell your health care provider if you are taking any other medicines. (This includes all complementary or traditional medicines.)

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- 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 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)**.**

Taking STREPSILS INTENSIVE SPRAY with food, drink and alcohol

Avoid alcohol whilst using STREPSILS INTENSIVE SPRAY, as it may increase the risk of bleeding in the stomach or intestines.

Pregnancy, breast-feeding and fertility

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You should not use STREPSILS INTENSIVE SPRAY if you are pregnant or breast feeding as it may cause harm to your unborn baby or your breastfeeding baby.

Flurbiprofen as contained in STREPSILS INTENSIVE SPRAY, belongs to a group of medicines which may impair fertility in women. This effect is reversible when the medicine is stopped being taken however, tell your doctor before taking this medicine if you have problems becoming pregnant.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking any medicine.

Driving and using machines

STREPSILS INTENSIVE SPRAY 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.

STREPSILS INTENSIVE SPRAY contains Methyl parahydroxybenzoate (E218) and Propyl parahydroxybenzoate (E216)

May cause allergic reactions (possibly delayed).

3. HOW TO USE STREPSILS INTENSIVE SPRAY

Do not share medicines prescribed for you with any other person.

Always use STREPSILS INTENSIVE SPRAY exactly as described in this leaflet or as your doctor, or pharmacist, or nurse have told you. Check with your doctor or pharmacist or nurse if you are not sure.

Recommended dose

Adults aged 18 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.

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Do not use this medicine in children or adolescents under 18 years.

For throat 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 SPRAY is for **short-term use** only.

You should use as few doses as you need for the shortest time necessary to relieve your symptoms. If mouth irritation occurs, flurbiprofen treatment should be withdrawn.

Do not use this medicine for more than 3 days

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

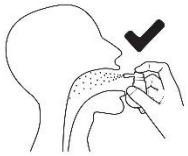
Priming the pump

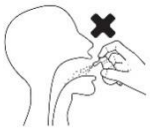
When using the pump for the first time (or after storage for a long period of time) you must first prime the pump.

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.

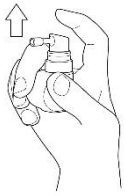




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Using a smooth rapid motion, depress the pump **three times**, taking care to fully depress the pump for each spray, whilst removing the finger from the top of the pump between each spray.





Do not inhale whilst spraying.

If you use more STREPSILS INTENSIVE SPRAY than you should:

Talk to a doctor or pharmacist or go to your nearest hospital or poison centre 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.

If you forget to use STREPSILS INTENSIVE SPRAY:

Do not use double dose to make up for forgotten individual doses

4. POSSIBLE SIDE EFFECTS

STREPSILS INTENSIVE SPRAY can have side effects.

Not all side effects reported for STREPSILS INTENSIVE SPRAY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Strepsils Intensive Spray, please consult your health care provider for advice.

Stop taking this medicine and contact a doctor or go to the casualty department at your nearest hospital immediately if you develop:

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

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- 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 membrane.
- DRESS syndrome: a life-threatening reaction which may resemble a flu-like infection, other signs may include rash, facial swelling, abdominal pain and abnormal heartbeat.

These are all very serious effects. If you have them, you may have had a serious reaction to STREPSILS INTENSIVE SPRAY. You may need urgent medical attention or hospitalisation.

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

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- 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 (face, tongue or throat swelling, shortness of breath, wheezing, dizziness and rash).

Not known (*frequency cannot be estimated from the available data*)

- anaemia (fatigue, shortness of breath), thrombocytopenia (low platelet count in the blood that can give rise to bruising and bleeding)
- swelling (oedema), high blood pressure, heart failure (shortness of breath, leg or ankle swelling, fatigue) or heart attack (chest pain, shortness of breath)
- 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)
- hepatitis (inflammation of the liver)
- high blood pressure

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist, or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of STREPSILS INTENSIVE SPRAY.

5. How to store STREPSILS INTENSIVE SPRAY:

Store all medicines out of reach of children.

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Store at or below 25 ºC.

Do not refrigerate or freeze.

Protect from light/moisture

Do not store in a bathroom

Do not use after the expiry date stated on the bottle and the carto

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

Return all unused medicine to your pharmacist

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information:

What STREPSILS INTENSIVE SPRAY contains:

The active substance is flurbiprofen.

The other ingredients are: Betadex, disodium phosphate dodecahydrate, citric acid monohydrate, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium hydroxide, mint flavour, cherry flavour, N, 2,3-Trimethyl-2-isopropylbutanamide, saccharin sodium, hydroxypropylbetadex and purified water.

What STREPSILS INTENSIVE SPRAY looks like and contents of the pack:

The throat spray, solution is clear colourless to slightly yellow solution with a taste of cherry and mint.

Pack size: 15 ml throat spray, solution

Holder of Certificate of Registration:

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road

Elandsfontein

1601

0861 11 11 00

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This leaflet was last revised in:

25 November 2022

Registration Number

50/16/0351

Access to the corresponding Professional Information

The PI will be included in the medicine package