

**Applicant:** Reckitt Benckiser Pharmaceuticals (Pty) Ltd  
**Product:** Strepsils Intensive  
**Dosage:** Lozenges  
**Strength:** Flurbiprofen 8,75 mg  
PI/PIL approval: 27 June 2024

### 1.3.2. CLEAN PROPOSED PATIENT INFORMATION LEAFLET FOR STREPSILS INTENSIVE

#### SCHEDULING STATUS

S1

#### STREPSILS INTENSIVE 8,75 mg Lozenges

Flurbiprofen.

Contains 2,3 g of sugar:

Sucrose 1,407 g per lozenge

Glucose 1,069 g per lozenge

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

STREPSILS INTENSIVE is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use STREPSILS INTENSIVE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share STREPSILS INTENSIVE 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 is and what is it used for
2. What you need to know before you use STREPSILS INTENSIVE
3. How to take STREPSILS INTENSIVE
4. Possible side effects
5. How to store STREPSILS INTENSIVE
6. Contents of the pack and other information

**Applicant:** Reckitt Benckiser Pharmaceuticals (Pty) Ltd  
**Product:** Strepsils Intensive  
**Dosage:** Lozenges  
**Strength:** Flurbiprofen 8,75 mg  
PI/PIL approval: 27 June 2024

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

STREPSILS INTENSIVE belong to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by changing the body's response to pain, swelling, and high temperature.

STREPSILS INTENSIVE is indicated for the relief of pain of sore throats.

## 2. What you need to know before you take STREPSILS INTENSIVE

### Do not take STREPSILS INTENSIVE:

- If you are hypersensitive (allergic) to flurbiprofen or any of the other ingredients of STREPSILS INTENSIVE (listed in section 6).
- If you have or have had a peptic ulcer (ulcer in your stomach or duodenum)
- If you have ever had asthma, unexpected wheezing or shortness of breath, a runny nose, facial swelling or itchy rash (hives) after taking aspirin or any other NSAID medicine.
- If you are pregnant or breastfeeding.
- In children under the age of 12 years.
- If you have severe heart failure, severe kidney failure or severe liver failure.
- If you have a history of stomach ulcers or bleeding or intestinal ulcers related to previous use of NSAIDs including STREPSILS INTENSIVE.

### Warnings and precautions

Take special care with STREPSILS INTENSIVE:

- If you have or have had asthma or suffer from allergies.
- If you have heart, kidney or liver problems.
- If you are taking anti-coagulants (medicines that prevent the blood from clotting) or suffer from bleeding disorders.
- If you are taking other NSAIDs.
- If you are elderly, as you are more likely to experience the side effects listed in this leaflet.

**Applicant:** Reckitt Benckiser Pharmaceuticals (Pty) Ltd

**Product:** Strepsils Intensive

**Dosage:** Lozenges

**Strength:** Flurbiprofen 8,75 mg

PI/PIL approval: 27 June 2024

- If you have serious skin reactions STREPSILS INTENSIVE should be stopped at the first appearance of skin rash or any other sign of hypersensitivity.
- If you suffer from chronic autoimmune disease such as systemic lupus erythematosus and mixed connective tissue disease.

**You need to discontinue STREPSILS INTENSIVE treatment and consult your doctor if this occurs during treatment:**

- Drug reaction with eosinophilia and systemic symptoms (DRESS): a life-threatening reaction which may resemble a flu-like infection, other signs may include rash, facial swelling, abdominal pain and abdominal heartbeat.

#### **Other medicines and STREPSILS INTENSIVE**

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

You should not take STREPSILS INTENSIVE if you are taking or using the following medicines:

- Water tablets (diuretics, including potassium sparing drugs)
- Other NSAID medicines or corticosteroids (such as celecoxib, ibuprofen, diclofenac sodium or prednisolone)
- Low dose aspirin (up to 75 mg daily)
- Medicines for thinning the blood (anticoagulants, antiplatelet agents)
- Medicines for high blood pressure or heart failure (antihypertensives, cardiac glycosides)
- Ciclosporine or tacrolimus (to suppress the immune system)
- Lithium or SSRIs (for depression)
- Methotrexate (to treat autoimmune diseases or cancer)
- Mifepristone (a medicine used for pregnancy termination)
- Oral antidiabetics (to treat diabetes)
- Phenytoin (to treat epilepsy)

**Applicant:** Reckitt Benckiser Pharmaceuticals (Pty) Ltd

**Product:** Strepsils Intensive

**Dosage:** Lozenges

**Strength:** Flurbiprofen 8,75 mg

PI/PIL approval: 27 June 2024

- Medicines for gout (probenecid, sulfapyrazone)
- Quinolone antibiotics (such as ciprofloxacin)
- Zidovudine (to treat HIV)

### **STREPSILS INTENSIVE with food, drink and alcohol**

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

### **Pregnancy, breastfeeding and fertility**

Do not take STREPSILS INTENSIVE medicine if you are pregnant or breastfeeding.

STREPSILS INTENSIVE belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine.

### **Driving and using machines**

Dizziness and feeling sleepy have been reported in patients taking STREPSILS INTENSIVE. If affected, the patient should not drive or operate machinery.

It is not always possible to predict to what extent STREPSILS INTENSIVE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which STREPSILS INTENSIVE affects them.

### **STREPSILS INTENSIVE contains sucrose and glucose**

STREPSILS INTENSIVE contains Liquid Glucose 1069 mg and Liquid Sucrose 1407 mg per lozenge.

This 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 medicine.

### **3. How to take STREPSILS INTENSIVE**

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

Always take STREPSILS INTENSIVE exactly as described in this leaflet or as your doctor or pharmacist or

**Applicant:** Reckitt Benckiser Pharmaceuticals (Pty) Ltd  
**Product:** Strepsils Intensive  
**Dosage:** Lozenges  
**Strength:** Flurbiprofen 8,75 mg  
PI/PIL approval: 27 June 2024

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

**Adults and children over 12 years:**

The usual dose is one lozenge sucked/dissolved slowly in the mouth every 3-6 hours as required. Always move

the lozenge around whilst sucking.

**Do not take more than 5 lozenges in a 24 hour period.**

**Do not give to children under 12 years.**

**Do not take for longer than 3 days** unless your doctor tells you to. If symptoms persist consult your doctor or pharmacist.

**If you take more STREPSILS INTENSIVE than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forget to take STREPSILS INTENSIVE**

Do not take a double dose to make up for forgotten individual doses.

**4. Possible side effects:**

STREPSILS INTENSIVE can have side effects.

Not all side effects reported for STREPSILS INTENSIVE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking STREPSILS INTENSIVE, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking STREPSILS INTENSIVE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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.)

**Applicant:** Reckitt Benckiser Pharmaceuticals (Pty) Ltd

**Product:** Strepsils Intensive

**Dosage:** Lozenges

**Strength:** Flurbiprofen 8,75 mg

PI/PIL approval: 27 June 2024

- Severe skin reactions such as peeling, blistering or flaking skin.

These are all very serious side effects. If you have them, you may have had a serious reaction to STREPSILS INTENSIVE.

You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Build-up of fluid in the body
- High blood pressure
- Heart failure

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

**Frequent side effects:**

- dizziness
- headache
- paraesthesia (abnormal sensation)
- throat irritation
- diarrhoea
- mouth ulceration
- nausea
- oral pain
- oral discomfort (warm or burning feeling or tingling of the mouth).

**Less Frequent side effects:**

- jaundice (yellowing of the skin or whites of the eyes)
- agranulocytosis (low white blood cells in the blood)
- allergic reaction

**Applicant:** Reckitt Benckiser Pharmaceuticals (Pty) Ltd

**Product:** Strepsils Intensive

**Dosage:** Lozenges

**Strength:** Flurbiprofen 8,75 mg

PI/PIL approval: 27 June 2024

- insomnia (difficulty in falling asleep)
- somnolence (feeling sleepy)
- worsening of asthma
- bronchospasm (narrowing of the airways to the lungs)
- dyspnoea (difficult or laboured breathing)
- wheezing
- blistering in the mouth or throat
- numbness in the throat
- stomach bloating
- abdominal pain
- constipation
- dry mouth
- dyspepsia (upset stomach)
- flatulence (passing wind)
- glossodynia (pain in the tongue)
- dysgeusia (altered sense of taste)
- oral dysaesthesia (abnormal sensation in the mouth)
- vomiting
- various skin rashes
- pruritus (itchy skin)
- pyrexia (fever)
- pain

**Frequency unknown side effects:**

- anaemia (deficiency of red cells in the blood)
- thrombocytopenia (low platelet count in the blood that can give rise to bruising and bleeding)

**Applicant:** Reckitt Benckiser Pharmaceuticals (Pty) Ltd  
**Product:** Strepsils Intensive  
**Dosage:** Lozenges  
**Strength:** Flurbiprofen 8,75 mg  
PI/PIL approval: 27 June 2024

- oedema (swelling)
- high blood pressure
- heart failure
- gastrointestinal bleeding
- hepatitis (inflammation of the liver)
- severe forms of skin reactions such as bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis
- DRESS reaction (rash, facial swelling accompanied by abnormal heart rates)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of suspected adverse reactions**

If you get side effects, talk to your doctor, 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

### **5. How to store STREPSILS INTENSIVE**

Store all medicines out of the reach of children.

Store at or below 25 °C in a dry place, protected from light.

Store in the original package

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 contains**

The active substance is flurbiprofen 8,75 mg per lozenge

The other ingredients are: Macrogol 300, potassium hydroxide, lemon flavour 502904 A, levomenthol, liquid glucose, liquid sucrose, honey.

**Applicant:** Reckitt Benckiser Pharmaceuticals (Pty) Ltd  
**Product:** Strepsils Intensive  
**Dosage:** Lozenges  
**Strength:** Flurbiprofen 8,75 mg  
PI/PIL approval: 27 June 2024

**What STREPSILS INTENSIVE looks like and contents of the pack**

A round, pale yellow to brown lozenge with a characteristic honey and lemon taste and the S-brand icon intagliated on both sides.

Cartons containing 12 blister packed lozenges.

**Holder of Certificate of Registration:**

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road

Elandsfontein

1601

**This leaflet was last revised in**

27 June 2024

**Registration number:**

35/16/0015

**Access to the corresponding Professional Information**

To be made available electronically at: <https://cpdcentre.co.za/rb-product-inserts/>