

Strepsils Max Pro Direct Spray 8.75mg per dose

Contains Flurbiprofen 8.75mg per dose

INFORMATION FOR THE USER

Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. However, you still need to use Strepsils Max Pro Direct Spray carefully to get the best results from it.

Keep this leaflet. You may want to read it again.

If you have any further questions after you have read it, please approach your doctor or pharmacist.

You must contact a doctor if your symptoms worsen or do not improve after 3 days.

If any side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Strepsils Max Pro Direct Spray is and what it is used for
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1. WHAT STREPSILS MAX PRO DIRECT SPRAY IS AND WHAT IT IS USED FOR

The active ingredient (which makes Strepsils Max Pro Direct Spray works) is Flurbiprofen. It belongs 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 Max Pro Direct Spray is used for the short term symptomatic relief of sore throat such as throat soreness, pain, difficulty swallowing and swelling.

This medicine is for adults of age 18 years and over.

2. BEFORE USING STREPSILS MAX PRO DIRECT SPRAY

Do not use Strepsils Max Pro Direct Spray if you:

- are allergic to Flurbiprofen or any of the other ingredients (see section 6) or to aspirin or other painkillers
- have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding
- have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking Flurbiprofen, aspirin or similar medicines
- have had gastrointestinal bleeding or perforation when previously taking NSAIDs
- are taking other NSAIDs painkillers or more than 75mg aspirin a day
- have severe liver or kidney problems
- have heart problems, high blood pressure or blood coagulation disorder
- have breathing difficulties
- are in the last 3 months of pregnancy
- are under 18 years old.

Check with your pharmacist or your doctor before using this product if you:

- have or have had asthma
- have kidney, heart, liver or bowel problems

- have high cholesterol or previously have had a heart attack or stroke
- have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease)
- have Systemic Lupus Erythematosus (a condition of the immune system causing joint pain, skin changes and other organ disorders)
- are a smoker
- are in the first 6 months of pregnancy.

Taking other medicines

To reduce the risk of side effects, do not take this product with other NSAID containing products (e.g. aspirin, ibuprofen). If you are on low-dose aspirin (up to 75mg daily), speak to your doctor or pharmacist before you take this medicine.

Some medicines may affect or be affected by treatment with Flurbiprofen. Avoid taking this product with corticosteroid tablets, quinolone antibiotics or drugs that are prescribed:

- to thin your blood or prevent clotting (e.g. warfarin),
- to stimulate your heart (e.g. glycosides)
- to help you in passing water (diuretics),
- for the temporary suppression of your immune system (e.g. methotrexate, cyclosporine, tacrolimus),
- for mania or depression (e.g. Lithium or SSRIs)
- for pregnancy termination (e.g. mifepristone)
- for HIV treatment (e.g. zidovudine).

Strepsils Max Pro Direct Spray should be used with caution in combination with antihypertensive drugs, oral antidiabetics, phenytoin and alcohol.

Speak to your pharmacist or doctor before taking Flurbiprofen with other medicines

Other warnings

- Strepsils Max Pro Direct Spray belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. It is unlikely that Strepsils Max Pro Direct Spray, used occasionally will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.
- Medicines such as Strepsils Max Pro Direct Spray may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high dose of prolonged treatment. Do not exceed the recommended dose and duration.
- The lowest effective dose should be taken for the shortest possible time to reduce the risk of side effects.
- If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes, or high cholesterol or are a smoker), you should discuss your treatment with your doctor or pharmacist.

Pregnancy and breast feeding

Do not take this medicine in the last 3 months of pregnancy or if you are breastfeeding. Speak to your doctor if you are in the first 6 months of pregnancy.

Taking NSAIDs at about 20 weeks of pregnancy or later may harm your unborn baby.

3. HOW TO USE STREPSILS MAX PRO DIRECT SPRAY

Adults aged 18 years and older:

Administer 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.

Spray at the back of the throat only. Do not inhale whilst spraying.

Do not use more than 5 doses (15 sprays) in a 24 hours period.

Do not give to adolescents and children under 18 years.

Do not use for longer than 3 days unless your doctor tells you to.

If symptoms persist or the pain worsen, or if any new symptoms occur, consult your doctor or pharmacist.

If you use more Strepsils Max Pro Direct Spray than you should, you may feel drowsy or nauseous. You should seek immediate medical advice in the event of an overdose, even if you feel well.

If you forget to use Strepsils Max Pro Direct Spray.

Do not 'double dose' to make up for a forgotten dose. Simply carry on with your next dose as required.

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.

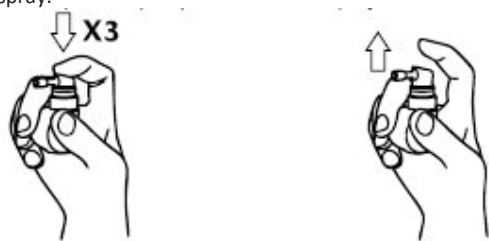
Point the nozzle away from you and spray a minimum of four times until a fine, consistent mist is produced. The pump is then primed and ready to use.

Using the spray

Aim the nozzle towards the back of the throat.



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.

4. POSSIBLE SIDE EFFECTS

STOP USING the medicine and seek immediate medical help if you develop:

- Signs and symptoms of heart problems or stroke, such as chest pain, shortness of breath, weakness in one part or side of body, or slurring of speech.
- 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).

- Sign of hypersensitivity and skin reactions such as redness, swelling, peeling, blistering, flaking or ulceration of skin and mucous membrane.

Tell your doctor or pharmacist if you experience:

Common

- 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

- 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

- Anaphylactic reaction.

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.

5. HOW TO STORE STREPSILS MAX PRO DIRECT SPRAY

Keep all medicines out of the sight and reach of children.

Do not use after the expiry date stated on the carton.

Do not store below 30°C. Do not refrigerate or freeze.

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

6. FURTHER INFORMATION

The active ingredient 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, Hydroxypropyl betadex and Purified water.

Product Registration holder: Reckitt Benckiser (Singapore) Pte. Ltd. 12 Marina Boulevard #19 – 01, Marina Bay Financial Centre, Tower 3, Singapore 018982.

Manufacturer: Reckitt Benckiser Healthcare Manufacturing (Thailand) Ltd. 65 Moo 12. Lardkrabang-Bangplee Road. Samutprakarn Thailand 10540.

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For Singapore Market use only.

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