

Package Leaflet: Information for the User

Strepsils Intensive Mint 8.75mg granules

Flurbiprofen 8.75mg

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

This medicine is available without prescription. However, you still need to take this medicine carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- 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 effects not listed, stop taking this medicine and tell your doctor or pharmacist.

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1 What Strepsils Intensive Mint 8.75mg granules are and what they are used for

Strepsils Intensive Mint 8.75mg granules contain flurbiprofen. Flurbiprofen belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by changing how the body responds to pain, swelling and high temperature. Strepsils Intensive Mint 8.75mg granules are used to relieve the symptoms of sore throats such as throat soreness, pain and swelling.

2 Before you take Strepsils Intensive Mint 8.75mg granules

Do not take Strepsils Intensive Mint 8.75mg granules if you have or ever have suffered from:

- allergic (hypersensitive) reactions to flurbiprofen or to any of the other ingredients (see Section 6)
- allergic (hypersensitive) reactions to aspirin or to any other NSAIDs medicine
- heart, kidney or liver failure
- wheezing, an irritated nose or itchy rash (hives) after taking aspirin or any other NSAIDs medicine
- stomach ulcers or bleeding in the stomach or intestines, or severe colitis
- blood problems including where your blood did not clot properly

Do not take Strepsils Intensive Mint 8.75mg granules if you:

- are taking high dose aspirin (75mg or above daily). If you are on low-dose aspirin (up to 75mg daily), speak to your doctor or pharmacist before you take Strepsils Intensive Mint 8.75mg granules
- are taking another NSAIDs medicine (such as celecoxib, ibuprofen, diclofenac sodium etc.)
- are in the last 3 months of pregnancy
- are under 12 years of age

Take special care with Strepsils Intensive Mint 8.75mg granules and speak to your doctor before taking these sachets if you are suffering from:

- asthma
- a bacterial infection (yellow-green mucus producing cough, painful sinuses, sore throat)
- kidney or liver problems
- heart problems, previous stroke or think that you might be at risk of these conditions (e.g. if you have high blood pressure, diabetes or high cholesterol or are a smoker)
- high blood pressure
- a chronic autoimmune disease (including systemic lupus erythematosus)
- regular headaches
- have any serious skin conditions, (including Stevens-Johnson syndrome)
- phenylketonuria as Strepsils Intensive Mint 8.75mg granules contains aspartame which is a source of phenylalanine and this may be harmful for people with phenylketonuria
- are elderly, as you are more likely to experience the side effects listed in this leaflet

Taking other medicines

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, consult them before using these sachets if you are taking:

- low dose aspirin (up to 75 mg daily)

- medicines for high blood pressure or heart failure
- water tablets (diuretics, including potassium sparing drugs)
- medicines for thinning the blood (anti-coagulants)
- medicines for gout (e.g. Probenecid Sulfinpyrazone)
- another NSAIDs medicine or steroids (such as celecoxib, ibuprofen, diclofenac sodium or prednisolone)
- mifepristone (a medicine used for pregnancy termination)
- quinolone antibiotics (such as ciprofloxacin)
- cyclosporin or tacrolimus (to suppress the immune system)
- phenytoin (to treat epilepsy)
- methotrexate (to treat cancer)
- lithium or SSRI's (for depression)
- oral antidiabetics (to treat diabetes)
- zidovudine (to treat HIV)
- corticosteroids (Steroid hormones)
- tacrolimus (an immunosuppressant drug)

Taking Strepsils Intensive Mint 8.75mg granules with Food and drink

Alcohol should be avoided during treatment with Strepsils Intensive Mint 8.75mg granules.

There are no known effects of taking Strepsils Intensive Mint 8.75mg granules with or without food.

Pregnancy and breast-feeding

Strepsils Intensive Mint 8.75mg granules belong to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that the occasional use of Strepsils Intensive Mint 8.75mg granules will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.

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 product.

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

Driving and using machines

Strepsils Intensive Mint 8.75mg granules should not affect your ability to drive or use machines. Dizziness and visual disturbances are possible undesirable side effects after taking NSAIDs. If affected you should not drive or operate machinery.

Important information for sufferers of phenylketonuria

Strepsils Intensive Mint 8.75mg granules contains aspartame which is a source of phenylalanine and this may be harmful for people with phenylketonuria.

Special warnings

Medicines such as Strepsils Intensive Mint 8.75mg granules may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment (3 days).

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.

3 How to take Strepsils Intensive Mint 8.75mg granules

For adults and children 12 years and older. (Do not give Strepsils Intensive Mint 8.75mg granules to children under 12 years).

- Tip the contents of the sachet into your mouth and allow to dissolve in the mouth before swallowing.
- The granules should start to work within 30 minutes.
- Then take one sachet every 3-6 hours, if required.
- There are no known effects of taking Strepsils Intensive Mint 8.75mg granules with or without food
- **Do not take more than 5 sachets in a 24 hour period.**

These sachets are for short-term use only.

You should take as few sachets as you need for the shortest time necessary to relieve your symptoms.

Do not take Strepsils Intensive Mint 8.75mg granules for more than 3 days, unless your doctor tells you to. If you do not get better or you get worse, or if new symptoms occur such as a bacterial infection, talk to a doctor or pharmacist.

If you take more 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 questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines Strepsils Intensive Mint 8.75mg granules can cause side effects, although not everybody gets them.

STOP TAKING this medicine and contact a doctor immediately if you develop:

- **Signs of gastrointestinal bleeding** such as passing blood in the stools/motions, black tarry stools, vomiting blood or dark particles that look like coffee grounds.
- **Very rare allergic reactions** such as asthma, unexpected wheezing, shortness of breath, swelling of the face, lips or tongue, skin reactions (such as hives, itching rashes), fainting.
- **Abdominal symptoms** such as indigestion, heartburn, stomach ache/pain or other unusual stomach symptoms.

Tell your doctor or pharmacist if you notice any of the following effects or any effects not listed:

Very common (*occur in more than 1 in 10 patients*)

- Oral discomfort such as burning or warm feeling in the mouth.

Common (*occur in more than 1 in 100 patients*):

- Stomach ache, feeling sick, diarrhoea
- Dry or tingling mouth, mouth ulcers
- Influenza like illness
- Upper respiratory tract infection (throat infection)
- Headache, dizziness.
- Cough, throat irritation or wheezing

Uncommon (*occur in more than 1 in 1000 patients*)

- Enlarged lymph nodes
- Ear pain, ear infection, eye infection
- Dry throat, dry mouth, burning sensation in the mouth, inflammation in the mouth (stomatitis), mouth and throat ulcers, difficulty in swallowing, gum infection, decreased oral sensitivity
- Inflammation of the larynx (laryngitis), inflammation of the pharynx (pharyngitis), infection of the tonsils (tonsillitis), oral herpes, aphonia, dysphonia
- Throat redness, throat numbness
- Sneezing, nasal congestion, nasal discomfort
- Being sick (vomiting), upset stomach, constipation, abdominal discomfort
- Back pain, joint pain
- Sleeping disorders: feeling sleepy, drowsiness, difficulty sleeping
- Breathing disorders: shortness of breath, asthma, crackling lung sounds (rales), chest discomfort, lower respiratory tract infections
- Nose bleed, runny nose, pain in the nose, inflammation of the lining of the sinuses (sinusitis)
- Skin rashes and itching
- Fever, productive cough, common cold, migraine
- Increased perspiration
- Viral infection, influenza
- Increased upper airway secretion

Rare (*occur in less than 1 in 1000 patients*)

- Ear discomfort, ear congestion, deafness
- Eye irritation, itching eyes, red eyes, conjunctivitis, blurred vision, increased tear production
- Dry tongue, swollen tongue, coated tongue, loss of taste function
- Mouth swellings (ulcerative stomatitis), pharyngeal swelling, tonsillitis complications (Peritonsillar abscess)
- Heart palpitations, chest pain
- Dizziness (vertigo), sensitivity to light, sinus congestion
- Wind (flatulence), black tarry stools
- Coughing blood (haemoptysis)
- Gum pain, gum bleeding, gum ulcers
- Heartburn
- Acne, dry skin, eczema, psoriasis, skin nodule
- Hot flush, thirst, dehydration, increase in body temperature
- Joint swelling, neck pain, muscle spasm, pain in extremities
- Sensation of a foreign body, chills
- Confusional state, abnormal dreams
- Bronchitis, bronchospasm, seasonal allergy, shortness of breath
- Physical weakness, exhaustion
- Facial swelling, lower limb swelling
- Urinary tract infection, vulvovaginal candidiasis, increased urinary frequency, abnormal urine colour
- Prolonged menstruation
- Increase in blood glucose
- Kidney dysfunction (including interstitial nephritis, nephritic syndrome and renal failure)
- Haematological reactions (including anaemia, prolonged bleeding time)

- Gastrointestinal bleeding, ulceration, perforation,

Very Rare (affects less than 1 user in 10000)

- liver problem causing jaundice (yellowing of the skin and white of the eyes)
- severe skin conditions such as Steven-Johnson Syndrome (skin rash and blisters, mouth and eye ulcers), and Lyell's syndrome (red tender peeling skin).

Other side effects (reported in similar NSAIDs medicine such as ibuprofen):

- Inflammation of the stomach (very rare)
- Rare and small increased risk of heart attack, high blood pressure, inflammation of the brain.

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

5 How to store Strepsils Intensive Mint 8.75mg granules

- Keep out of the reach and sight of children
- Do not use this medicine after the expiry date, which is stated on the pack
- Store in the original packaging
- Do not store above 25°C

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Strepsils Intensive Mint 8.75mg granules contain:

The active ingredient (the ingredient which makes the medicine work) is flurbiprofen 8.75 mg. The other ingredients are Mannitol, Xylitol, Sodium hydrogen carbonate, Carbomer, Citric acid Anhydrous, Cool Mix flavour, Sodium chloride, Peppermint flavour, Aspartame and Silicon dioxide.

What Strepsils Intensive Mint 8.75mg granules look like and contents of the pack

Strepsils Intensive Mint 8.75mg granules is a white to cream-coloured free-flowing granule with a characteristic mint odour and taste of mint.

The pack contains 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15 or 16 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder: Reckitt Benckiser Ireland Ltd. 7 Riverwalk, Citywest Business Campus, Dublin 24.
Manufacturer: RECKITT BENCKISER HEALTHCARE INTERNATIONAL, Nottingham NG90 2DB

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