

Package leaflet: Information for the patient

Flursil Relief Sugar Free 8.75mg lozenges

Flurbiprofen

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take 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

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2. What you need to know before you take Flursil Relief Sugar Free
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6. Contents of the pack and other information

1. What Flursil Relief Sugar Free is and what it is used for

Flursil Relief Sugar Free contains 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. Flursil Relief Sugar Free lozenges are used for the short-term relief of symptoms of sore throat such as throat pain and soreness in adults and children over the age of 12 years.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Flursil Relief Sugar Free

Do not take Flursil Relief Sugar Free if you:

- are allergic to flurbiprofen or to any of the other ingredients of this medicine (listed in section 6)
- currently have (or have had two or more episodes of) a stomach ulcer, intestinal ulcers, or gastrointestinal bleeding
- have ever had asthma, unexpected wheezing or shortness of breath, a runny nose, facial swelling or itchy rash (hives) after taking acetylsalicylic acid (aspirin) or any other NSAID medicine
- have had gastrointestinal bleeding or perforation, severe colitis (inflammation of the bowel) or bleeding disorders when taking NSAID medicines in the past
- are taking high dose acetylsalicylic acid (more than 75 mg aspirin per day) or another NSAID medicine (such as celecoxib, ibuprofen, diclofenac sodium etc)
- have severe heart, severe kidney or severe liver failure

- are in the last 3 months of pregnancy.

Warnings and precautions

Talk to your doctor or pharmacist before taking Flursil Relief Sugar Free if you:

- have or have had asthma or suffer from allergies
- have tonsillitis (inflamed tonsils) or think you may have a bacterial throat infection (as you may need antibiotics)
- have heart, kidney or liver problems
- have a history of hypertension
- have had a stroke
- have a history of bowel disease (such as ulcerative colitis, Crohn's disease)
- suffer from chronic autoimmune disease such as systemic lupus erythematosus and mixed connective tissue disease
- are elderly, as you are more likely to experience the side effects listed in this leaflet
- are in the first 6 months of pregnancy or breast-feeding.

Other medicines and Flursil Relief Sugar Free

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell them if you are taking:

- low dose acetylsalicylic acid (aspirin) (up to 75 mg daily)
- medicines for high blood pressure or heart failure (antihypertensives, cardiac glycosides)
- water tablets (diuretics, including potassium sparing drugs)
- medicines for thinning the blood (anticoagulants, antiplatelet agents)
- medicines for gout (probenecid, sulfinpyrazone)
- another NSAID medicine or corticosteroids (such as celecoxib, ibuprofen, diclofenac sodium or prednisolone)
- mifepristone (a medicine used for pregnancy termination)
- quinolone antibiotics (such as ciprofloxacin)
- cyclosporine or tacrolimus (to suppress the immune system)
- phenytoin (to treat epilepsy)
- methotrexate (to treat autoimmune diseases or cancer)
- lithium or SSRIs (for depression)
- oral antidiabetics (to treat diabetes)
- zidovudine (to treat HIV).

Flursil Relief Sugar Free with alcohol

Alcohol should be avoided during treatment with Flursil Relief Sugar Free as it increases the risk of bleeding in the stomach or intestines.

Pregnancy, breast-feeding and fertility

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, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Flurbiprofen can appear in the breast milk in very low concentrations, therefore Flursil Relief Sugar Free should be avoided when breast-feeding.

Flursil Relief Sugar Free belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that the lozenges, used occasionally, will affect your chances of becoming pregnant; however, tell your doctor before taking this medicine if you have problems becoming pregnant.

Driving and using machines

Dizziness, drowsiness, fatigue and visual disturbances are possible side effects after taking NSAIDs. If affected, do not drive or operate machinery.

Flursil Relief Sugar Free contains maltitol and isomalt

Each lozenge contains 2160 mg isomalt and 383 mg maltitol.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

May have a mild laxative effect.

Calorific value 2.3 kcal/g maltitol (or isomaltitol).

Flursil Relief Sugar Free contains butylated hydroxyanisole (E320)

Butylated hydroxyanisole may cause local skin reactions (e.g. contact dermatitis) and local irritation to the mucous membranes in the mouth.

3. How to take Flursil Relief Sugar Free

Always take 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.

The recommended dose in adults and children aged 12 years and over is:

- Take one lozenge by mouth and suck slowly.
- Always move the lozenge around whilst sucking.
- The lozenges should start to work within 30 minutes.
- Then take one lozenge every 3-6 hours, if needed.
- **Do not take more than 5 lozenges in a 24 hour period.**

Do not give to children under 12 years.

Some elderly patients may be more prone to side effects.

These lozenges are for short-term use only. You should take as few lozenges as you need for the shortest time necessary to relieve your symptoms. If mouth irritation occurs, flurbiprofen treatment should be withdrawn.

Do not take Flursil Relief Sugar Free for longer than 3 days unless your doctor tells you to. If symptoms persist or the pain worsens, or if any new symptoms occur, consult your doctor or pharmacist.

If you take more Flursil Relief Sugar Free 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 take Flursil Relief Sugar Free

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

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 seek immediate medical help if you develop:

- 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)
- severe skin reactions such as peeling, blistering or flaking skin.

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, throat pain
- mouth ulcers or pain in the mouth, discomfort or unusual sensation in the mouth (such as warmth, burning, tingling, prickling, etc.)
- 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, vomiting
- 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 (may affect up to 1 in 1,000 people)

- anaphylactic reaction.

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
- severe forms of skin reactions such as bullous reactions, including Stevens-Johnson syndrome, Lyell's syndrome and toxic epidermal necrolysis
- hepatitis (inflammation of the liver), yellowing of the skin or whites of the eyes caused by liver problems (jaundice), abnormal liver function
- depression, confusional state, hallucination
- visual disturbances
- ear ringing (tinnitus)
- tiredness, swelling or puffiness in the face, abdomen, thighs or ankles, passing less urine or problems urinating and back pain (symptoms of kidney problems)
- generally feeling unwell or tired
- increased sensitivity of the skin to sun
- stroke
- inflammation of the protective membrane surrounding the brain (aseptic meningitis) with symptoms of stiff neck, headache, nausea, vomiting, fever or disorientation.

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 side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie;

E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flursil Relief Sugar Free

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 carton and blister after EXP. The expiry date refers to the last day of that month.

PVC/PVDC/Alu blister (250µm/120µm/20µm or 30µm):

Do not store above 25°C.

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 protect the environment.

6. Contents of the pack and other information

What Flursil Relief Sugar Free contains

- The active substance is Flurbiprofen. Each lozenge contains 8.75 mg Flurbiprofen.
- The other excipients are isomalt (E953), maltitol (E965), sucralose, potassium hydroxide, macrogol 300, orange oil flavour, butylated hydroxyanisole (E320), blood orange flavour, levomenthol, beta carotene.

What Flursil Relief Sugar Free looks like and contents of the pack

Flursil Relief Sugar Free is a round, orange lozenge with typical line marking and without debossment, with an orange flavour and a diameter of approximately 19 mm and packed in an opaque PVC/PVDC/Alu blister.

Pack sizes: 8, 10, 16, 24 lozenges

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Soldan Holding + Bonbonspezialitäten GmbH., Hoechstatter Strasse 33, 91325 Adelsdorf Bayern, Germany.

LEK Pharmaceuticals d.d., Verovškova ulica 57, 1526 Ljubljana, Slovenia.

Lek S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.

Salutas Pharma GmbH., Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

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

Austria	Flurbiangin akut 8,75 mg – Lutschtabletten
Belgium	Flubilarin 8,75 mg zuigtabletten
Bulgaria	АНГАЛ Интензив 8,75 mg таблетки за смучене, отляти
Cyprus	Flurbiprofen Sandoz Orange
France	FLURBIPROFENE SANDOZ CONSEIL 8,75 mg ORANGE SANS SUCRE, pastille édulcorée au sucralose
Germany	FlurbiAngin 8,75 mg Lutschtabletten
Hungary	Angifort 8,75 mg narancsízű szopogató tabletta
Ireland	Flursil Relief Sugar Free 8.75mg lozenges
Italy	Formitrol Gola
Netherlands	Flurbiprofen Sandoz sinaasappel suikervrij 8,75 mg, zuigtabletten
Portugal	Flurbiprofeno Sandoz
Romania	DOLIPS cu aroma de portocala 8,75 mg PASTILE
Spain	Flurbiprofeno Sandoz care 8,75 mg pastillas para chupar sabor naranja

This leaflet was last revised in 05/2019.