

PACKAGE LEAFLET: INFORMATION FOR THE USER

Medisils Intensive 8.75 mg 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, pharmacist or nurse 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, pharmacist or nurse. 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

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

1. What Medisils Intensive is and what it is used for

Medisils Intensive contains flurbiprofen. Flurbiprofen belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) which have analgesic, antipyretic and anti-inflammatory properties.

Medisils Intensive is used for the local short-term relief of symptoms of sore throat such as throat soreness, pain and swelling, and difficulty in swallowing, in adults and adolescents 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 Medisils Intensive

DO NOT take Medisils Intensive if you:

- are allergic to flurbiprofen or any of the other ingredients of this medicine (listed in section 6)
- have ever had asthma, unexpected wheezing or shortness of breath, a runny nose, facial swelling or itchy rash (hives) after taking acetylsalicylic acid or any other NSAID medicine
- currently have or have ever had two or more episodes of a stomach ulcer, intestinal ulcers, or gastrointestinal bleeding
- have had gastrointestinal bleeding or perforation, severe colitis (inflammation of the bowel) or bleeding disorders when taking NSAID medicines in the past
- are in the last 3 months of pregnancy
- have severe heart, severe kidney or severe liver failure

Warnings and precautions

Talk to your doctor or pharmacist before taking Medisils Intensive if you:

- have ever 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 an infection – please see heading “Infections” below.
- have heart, kidney or liver problems

- have had a stroke
- have a history of bowel disease (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.
- have high blood pressure
- have analgesic-induced headache
- are already taking any other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), corticosteroids or acetylsalicylic acid; see "Other medicines and Medisils Intensive" below

Infections

Non-steroidal anti-inflammatory drugs (NSAIDs) may hide signs of infections such as fever and pain. This may delay appropriate treatment of infection, which may lead to an increased risk of complications. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor or pharmacist without delay.

Whilst using Medisils Intensive

- At the first sign of any skin reaction (rash, peeling, blistering) or other signs of an allergic reaction, stop using this medicine 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.
- The use of medicines containing flurbiprofen 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).

Children

This medicine is not intended for children under the age of 12 years.

Other medicines and Medisils Intensive

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

- low dose acetylsalicylic acid (up to 75 mg daily)
- medicines for high blood pressure or heart failure (antihypertensives, cardiac glycosides)
- water tablets (diuretics, including potassium-sparing medicines)
- medicines for thinning the blood (anticoagulants, antiplatelet agents)
- medicines for gout (probenecid, sulfinpyrazone)
- other NSAIDs including cyclooxygenase-2 selective inhibitors 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 (medicines used to suppress the immune system)
- phenytoin (medicine to treat epilepsy)
- methotrexate (medicine to treat autoimmune diseases or cancer)
- lithium or selective serotonin reuptake inhibitors (medicines for depression)
- oral antidiabetics (to treat diabetes)
- zidovudine (to treat HIV)

Medisils Intensive with food, drink and alcohol

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

Pregnancy, breast-feeding and fertility

Oral forms (e.g. tablets) of flurbiprofen can cause adverse effects in your unborn baby. It is not known if the same risk applies to Medisils Intensive. If you are pregnant or 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.

Do not use Medisils Intensive if you are in the last 3 months of pregnancy.

You should not use Medisils Intensive during the first 6 months of pregnancy unless clearly necessary and advised by your doctor. If you need treatment during this period, the lowest dose for the shortest time possible should be used.

This medicine is not recommended if you are breast-feeding.

Flurbiprofen 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

No studies on the effects of this medicine on the ability to drive and use of machines have been performed. However, dizziness and visual disturbances are possible side effects after taking NSAIDs. If affected, do not drive or operate machinery.

Medisils Intensive contains Isomalt (E 953), Maltitol liquid (E 965), Cochineal Red A (E 124), Sunset yellow FCF (E 110) and orange flavour with limonene, citral and citronellol

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

Calorific value 2.3 kcal/g Maltitol liquid (E965) and Isomalt.

May have a mild laxative effect.

Cochineal Red A (E 124) and Sunset yellow FCF (E 110) may cause allergic reactions.

This medicine contains orange flavour with limonene, citral, and citronellol allergens. Limonene, citral and citronellol may cause allergic reactions.

3. How to take Medisils Intensive

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 is: Adults and adolescents over the age of 12 years

- 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 24 hours.**

Use in children

This medicine is not intended for children under the age of 12 years.

These lozenges are for short-term use only. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor or pharmacist without delay if symptoms (such as fever and pain) persist or worsen (see section 2). If mouth irritation occurs, flurbiprofen treatment should be withdrawn.

Do not take Medisils Intensive for more than 3 days unless your doctor tells you to. If you do not get better, you get worse, or if you develop new symptoms, talk to a doctor or pharmacist.

If you take more Medisils Intensive 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 forget to take Medisils Intensive

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

If you have any further questions on the use of this product, 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 contact a doctor immediately 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
- mouth ulcers or pain in the mouth
- throat pain
- 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

Frequency not known (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)

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, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Medisils Intensive

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.

Store in the original package in order to protect from light.

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 Medisils Intensive contains

The active substance is flurbiprofen. Each lozenge contains 8.75 mg of flurbiprofen.

The other ingredients are:

Isomalt (E 953)
 Maltitol Liquid (E 965)
 Potassium acesulfame (E 950)
 Macrogol 300 (E 1521)
 Orange flavor (contains limonene, decanal, citral, citronellol)
 Cochineal Red A (E 124)
 Sunset yellow FCF (E 110)
 Potassium hydroxide (E 525)
 Levomenthol

What Medisils Intensive looks like and contents of the pack

Medisils Intensive 8.75mg orange flavoured lozenges without sugar: A round orange lozenge of 19 mm diameter and 7.5 mm thickness.

The lozenges are available in PVC-PVdC/Aluminium blisters packs.

Pack sizes: 8, 10, 12, 16, 20, 24, 30, 36 lozenges

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

Lozy's Pharmaceuticals S.L., Campus Empresarial Lekaroz nº1, 31795 Lecároz, Navarra, Spain

STADA Arzneimittel AG, Stadastrasse 2 – 18, 61118 Bad Vilbel, Germany

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

STADA Arzneimittel GmbH, Muthgasse 36, 1190 Wien, Austria

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

Austria:	Lemocin Flurbiprofen 8,75 mg Lutschtabletten mit Orangengeschmack
Belgium:	Flurbiprofen EG Suikervrij 8,75 mg zuigtabletten
Bulgaria:	Orofar Intense Orange sugar-free 8,75 mg lozenges
Croatia:	Orofar bez šećera 8,75 mg pastile
Cyprus:	Flurbiprofen Stada 8,75 mg τροχίσκοι
Czechia:	Flurbiprofen STADA
Germany:	Flurbiprofen AL mit Orangengeschmack 8,75 mg Lutschtabletten
Denmark:	Flurbiprofen STADA
Estonia:	Flurbiprofen STADA
Finland:	Flurbiprofen STADA 8,75 mg imeskelytabletti
Greece:	OROFEN® ORANGE SUGAR-FREE
Hungary:	Flurbiprofen Stada 8,75 mg szopogató tableta
Ireland:	Medisils Intensive 8.75 mg lozenges
Italy:	FLURBIPROFENE EG STADA
Luxembourg:	Flurbiprofen EG Sans Sucre 8,75 mg pastilles
Latvia:	Flurbiprofen STADA 8,75 mg sūkājamās tabletes
Norway:	Flurbiprofen STADA
Netherlands:	Flurbiprofen HTP 8,75 mg sinaasappel suikervrij, zuigtabletten
Portugal:	Mebocaína Intens
Poland:	Cholinex Direct smak pomarańczowy
Romania:	Orofar Intensiv Portocale fără zahăr, 8,75 mg pastile
Slovenia:	lurbiprofen STADA 8,75 mg pastile
Slovakia:	Oroflurb pastilky s pomarančovou príchuťou cukru
Sweden:	Flurbiprofen STADA

This leaflet was last revised in August 2025.