Flubrix Flurbiprofen solution 8.75 mg/dose Oromucosal Spray

Flurbiprofen (8.75 mg/0.54ml)

What is in this leaflet

What Flubrix Flurbiprofen solution 8.75 mg/dose Oromucosal Spray is used for

Flubrix Flurbiprofen solution 8.75 mg/dose Oromucosal Spray is indicated for the short term symptomatic relief of acute sore throat in adults.

How Flubrix Flurbiprofen solution 8.75 mg/dose Oromucosal Spray works

The active ingredient (which makes the medicine work) is flurbiprofen. It belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines provide relief by changing how the body responds to pain and high temperature.

Before you use What Flubrix Flurbiprofen solution 8.75 mg/dose Oromucosal Spray

-When you must not use it:

Do not take Flubrix Flurbiprofen solution 8.75 mg/dose Oromucosal Spray if you

- If you are allergic to flurbiprofen or to any of the excipients
- have had a previous allergic reaction after taking Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or aspirin (acetylsalicylic acid); e.g. asthma, wheezing, itching, runny nose, skin rashes, swelling
- If you have (or have had two or more episodes of) a stomach ulcer or bleeding of the stomach
- If you have a history of gastrointestinal bleeding or perforation related to previous NSAID therapy
- During the last three months of pregnancy
- If you have severe liver, kidney or heart failure
- Or give to children and adolescents below 18 years.

Pregnancy and lactation

Do not take this medicine 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 medicine.

-Before you start to use it

Talk to your doctor or pharmacist before taking Flubrix Flurbiprofen solution 8.75 mg/dose Oromucosal Spray if you

- are already taking any other NonSteroidal Anti-Inflammatory Drugs (NSAIDs) or aspirin.
- have tonsillitis (inflamed tonsils) or think you may have a bacterial throat infection (as you may need antibiotics).
- are elderly (as you may be more likely to have side effects).
- have or have ever had asthma or suffer from allergies.
- suffer from a skin condition called systemic lupus erythematosus or mixed connective tissue disease.
- have hypertension (high blood pressure).
- have a history of bowel disease (ulcerative colitis, Crohn's disease).
- have heart, kidney or liver problems.
- have had a stroke.
- are in the first 6 months of pregnancy or breastfeeding.

-Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, tell them if you are taking:

- other Non-Steroidal Anti Inflammatory Drugs (NSAIDs) including cyclooxygenase-2 selective inhibitors for pain or inflammation, as these may increase the risk of bleeding from the stomach or intestines
- warfarin, aspirin (acetylsalicylic acid) and other blood thinning or anticlotting medicines

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- ACE inhibitors, angiotensin-IIantagonists (medicines which lower blood pressure)
- diuretics (water tablets) including potassium sparing diuretics
- SSRIs (selective serotonin re-uptake inhibitors) for depression
- cardiac glycosides (for heart problems) such as digoxin
- cyclosporine (to prevent organ rejection after transplant)
- corticosteroids (to reduce inflammation)
- lithium (for mood disorders)
- methotrexate (for psoriasis, arthritis and cancer)
- mifepristone (used to terminate pregnancy) NSAIDs should not be used for 8 – 12 days after taking mifepristone, as they can reduce the effect of mifepristone
- oral antidiabetic medicines
- phenytoin (for epilepsy)
- probenecid, sulfinpyrazone (for gout and arthritis)
- quinolone antibiotics (for bacterial infections) such as ciprofloxacin, levofloxacin
- tacrolimus (immunosuppressant used after organ transplant)
- zidovudine (for HIV).

How to use Flubrix Flurbiprofen solution 8.75 mg/dose Oromucosal Spray

-How much to use

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

Recommended dose

For oromucosal administration and short-term use only.

Adults aged 18 years and over:

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.

One dose (3 sprays) contains 8.75 mg of Flurbiprofen.

Do not use this medicine in children or adolescents under 18 years.

Spray at the back of the throat only.

Do not use this medicine for more than 3 days unless instructed to do so by your doctor.

If you do not get better, you get worse, or if new symptoms occur, talk to a doctor or pharmacist.

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. If the product is not used for a period of time, point the nozzle away from you and spray a minimum of once ensuring a fine, consistent mist is produced. Always ensure a fine consistent mist is produced before dosing the product.

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.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Take Flubrix Flurbiprofen solution 8.75 mg/dose Oromucosal Spray as long as your doctor recommends.

-If you forget to use it

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it.

-If you use too much (overdose)

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 further questions on the use of this medicine, ask your doctor or pharmacist.

While you are using it

-Things you must do

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- At the first sign of any skin reaction (rash, peeling, blistering) or other sign of an allergic reaction, stop using the spray 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.
- Medicines such as Flurbiprofen may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with higher doses or prolonged treatment. Do not exceed the recommended dose or duration of treatment

-Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Flubrix Flurbiprofen solution 8.75 mg/dose Oromucosal Spray to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the spray makes you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Flubrix Flurbiprofen solution 8.75 mg/dose Oromucosal Spray can cause side effects, although not everybody gets them.

STOP TAKING the medicine and seek immediate medical help if you develop:
- 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).
- signs 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 notice any of the following effects or any effects not listed:

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

Not known:
• 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
• hepatitis (inflammation of the liver)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Flubrix Flurbiprofen solution 8.75 mg/dose Oromucosal Spray

-Storage

Keep all medicine out of reach of children.

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

Discard 6 months after opening.

- *Disposal*

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

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Product Description

-What it looks like

A colourless to slightly yellow solution with a characteristic odour.

- Ingredients

-Active Ingredient

The active substance is flurbiprofen.

One dose (3 sprays) contains 8.75 mg.

-Inactive ingredients:

Betadex (E459), Disodium phosphate dodecahydrate, Citric acid monohydrate, Methyl parahydroxybenzoate (E218), Saccharin sodium (E954), Hydroxypropyl betadex, Sodium hydroxide (for pH adjustment), Mint flavour, Cherry flavour, N,2,3-Trimethyl-2-isopropylbutanamide, Purified water. Qualitative composition of Mint flavour: Natural mint essential oil, Mint natural extract, Maltodextrines, Menthofuran, Pulegon, Acacia (E414). Qualitative composition of Cherry flavour: Flavouring substance(s), Flavouring preparation(s), Natural flavouring substances, Maltodextrin, Triacetin (E1518), Acacia (E414).

- MAL number:

Manufacturer

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Product Registration Holder

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