

## **Package Leaflet: information for the user**

### **Vocafen sugar free orange flavour 8.75 mg lozenges** flurbiprofen

**Read all of this leaflet carefully before you start using 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 have 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 Vocafen sugar free orange flavour is and what it is used for
2. What you need to know before you use Vocafen sugar free orange flavour
3. How to take Vocafen sugar free orange flavour
4. Possible side effects
5. How to store Vocafen sugar free orange flavour
6. Contents of the pack and other information

#### **1. What Vocafen sugar free orange flavour is and what it is used for**

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

Vocafen sugar free orange flavour are used for the 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 Vocafen sugar free orange flavour**

**Do not take** Vocafen sugar free orange flavour

- If you are allergic to flurbiprofen or any of the other ingredients of this medicine (listed in section 6)
- If you have had asthma, breathing unexpected noises or difficulty breathing, runny nose, facial swelling or skin rash like with itching (hives) after taking acetylsalicylic acid (aspirin) or any other NSAID medicine.
- If you have or had an ulcer (two or more episodes of gastric ulcer or duodenal ulcer) in your stomach or intestines.
- If you had a bleeding or gastrointestinal perforation, severe colitis or blood disorders after using another NSAID.
- If you are taking high dose aspirin or another NSAID medicine (such as celecoxib, ibuprofen, diclofenac sodium, etc.)
- If you are in the last 3 months of pregnancy.
- If you have or had severe heart, liver or kidney failure.

## **Warnings and precautions**

Talk to your doctor or pharmacist before taking Vocafen sugar free orange flavour.

- If you have ever had asthma or suffer from allergies
- If you have tonsillitis (tonsils swelling) or think you may have a throat bacterial infection (as you may need antibiotics medicines)
- if you have an infection - please see heading "Infections" below
- If you have heart, liver or kidney problems
- If you have had a stroke
- If you have a history of intestinal diseases (ulcerative colitis, Crohn's disease)
- If you suffer from chronic autoimmune disease (including Systemic Lupus Erythematosus or mixed connective tissue disease)
- If you are elderly, as you are more likely to experience the side effects listed in this leaflet.
- If you are in the first 6 months of pregnancy or during breastfeeding period.
- If you have analgesic-induced headache

## **Whilst using Vocafen sugar free orange flavour**

- At a first sign of a skin reaction (rash, exfoliation) or other signs of an allergic reaction, stop taking this medicine and consult a doctor immediately.
- Report any unusual abdominal symptoms (especially bleeding) to your doctor. If you do not get better, you get worse, or develop new symptoms, talk your doctor.
- The use of medicines containing flurbiprofen can be associated with a small increase in the risk of suffering a heart attack (myocardial infarction) or stroke. Any risk is more likely at high doses and prolonged treatments. Do not exceed the recommended dose or duration of treatment (3 days).

## **Children and adolescents**

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

## **Other medicines and Vocafen sugar free orange flavour**

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

- low doses of acetylsalicylic acid (aspirin) (up to 75 mg daily)
- medicines for high blood pressure or heart failure (antihypertensive, cardiac glycosides)
- amending water balance tablets (diuretics, including potassium-sparing drugs)
- medicines for thinning the blood (anticoagulants, antiplatelet agents)
- medicines for gout (probenecid, sulfinpyrazone)
- other NSAIDs medicines or corticosteroids (such as celecoxib, ibuprofen, diclofenac sodium or prednisolone)
- mifepristone (a drug used for termination of pregnancy)
- quinolone-class 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 infection).
- fluconazole (antifungal medication used for a number of fungal infections)
- antacids (to treat stomach acid)
- acetazolamide (to treat glaucoma or fluid retention)

## **Vocafen sugar free orange flavour with food, drink and alcohol**

Alcohol should be avoided during treatment with Vocafen sugar free orange flavour since it may increase the risk of bleeding from the stomach or intestine. Co-administration with food could delay the onset of efficacy

### **Pregnancy and breast-feeding**

**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 these lozenges.

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.

### **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

### **Driving and using machines**

Vocafen sugar free orange flavour should not affect the ability to drive and use of machines. However, dizziness and visual disturbances are possible side effects after taking NSAIDs. If affected, do not drive or operate machinery.

### **Vocafen sugar free orange flavour contains isomalt (E953) and maltitol (E965)**

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

Vocafen sugar free orange flavour contains fragrance with citral, citronellol, geraniol and linalool which may cause allergic reactions.

## **3. How to take Vocafen sugar free orange flavour**

Always take Vocafen sugar free orange flavour 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:

1 lozenge every 3-6 hours, if needed.

Do not take more than 5 lozenges in 24 hours.

Take 1 lozenge and dissolve slowly in the mouth. Always move the lozenge in your mouth while it dissolves. The lozenges should start to work within 30 minutes

### **Use in children:**

The lozenges are not intended for children under 12 years of age.

**These lozenges are only for short-term treatments.** 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 Vocafen sugar free orange flavour for more than 3 days.** If you do not get better, you get worse, or if you develop new symptoms, talk to a doctor.

### **If you take more Vocafen sugar free orange flavour 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 further questions on the use of this product ask your doctor or pharmacist.

**If you forget to take Vocafen sugar free orange flavour**

If you forget to take this product, do not 'double dose' to make up for a forgotten dose.

**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:

- sign of an allergic reactions such as asthma, unexpected 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 have any of the following effects or any other effect not described:

**Common** (*may affect up to 1 in 10 people*)

- dizziness, headache, paraesthesia
- 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 1000 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Vocafen sugar free orange flavour**

Keep this medicine out of the sight and reach of children.

Do not use Vocafen sugar free orange flavour after the expiry date which is stated on the carton and the blister foil after EXP. The expiry date refers to the last day of that month.

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 Vocafen sugar free orange flavour contains**

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

The other ingredients are:

Isomalt (E953)

Maltitol liquid (E965)

Acesulfame Potassium (E950)

Macrogol 400

Levomenthol

Orange flavor (contains Citral, Citronellol, Geraniol, Linalool)

### **What Vocafen sugar free orange flavour looks like and contents of the pack**

Vocafen sugar free orange flavour 8.75 mg lozenges is presented as white to pale yellow coloured, round, flat bevelled lozenge with orange flavor and with a thickness of 7.0 to 8.0 mm and a diameter of 18.0 to 19.0 mm.

The lozenges are available in PVC-PVDC/Aluminium blister packs

Pack size: 16 lozenges

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder:**

Mapaex Consumer Healthcare (Ireland) Private Limited  
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KILDARE  
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