Package Leaflet: information for the user

Vocasept 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 Vocasept is and what it is used for
2. What you need to know before you use Vocasept
3. How to takeVocasept
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1. What Vocasept is and what it is used for

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

Vocasept are 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 Vocasept

Do not take Vocasept
- if you are allergic to flurbiprofen or any of the other ingredients of this medicine (listed in section 6)
- if you have ever had asthma, unexpected wheezing or shortness of breath, runny nose, facial swelling or itchy rash (hives) after taking acetylsalicylic acid or any other NSAID medicine.
- if you currently have or have ever had an ulcer (two or more episodes of stomach ulcer or intestinal ulcer) or bleeding in your stomach or intestines.
- if you have had a gastrointestinal bleeding or perforation, severe colitis (inflammation of the bowel) or blood disorders after using another NSAID.
- if you are taking high dose acetylsalicylic acid or another NSAID medicine (such as celecoxib, ibuprofen, diclofenac sodium, etc.)
- if you are in the last 3 months of pregnancy
- if you have severe heart, liver or kidney failure.

Warnings and precautions
Talk to your doctor or pharmacist before taking Vocasept:
- if you have ever had asthma or suffer from allergies
- if you have tonsillitis (inflamed tonsils) or think you may have a throat bacterial infection (as you may need antibiotic medicines)

- if you have an infection – please see heading “Infections” below
- if you have high blood pressure, heart, liver or kidney problems
- if you have had a stroke
- if you have a history of bowel 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.

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 Vocasept
- At a first sign of a skin reaction (rash, peeling, blistering) 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 to 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 use in children under 12 years of age.

Other medicines and Vocasept
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, let them know if you are taking:
- low doses of acetylsalicylic acid (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)
- other NSAIDs medicines or corticosteroids (such as celecoxib, ibuprofen, diclofenac sodium or prednisolone)
- mifepristone (a medicine 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).

Vocasept with food, drink and alcohol
Alcohol should be avoided during treatment with Vocasept since it may increase the risk of bleeding from the stomach or intestine.

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 Vocasept.
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 take this medicine if you're in the last three months of pregnancy. You should not use this medicine 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.

The product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

Driving and using machines
No studies on the effects 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.

Important information about some of the ingredients of Vocasept
This medicine contains isomalt and liquid maltitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. May have a mild laxative effect. Calorific value 2.3 kcal/g maltitol and isomalt.

This medicine contains fragrances with citral, citronellol, geraniol, limonene and linalool which may cause allergic reactions.

3. How to take Vocasept

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:
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.

Use in children:
This medicinal product is not intended for use in children under 12 years of age.

These lozenges are only for short-term treatment. 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 Vocasept 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.

If you take more Vocasept 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 Vocasept
Do not take the double dose to make up for a missed 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, 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.

Talk to your doctor or pharmacist if you have any of the following effects or any other effect not described:

Further side effects that may occur:

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)*
- feeling sleepy or difficulty to fall asleep
- worsening of asthma, wheezing, shortness of breath
- blistering in the mouth or throat, numbness in the throat
- dry mouth
- burning sensation in the mouth, altered sense of taste
- stomach bloating, abdominal pain, wind, constipation, indigestion, vomiting
- reduced sensation in the throat
- fever, pain
- skin rashes, itchy skin

Rare *(may affect up to 1 in 1000 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 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 Vocasept

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.

This medicine does not require any special storage conditions.

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

The other ingredients are:

Isomalt (E953)
Maltitol, liquid
Acesulfame potassium (E950)
Macrogol
Levomenthol
Honey flavour (contains ethyl phenyl acetate, phenyl ethyl acetate, citronellol, aldehyde C-16, propylene glycol (E1520))
Lemon flavour (contains citral, citronellol, geraniol, limonene and linalool)

This medicine may contain trace amounts of light liquid paraffin used as processing aid.

What Vocasept looks like and contents of the pack
Vocasept is presented as white to pale yellow coloured, round, flat bevelled lozenge with honey lemon flavour and with a thickness of 7 to 8 mm and a diameter of 18 to 19 mm.

The lozenges are available in PVC/PVDC//Aluminium blister packs.
Package sizes: 8 and 16 lozenges.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
MAPAEX CONSUMER HEALTHCARE (IRELAND) PRIVATE LIMITED
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Manufacturer
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This medicine is authorised in the Member States of the European Economic Area under the following names:
Finland: Vocaflam 8,75 mg imeskelytabletti / Vocaflam 8,75 mg sugtablett
Slovakia: Vocasept s medu a citróna príchuťou bez cukru 8,75 mg tvrdé pastilk
Poland: Vocaflam smak miodowo-cytrynowy bez cukru
Hungary: Vocafen cukormentes méz-citrom ízű 8,75 mg szopogató tabletta
Czech Republic: Vocafen med a citron bez cukru
Romania: Vocasept miere și lămâie fără zahăr 8,75 mg pastile
Ireland: Vocasept 8.75 mg Lozenges

This leaflet was last revised in