OXOFEN 2 mg/mL syrup

PATIENT INFORMATION LEAFLET

OXOFEN 2 mg/mL syrup

For oral use

Active substance: Each 5 mL contains 10 mg fenspiride hydrochloride

Excipients: Sucrose, methyl paraben, propyl paraben, citric acid monohydrate, titanium dioxide dicyanate, 70% sorbitol liquid, yellow orange sunset yellow SE, 184, methyl 7675, masking flavour, propylene glycol, banana flavour, orange flavour

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

1. What OXOFEN is and what it is used for?

OXOFEN is an orange-coloured liquid. This syrup belongs to the drug class used for obstructive respiratory tract disease. It is presented in 150 mL amber-coloured type III glass bottle capp with white colored PE screw-cap. A 15 mL measurement cap marked with 5, 10 and 15 mL is also provided in the carton box.

OXOFEN is a drug that is used to treat the symptoms of acute and chronic inflammatory ear, nose and throat and respiratory tract disease. It is used to treat allergic reactions including seasonal and perennial rhinitis, and allergic rhinoconjunctivitis.

OXOFEN is also used in the treatment of respiratory diseases and infections as a result of measles and influenza.

2. What you need to know before you take OXOFEN

Do not use OXOFEN:

- If you have an allergy (hypersensitivity) to fenspiride or any other component of OXOFEN
- In children below the age of 2 years.
- During the usage of this drug, when you visit the doctor or the hospital, inform your doctor about this.
- Do not use a dose above or below the dose prescribed for you.

3. How to take OXOFEN?

In this leaflet:

1. What is OXOFEN and what it is used for?
2. What you need to know before you take OXOFEN
3. How to take OXOFEN?
4. Possible side effects
5. How to store OXOFEN

1. What OXOFEN is and what it is used for?

OXOFEN is used to treat allergic reactions including seasonal and perennial rhinitis, and allergic rhinoconjunctivitis.

It is used to treat respiratory tract disease such as cough, phlegm production, wheezing, and other symptoms related to obstructive respiratory tract disease.

2. What you need to know before you take OXOFEN

Do not use OXOFEN:

- If you have an allergic (hypersensitivity) to fenspiride active substance or any of the other components of OXOFEN
- In patients at or under the age of 2 years.
- During the usage of this drug, when you visit the doctor or the hospital, inform your doctor about this.

Take special care with OXOFEN:

- If you have renal dysfunction
- If you have hepatic disease
- You have fructose intolerance, glucose-galactose malabsorption syndrome, sucrose-isoamylase deficiency.

If these warnings at any time in history even apply to you, please consult your doctor.

Using OXOFEN with food and drink:

OXOFEN should be taken pre-main. OXOFEN should not be taken with alcohol.

Precaution:

Ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant or breast feeding consult your doctor before taking OXOFEN.

Breast Feeding

Ask your doctor or pharmacist for advice before taking this medicine.

If you are breast feeding, tell your doctor: OXOFEN should not be used in the lactation period.

Driving and using machine

Due to the high possibility of drowsiness when used OXOFEN with alcohol especially at the initial of the treatment, you should be careful while driving a car or operating machinery.

Important information regarding some excipients in OXOFEN:

Sorbitol and sorbitol are included in the composition of this medicinal product.

If you have been told by your doctor that you cannot tolerate some sorbitol, talk to your doctor before taking this medicinal product.

Yellow orange sunset yellow including in this product may cause allergic reactions.

OXOFEN contains propylene glycol. This may cause alcohol-like symptoms.

This medicinal product contains methyl paraben and propyl paraben as preservatives. These substances may cause allergic reactions (possibly delayed).

OXOFEN contains titanium dioxide. Each measure (5 mL) contains 0,658 mg sodium. This should be considered for patients in the sodium diet.

Taking with other drugs

Please inform your doctor if you are taking or have recently taken any other medicines, including herbal and OTC drugs.

Ask your doctor or pharmacist before taking any medicinal product.

Using subjected medicinal products is not recommended during treatment with OXOFEN.

If you are taking or have recently taken any other medicines including medicines obtained with or without a prescription, please tell your doctor or pharmacist.

3. How to take OXOFEN?

Instruction for appropriate use and dosage/application frequency:

Always take OXOFEN exactly as your doctor has told you.

If you are not sure how to take OXOFEN, please ask your doctor or pharmacist.

The recommended daily dose of OXOFEN is 4 mg/kg for children above 2 years of age.

- Take 5 mL syrup for 2 or 4 times in a day for children below 10 kg body weight. Use the measuring cup by filling to 5 ml.
- Take 15 mL syrup for 2 or 4 times for children above 10 kg body weight.

Common:

- Nausea
- Abdominal pain

Rare:

- Somnolence
- Tachycardia (faster heart beat than usual)
- Rash
- Urticaria
- Erythema (redness of skin due to the blood accumulation in capillary vessel)

Unknown

- Dysuria
- Itching and swelling of skin
- Polyuria
- Hypertension
- Diarrhea
- Vomiting
- Itching
- Toxic epidermal necrolysis (a serious skin illness with blisters filling with fluid)
- Stevens-Johnson syndrome (inflammation characterized by hyperemia, swelling and redness of skin and eyes)
- Asthma (swelling)
- Fatigue

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 clicking “Notification of Drug Side Effects” icon on the website www.titck.gov.tr or Turkish Pharmacovigilance Center by calling the phone number 0 800 34 04 08 for side effects notification line. By reporting side effects, you can help provide more information on the safety of this medicine.

4. Possible side effects

Like all medicines, side effects may occur in people who are hypersensitive to the ingredients of OXOFEN.

If you notice any of the following serious side effects, stop taking OXOFEN and contact a doctor IMMEDIATELY or go to the emergency department of the nearest hospital:

- Sensory allergic and anaphylaxis - sudden itching, rash, urticaria, swelling of hands, feet, face, lips, mouth or throat (have difficulties breathing or swallowing) and feeling fainting.

These are very serious side effects. If you have any of these symptoms, get medical attention immediately. If you notice any further questions on the use of OXOFEN, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, side effects may occur in people who are hypersensitive to the ingredients of OXOFEN.

If you notice any of the following serious side effects, stop taking OXOFEN and contact a doctor IMMEDIATELY or go to the emergency department of the nearest hospital:

- Sensory allergic and anaphylaxis - sudden itching, rash, urticaria, swelling of hands, feet, face, lips, mouth or throat (have difficulties breathing or swallowing) and feeling fainting.

If you notice any of these symptoms, get medical attention immediately. If you notice any further questions on the use of OXOFEN, ask your doctor or pharmacist.

5. How to store OXOFEN

Keep OXOFEN out of reach of sight and reach of children in its original packaging.

Store at room temperature below 25 °C.

Use within shelf life:

Do not use OXOFEN after the expiry date which is stated on the packet.

Do not use OXOFEN if you notice any defects in product and/or package.

Manufacturing authorization holder:

Parapharm Sabih Ağa Çınar San. ve Tic. Ltd. Şti.

Arazit Mak. 531 Sok. No: 16/74, P.K: 34522,

Konya - Eşme (Japan) / Turkey

Manufacturer:

Merka Lab. Baş Çan. ve Tic. A.Ş.

Çamtık Ağı Sığ Novel Aına Sok. No: 5, P.K: 34787

Trabzon - Çukurova (Japan) / Turkey

This patient leaflet was approved on 03.09.2014.