

PATIENT INFORMATION LEAFLET

USYEX Spray

To be used by spraying into the oral cavity.

- **Active ingredients:** 30 ml spray contains 0.075 g of flurbiprofen and 0.036 g of chlorhexidine gluconate.
- **Excipients:** Glycerin, ethyl alcohol (96%), sorbitol (E420), cremophor RH40, sodium saccharine, sodium hydroxide, sodium benzoate (E211), perpermint essence, deionized water.

Read all of this PACKAGE INFORMATION LEAFLET carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others.
- Tell your doctor that you are taking this medicine, if you pay a visit to your doctor or to a medical facility.
- Follow these instructions carefully. Do not take higher or lower doses than recommended.

What is in this leaflet

- 1. What is USYEX and what is it used for?***
- 2. What should you know before using USYEX***
- 3. How to use USYEX?***
- 4. What are potential side effects?***
- 5. Storage conditions for USYEX.***

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

USYEX has a non-steroidal anti-inflammatory analgesic agent, i.e. flurbiprofen and an anti-septic (killing microbes) agent, i.e. chlorhexidine gluconate as active ingredients. USYEX is presented in white opaque plastic bottles of 30 ml in its cartoon box, together with the spray pump. It has mint essence and is in the form of a colorless, clear liquid.

USYEX is used for the treatment of the following conditions:

- Gingivitis (inflammation of the gingiva), stomatitis (inflammation of the oral cavity), throat inflammation (pharyngitis), tonsillitis, and aphthous lesions of the oral and throat mucosa.
- Inhibition of the microbial growth in the mouth and throat, relief of swallowing functions, as well as the symptomatic treatment of gingival diseases.
- Before and after dental procedures.
- Oral lesions (mucositis) due to radiotherapy or chemotherapy.
- Prevention of dental plaques.

2. What should you know before using USYEX.

USYEX SHOULD NOT BE USED in the following conditions:

- Hypersensitivity to flurbiprofen, chlorhexidine gluconate, or any of the excipients of this product.
- Hypersensitivity to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs.
- A history of bronchospasm (difficulty in breathing due to bronchial narrowing), or rhinitis or urticaria due to the use of acetylsalicylic acid or other non-steroidal anti-inflammatory drugs.
- Past or current history of peptic ulceration in the stomach or duodenum.
- Pregnancy or lactation.

CARE SHOULD BE EXERCISED in the following conditions when using USYEX

- Presence of renal, cardiac, or hepatic failure
- Should not be used in children under 12 years of age. In children over 12 years of age, this product can be used in accordance with a doctor's recommendation.
- This medicinal product may cause temporary discoloration in the oral cavity, tongue, and teeth due to chlorhexidine gluconate in its formula. The discoloration in the teeth is reversible and disappears spontaneously after discontinuation of the medicine.
- USYEX is only for use in the oral cavity. Avoid contact with eyes and ears.

If these apply to you or have ever applied to you in the past, please talk to your doctor.

Use of USYEX with food and drinks

USYEX does not interact with food or drinks due to its route of administration.

Pregnancy

Please talk to your doctor or pharmacists before taking any medicines.

Do not use USYEX if you are pregnant.

If you become pregnant during treatment, immediately talk to your doctor or pharmacist.

Lactation

Please talk to your doctor or pharmacist before taking any medicines.

Breastfeeding should be immediately stopped when taking USYEX, or the treatment should be discontinued.

Effects on the ability to drive and use machinery

The effect of USYEX on the ability to drive and use machinery has not been tested. However, based on its pharmacodynamic properties and general safety profile, no effects are expected.

Important information on some of the excipients of USYEX.

USYEX contains 0.06 g of sodium benzoate (E211) in 30 ml. This substance is a mild irritant for the eye, skin, and mucous membranes.

Concomitant use with other medications

Flurbiprofen may rarely reduce the diuretic activity of furosemide. Also, it may rarely interact with anticoagulant medications. No interaction between flurbiprofen and digoxin, tolbutamide, or antacids occur. No data exists regarding the interaction between other medicinal products and chlorhexidine gluconate.

If you are currently taking or have recently taken any prescribed or non-prescribed medications, please inform your doctor or pharmacist.

3. How to use USYEX

- **Instructions for appropriate use and dose/frequency of administration:**

USYSEX spray is directly sprayed onto the relevant oral area 3 times daily with two sprays in each administration.

- **Route and method of administration**

USYEX spray is sprayed onto the affected area in the mouth and throat and should not be swallowed.

Instructions for use:

- Before first use, the pump button should be pressed several times until a regular spraying is achieved. Care should be taken to avoid spraying onto the face.
- The applicator at the tip of the spray should be directed toward the desired location in the oral cavity and/or throat.
- After use, the product should be stored in its original packing in an upright position.

- **Different age groups**

Pediatric populations:

Should not be used in children under 12 years of age

Geriatric populations:

No data on use in geriatric individuals.

- **Special precautions for use:**

Renal failure:

Care should be taken when using this medicine in patients with renal failure.

Hepatic failure:

Care should be taken when using this medicine in patients with hepatic failure.

If you have an impression that the effect of USYEX is too weak or strong talk to your doctor or pharmacist.

If you have taken more USYEX than you should.

If you have taken more USYEX than you should, talk to your doctor or pharmacist.

If you forget to take USYEX

If you forget to take your dose of USYEX, wait, and take your next dose as scheduled.

Do not take double doses to make up for the missing dose.

Possible side effects that may occur upon discontinuation of USYEX.

No data exists regarding possible side effects that may occur upon discontinuing USYEX treatment.

4. What are potential side effects?

As with any other medicine, subjects with hypersensitivity to the ingredients of USYEX may experience side effects.

Stop taking USYEX and talk to your doctor or seek IMMEDIATE medical assistance if any of the following occurs:

- Allergic reactions
- Hypersensitivity reactions
- Sudden onset of shortness of breath, skin rashes, swelling in the face and/or tongue (anaphylaxis).

These represent very severe side effects. Presence of any of these shows that you have a severe allergic reaction to USYEX. You may need immediate medical assistance or admission to hospital.

These severe side effects occur very rarely.

If you notice any of the following, talk to your doctor.

- Signs of sensitivity
- Local irritations
- Reversible discoloration in the mouth or on the tongue and teeth
- Altered sense of taste
- Stinging or burning sensation in the mouth
- Dryness in the mouth or feeling of thirst
- Increased occurrence of dental calculus.

These represent mild side effects of USYEX.

If you experience any side effects not mentioned in these instructions for use, talk to your doctor or pharmacist.

Reporting of side effects

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

5. How to store USYEX

USYEX should be stored in its original packing out of the sight and reach of children.

Store in room temperature below 30°C.

Follow the instructions on the expiry date.

Do not use USYEX after the expiry date printed on the pack.

Marketing Authorization Holder:

Santa Farma Ilac Sanayii A.S.

Halide Edip Adivar Mahallesi, Boru Cicegi Sokak No 16

Sisli, Istanbul, Turkey

Tel: (+90 212) 220 64 00

Fax: (+90 212) 222 57 59

Manufacturer:

Demirciler Osb Mahallesi, Erol Kiresepi Caddesi No 8 Gebze V Kimya Ihtisas Organize
Sanayi Bolgesi, Dilovasi, Kocaeli, Turkey

Tel: (+90 262) 674 23 00

Fax: (+90 262) 674 23 21

This leaflet has been approved <{DD month YYYY}>. [To be completed nationally]