

## PATIENT INFORMATION LEAFLET

### **FLUREND<sup>®</sup> 0,25% oral spray** **Oromucosal spray.**

- **Active ingredient:** 30 ml oral spray contains 0.075 g flurbiprofen.
- **Excipients:** Glycerine, ethyl alcohol (96%), sorbitol (E420), cremophor RH 40, saccharin sodium, sodium hydroxide, sodium benzoate (E211), mint flavour, deionized water.

**Read all of this 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. Do not pass it on to others.*
- *Tell your doctor that you use this medicine when you go to a doctor and to a hospital.*
- *Follow the instructions of this leaflet carefully. Do not use doses **higher or lower than** prescribed doses.*

#### **In this leaflet:**

- 1. What FLUREND<sup>®</sup> is and it is used for?**
- 2. What you need to know before you use FLUREND<sup>®</sup>**
- 3. How to use FLUREND<sup>®</sup>?**
- 4. Possible side effects**
- 5. How to store FLUREND<sup>®</sup>?**

#### **1. What FLUREND<sup>®</sup> is and it is used for?**

FLUREND<sup>®</sup> is used as an anti-inflammatory drug in the symptomatic treatment, to relieve discomfort in oropharyngeal pains (eg. Gingivitis, oral infections, pharyngitis). Used as preservative after dental treatment.

FLUREND<sup>®</sup> is presented in 30 ml plastic opaque bottle in carton packaging with a spray pump.

#### **2. What you need to know before you use FLUREND<sup>®</sup>**

##### **Do not use FLUREND<sup>®</sup> if you:**

- Are allergic to flurbiprofen or any of the excipients used in the formulation of the product,
- Are allergic to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs,
- Have previously had bronchospasm (breathing difficulty caused by bronchial stenosis), rhinitis or urticaria due to use of acetylsalicylic acid or other non-steroidal anti-inflammatory drugs
- Have or ever had peptic ulcer

**Take special care with FLUREND<sup>®</sup> if you:**

- Have renal failure, heart failure or hepatic insufficiency

Please consult with your doctor if these warnings apply or have ever applied to you.

**Taking FLUREND<sup>®</sup> with food and drinks**

FLUREND<sup>®</sup> has no interaction with food and beverages because of its mode of administration.

**Pregnancy**

*Please consult with your doctor or pharmacist before taking this medicine.*

Tell your doctor if you are pregnant or planning to get pregnant.

*If you notice that you have become during treatment, consult with your doctor or pharmacist immediately*

**Breastfeeding**

*Please consult with your doctor or pharmacist before taking this medicine.*

Breastfeeding or medication must be discontinued while taking FLUREND<sup>®</sup>

**Effect on the use of machinery and driving vehicles**

FLUREND<sup>®</sup>'s effects on driving and using machine were not investigated. However no effect is expected based on its pharmacodynamics characteristics and general safety profile.

**Important information about some of the ingredients of FLUREND<sup>®</sup>**

FLUREND<sup>®</sup> contains sorbitol (E420). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

FLUREND<sup>®</sup> contains glycerin less than 10 g in each dose. With this dose, no effect is expected against glycerin.

FLUREND<sup>®</sup> contains sodium less than 1 mmol (23 mg) in each dose; with this dose no side effect related to sodium is expected.

This medicinal product contains a small amount of ethanol (alcohol) [less than 100 mg per dose)

FLUREND<sup>®</sup> contains 0.6 g sodium benzoate (E211) in 30 ml. It is mildly irritant to skin, eye and mucous membrane.

**Taking other medicines with FLUREND<sup>®</sup>**

FLUREND<sup>®</sup> may occasionally reduce diuretic activity of furosemide. Furthermore, flurbiprofen may rarely interact with anticoagulant drugs. However flurbiprofenin has no interaction with digoxin, tolbutamide and antacid.

*Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.*

**3. How to use FLUREND<sup>®</sup>?****-Instructions for proper use and dosing/administration frequency:**

One dose of 2 sprays 3 times a day is administered to the relevant area.

**-Method and route of administration:**

FLUREND<sup>®</sup> oral spray is sprayed to the relevant area.

## **Different age groups**

### **Pediatric population:**

Do not use in children under 12 years.

### **Geriatric population:**

There are no data regarding the use in the elderly.

## **Special conditions of use**

### **Renal failure:**

Use with caution in patients with renal failure.

### **Hepatic failure:**

Use with caution in patients with hepatic failure.

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

### **If you take more FLUREND<sup>®</sup> than you should**

*If you have taken more FLUREND<sup>®</sup> than you should, consult with your doctor or pharmacist.*

### **If you forget to take FLUREND<sup>®</sup>**

If you forget to take a dose please wait and take your next dose on time.

*Do not take a double dose to compensate for the missing dose.*

### **If you stop taking FLUREND<sup>®</sup>**

There is no information about the effects when the treatment with FLUREND<sup>®</sup> is discontinued.

## **4. Possible side effects?**

Like all medicines, FLUREND<sup>®</sup> can cause side effects to patients allergic to its ingredients.

### **Contact your doctor if you develop one of the following:**

- Sensitivity reactions
- Local irritations

These are mild side effects of FLUREND<sup>®</sup>.

*Tell your doctor or pharmacist if you notice any effect not listed in this leaflet.*

## **Reporting side affects**

Please inform your doctor, pharmacist or nurse if you get any side effect whether or not included in this leaflet. In addition, please report the side effect that you are experiencing to Turkish Pharmacovigilance Center (TÜFAM) by clicking to the icon "Reporting Drug Side Effects" at [www.tick.gov.tr](http://www.tick.gov.tr) or call the reporting hotline dialing 0 800 314 00 08. By reporting the side effects, you can help provide more information on the safety of this medicine.

## **5. How to store FLUREND<sup>®</sup>**

*Keep FLUREND<sup>®</sup> out of sight and reach of children, in its original packaging.*

Store at room temperature below 25°C.

**Do not use after the expiry date.**

*Do not use FLUREND<sup>®</sup> after the expiry date stated on the packaging*

**Authorization Holder:** Santa Farma İlaç San. A.Ş.

Okmeydanı, Boruçiçeği Sokak, No: 16 34382 Şişli-İSTANBUL

Tel: (+90 212) 220 64 00

Fax: (+90 212) 222 57 59

**Place of Manufacture:** Santa Farma İlaç Sanayii A.Ş.

GEBKİM 41455 Dilovası - KOCAELİ

Tel: (+90 262) 674 23 00

Fax: (+90 262) 674 23 21

*This patient information leaflet has been approved on .../.../.....*