

## PATIENT INFORMATION LEAFLET

### **MAXIMUS 0.25% Oral Rinse Solution**

**It is applied by shaking in the mouth.**

**Active ingredient:** 200 ml rinse solution contains 0.5 g flurbiprofen.

**Excipients:** Sodium benzoate, macrogolglycerol hydroxystearate 40, sodium bicarbonate, glycerol, saccharin sodium, sorbitol liquid non-crystalline (70%), ecocool MP, peppermint essence, patent blue V, propylene glycol, purified water

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed personally for you. Do not give it to others.
- If you visit your doctor or a hospital during the use of this drug, please tell your doctor that you are using this drug.
- Please follow these instructions strictly. Do not use dosages **higher** or **lower** than the dosage recommended to you.

### **What is in this leaflet:**

- 1. What MAXIMUS is and what it is used for*
- 2. Things to consider before using MAXIMUS*
- 3. How to use MAXIMUS*
- 4. Possible side effects*
- 5. How to store MAXIMUS*

**Titles are included.**

## **1. What is MAXIMUS and what it is used for?**

It is used in symptomatic treatment to relieving discomfort in pain due to oropharyngeal area (eg gingivitis, oral inflammations, pharynx inflammation) as anti-inflammatory. It is also used as a preservative after dental treatments.

MAXIMUS is presented in a 200 ml amber colored PET bottle with a 15 ml PP scale in a cardboard box.

## **2. Things to consider before using MAXIMUS**

### **DO NOT USE MAXIMUS under following conditions:**

If;

- You are hypersensitive against flurbiprofen or any ingredient included in the composition of the product
- You are hypersensitive against acetylsalicylic acid or other non-steroidal anti-inflammatory drugs,
- You have had bronchospasm(breathing difficulty related to bronchial narrowing) or rhinitis or urticaria related to acetyl salicylic acid or other nonsteroidal anti-inflammatory drugs,
- You have peptic ulcer or if you had this disease in the past.

### **USE MAXIMUS CAREFULLY in the following conditions:**

- If you have renal failure, heart failure or liver failure.

Please inform your doctor if you have any of these conditions even if you have experienced them in the past.

### **Using with food and drink**

MAXIMUS does not interact with foods and drinks in relation with the route of its administration.

### **Pregnancy**

*Consult your doctor or pharmacist before taking this medicine,*

Tell your doctor if you are pregnant or plan to become pregnant.

*Tell your doctor if you notice that you are pregnant while you are using this medicine.*

### **Lactation**

*Consult your doctor or pharmacist for advice before taking this medicine,*

Either breastfeeding or drug must be stopped when using MAXIMUS.

### **Driving and using machines**

Effects of MAXIMUS on driving and using machines have not been studied; however, no effects are expected based on its pharmacodynamics properties and general safety profile.

### **Important information on some excipients included in MAXIMUS**

MAXIMUS contains glycerol, saccharine sodium, sorbitol and propylene glycol. But no warnings are required because of its administration route.

### **Using with other medicines**

MAXIMUS can rarely decrease the diuretic activity of furosemide. In addition, flurbiprofen can rarely interact with anticoagulant drugs. Together with this, flurbiprofen has no interactions with digoxin, tolbutamide or antacids.

*Tell your doctor or pharmacist if you are taking or you have recently taken or might take any other prescribed or non-prescribed medicines.*

## **3. How is MAXIMUS used?**

### **Instructions for proper use/ frequency of administration:**

10 ml of rinse solution is added to half a glass of water and rinsing or mouthwashing two or three times a day.

### **Route and method of administration:**

MAXIMUS rinse is for mouth rinsing and / or mouthwashing. After gargling, the remaining part should be thrown out and not swallowed.

### **Different Age groups:**

#### **Pediatric population:**

It must not be used in children younger than 12 years of age.

#### **Geriatric Population:**

There are not data related to the use in the elderly.

### **Special use conditions:**

#### **Renal failure:**

It must be used carefully in patients with renal failure.

**Liver failure:**

It must be used carefully in patients with liver failure.

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

**If you use MAXIMUS more than you should**

*Consult a doctor or pharmacist if you had used MAXIMUS in an amount more than you should.*

**If you forget to use MAXIMUS**

If you forget to use your drug, wait and use the next dose in time.

*Do not take a double dose in the aim of compensate the forgotten doses.*

**Effects that may occur when treatment with MAXIMUS is terminated**

There is no data about the effects related to the termination of the treatment with MAXIMUS.

**4. What are the possible side effects?**

Like all drugs, adverse effects can be seen in individuals who are hypersensitive against the contents of MAXIMUS.

Side effects are classified as follows:

Very common: (can be seen in at least one of 10 patients)

Common: (less than one out of 10 but more than one out of 100)

Uncommon: (less than one out of 100 but more than one out of 1000)

Rare: (less than one out of 1000 but more than one out of 10000)

Very rare: (less than one in 10 000 patients may be seen)

Unknown: (Unable to estimate from the available data)

**Stop using Maximus and notify your doctor IMMEDIATELY or contact the emergency department of your nearest hospital if one of the following occurs:**

**Unknown:**

- Sensitivity findings
- Local irritations

*Inform your doctor or pharmacist if you encounter any side effects not mentioned in these instructions for use.*

## **5. Storage of MAXIMUS**

Keep MAXIMUS out of the reach of children and in its packaging.

Store at room temperature below 25 ° C.

### **Use in accordance with expiration dates.**

*Do not use MAXIMUS after the expiration date specified on the packaging.*

Do not use MAXIMUS incase the product and/or packaging is damaged.

Do not dispose of expired or unused medicines! Hand over to the collection system determined by the Ministry of Environment and Urbanization.

**Marketing Authorization Holder :** Drogan İlaçları San. ve Tic. A.Ş.

Oğuzlar Mah. 1370. Sok . 7/3 Balgat - ANKARA

**Site of Manufacturing** : Drogan İlaçları San. ve Tic. A.Ş.

06760 Çubuk / Ankara

*This patient information leaflet was approved on 29/12/2017.*