PATIENT INFORMATION LEAFLET

MAXIMUS 0.25% Oral Spray

Used by spraying into the mouth

Active ingredient:

30 ml oral spray contains 0.075 g flurbiprofen

Excipients:

Sodium benzoate, Macrogolglycerol Hydroxystearate 40, Sodium bicarbonate, Glycerol, Saccharin sodium, Sorbitol,liquid,non-crystallized (70%), Ecocool MP, Peppermint, Patent V blue, Propylene glycol and 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.
- During the use of this drug, please tell your doctor that you are using this drug when you visit your doctor or a hospital.
- Please follow these instructions strictly. Do not use dosages **higher** or **lower** than the dosage recommended to you.

What is in this leaflet:

Titles are included.

1. WHAT MAXIMUS IS AND WHAT IT IS USED FOR

What is MAXIMUS ?

It is used as an anti-inflammatory agent in symptomatic treatment of pain related to an inflammation in the oropharyngeal area (e.g. gingival inflammation, oral inflammation, pharyngeal inflammation). It is used as protector following dental treatments.

MAXIMUS is avaliable in 30 ml White HDPE bottles with spray applicators packaged in carton boxes.

2. What should be taken into consideration 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 non-steroidal 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, cardiac failure or liver failure.

Please inform your doctor if you have any of the following conditions, or 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 studies; however, no effects are expected based on its pharmacodynamics properties end general safety profile.

Important information on some inactive ingredients of MAXIMUS

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

Using 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, 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:

It is three direct sprays to the related area three times a day. Each spray will contain 0.13ml containing 0.325 mg flurbipropen.

Route and method of administration:

MAXIMUS Oral Spray is administered to the relevant area in the oral cavity.

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 condition of use:

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 more MAXIMUS 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 ande use the next dose in time..

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

Possible effects that can be seen upon termination of MAXIMUS

There is no information about the possible 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 below:

Very common: At least 1 in 10 people.

Common: Less than 1 in 10 people, more than 1 in 100 people.

Not common: Less than 1 in 100 people, more than 1 in 1000 people.

Rare: Less than 1 in 1.000 people, more than 1 in 10.000 people.

Very rare: Less than 1 in 10.000 people.

Unknown: Cannot be estimated from the available data

Stop using KLOROBEN in the case of one of the following and contact your doctor or go to the emergency department of the nearest hospital IMMEDIATELY:

Unknown:

- Finding related to sensivity,
- Local irritation

If you become aware of any adverse effects not mentioned in this instruction of use, please inform your doctor or pharmacist.

5. Storage of MAXIMUS

Keep the MAXIMUS in places that children can not see, can not reach and on its packaging.

Store MAXIMUS below the room temperature of 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.

Marketing Authorization Holder : Drogsan İlaçları San. ve Tic. A.Ş.
Oğuzlar Mah. 1370. Sok . 7/3 Balgat - ANKARA

Site of Manufacturing **:** Drogsan İlaçları San. ve Tic. A.Ş.
06760 Çubuk / Ankara

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