

PATENT INFORMATION LEAFLET

MAXIMUS 100 mg film coated tablets N15

It is take orally.

- **Active substance:** 100 mg Flurbiprofen
- **Excipients:** Microcrystalline cellulose 200, croscarmellose sodium (Ac-Di-Sol), colloidal silicon dioxide (Aerosil 200), lactose monohydrate (Tablettose) (obtained from cow's milk), magnesium stearate, talc, opadry II 85G34747 pink.

Read all this leaflet carefully before you start taking this medicine, because it contains important information for you.

- Keep this leaflet as you may need to read it again.
- If you have additional questions, consult your doctor or pharmacist
- This medicine has been prescribed for you personally, do not give it to others
- When you go to a doctor or hospital during the use of this medicine, tell your doctor you are using this medicine.
- Please keep strictly to what is written in these instructions. Do not use **high or low** doses other than the recommended dose for the medication.

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Titles are included.

1. What is MAXIMUS and what is used for?

MAXIMUS is a pink film-coated tablet. Each film tablet is available in blister packs of 15 and 30 tablets containing 100 mg of flurbiprofen.

MAXIMUS is in the group known as non-steroidal anti-inflammatory drugs (NSAIDs), which are used to eliminate or alleviate various pains.

MAXIMUS,

- A disease (osteoarthritis) that occurs as a result of the wear of the joints and is also known as calcification among the people.
 - A persistent (chronic) disease that causes pain, swelling and deformity in the joints (rheumatoid arthritis)
 - A persistent (chronic) disease that causes pain, swelling and deformity in the joints (ankylosing spondylitis)
 - Rapidly progressive or advanced joint inflammation in the joint (acute gouty arthritis)
 - Acute musculoskeletal pain
 - Menstrual pain (dysmenorrhea)
- used in the treatment.

2. Things to pay attention before using MAXIMUS

Do not take MAXIMUS for the following situations:

If;

- You are hypersensitive to any of the ingredients of **MAXIMUS**,
- You have experienced asthma, hives or another allergic type reaction after taking aspirin or another non-steroidal anti-inflammatory drug,
- You have pain just before and after coronary artery bypass surgery,
- You have severe liver failure,
- You have severe kidney failure,
- You have severe heart failure,
- You have an active or previous peptic ulcer disease,
- You have a history of bleeding or perforation in your stomach or intestines due to previous NSAID use,
- You have bleeding in your stomach or intestines, brain bleeding or any other bleeding,
- You are in the late stage of pregnancy (from the 6th month), do not use.

Use MAXIMUS with caution in the following situations:

If;

- You have a known heart and blood vessel (cardiovascular) condition. In such a case, your doctor will use the lowest effective dose. Even if you have not experienced cardiovascular symptoms before, you and your doctor should be alert to the occurrence of such events, your doctor will inform you about what to do in such a situation,

- You have high blood pressure (hypertension). Your doctor will closely monitor your blood pressure during the initiation of **MAXIMUS** treatment and throughout the course of treatment,
- Fluid retention or edema occurs,
- You have respiratory failure, edema, liver enlargement and significant disease due to pre-existing heart failure,
- Inflammation, bleeding and perforation occur in the stomach and intestines,
- If you are elderly, have heart and blood vessel disease, take aspirin concomitantly, or have or are experiencing gastrointestinal disease such as ulceration, bleeding in your gastrointestinal tract, or inflammatory conditions.
- You have pre-existing asthma,
- You have anemia or have problems with blood clotting,
- You are planning to become pregnant,
- You have systemic lupus erythematosus (SLE) or other connective tissue diseases,
- You have heart failure, liver cirrhosis and advanced kidney disease. If you have impaired kidney function, your doctor will give you a low dose of flurbiprofen,
- Skin rash, mucous membrane disorders or any other sign of hypersensitivity occurs. In such a case, your doctor will interrupt your treatment,
- There are complaints about your eyes. In such a case, consult an ophthalmologist.

Do not use together with other similar pain relievers.

Serious skin reactions, including a type of skin disease called exfoliative dermatitis, stinging of the skin and around the eyes, inflammation with swelling and redness (Stevens-Johnson syndrome) and toxic epidermal necrolysis, may occur very rarely and some of them fatal, in association with flurbiprofen. You are most at risk for these events early in your treatment, with the majority of cases onset occurring within the first month of treatment.

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

Using MAXIMUS with food and drink

There is no data on the use of **MAXIMUS** with food and drink.

Pregnancy

Consult your doctor or pharmacist before using this medication.

MAXIMUS should not be used during pregnancy unless necessary.

Do not use **MAXIMUS** in the last period of pregnancy (from the 6th month). Use during pregnancy is not recommended unless recommended by your doctor.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using this medication

Do not breastfeed while taking this medicine. Because flurbiprofen passes into breast milk and may harm your baby.

Vehicle and machine use

MAXIMUS may cause side effects such as dizziness, restlessness, tremor, drowsiness. Therefore, if you have these symptoms, do not drive or use machinery.

Important information about some excipients in the content of MAXIMUS

This medicinal product contains 12 mg of croscarmellose sodium per tablet. Considering the amount of sodium it contains, no side effects are expected.

This medicinal product contains 26 mg of lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Concomitant use with other drugs

Some drugs that may interact with **MAXIMUS**:

- ADE inhibitors and angiotensin II antagonists (used to treat high blood pressure)
- Aspirin (pain reliever, blood thinner drug)
- Anticoagulants (blood thinners)
- Beta blockers (used to treat high blood pressure)
- Diuretics (diuretics)
- Corticosteroids (used to treat allergies and hormone imbalance)
- Zidovudine, ticlopidine, tacrolimus and cyclosporine (drugs used in organ transplantation)

- Lithium or selective serotonin reuptake inhibitors (psychiatric drugs)
- Methotrexate (used in cancer treatment)
- Digoxin (used in heart failure)
- Oral hypoglycemic agents (diabetes treatment drugs)
- Quinolone group antibiotics (used against some infections)
- Antiplatelet agents (used in the treatment of thrombosis)
- Cimetidine, ranitidine, antacids (used in some stomach ailments)
- Another pain reliever belonging to the group of non-steroidal anti-inflammatory drugs (NSAIDs)

If you are using it, tell your doctor. These drugs interact with **MAXIMUS**.

If you are currently using or have recently used any prescription or non-prescription drugs, please inform your doctor or pharmacist about them.

3. How MAXIMUS is used?

Instructions for proper use and dose / frequency of administration:

The recommended total daily dose is 150 mg-200 mg in divided doses. That means taking one and a half or 2 tablets a day. Depending on the severity of the symptoms of your disease, the dose can be increased up to 300 mg per day.

For the relief of signs and symptoms of rheumatoid arthritis (inflammation of the body's joints and sometimes other tissues) or osteoarthritis (non-inflammatory joint damage, pain and stiffness mostly seen in the elderly), the recommended dose of **MAXIMUS** is divided into two, three or four times a day. 200 to 300 mg per day for administration.

In menstrual cramps, you should initially take 100 mg, ie 1 tablet. Following this, you should take 50mg-100mg every 4-6 hours.

If you are going to use **MAXIMUS** more than once a day, the dose you will take at once should not exceed 100 mg.

Application route and method:

Take the tablets after meals with a sufficient amount of liquid (a glass of water).

Different age groups:

Use in children:

It should not be used in children as its efficacy and safety in children has not been proven.

Use in the elderly:

Since elderly patients are at risk for serious side effects, the lowest dose should be tried.

Special use cases:**Kidney/Liver failure:**

Long-term therapy has led to kidney damage in patients, and should not be used, especially in those with renal or hepatic impairment.

In addition, it should not be used in patients with severe renal impairment. It should be used with caution if there is a sign of kidney failure.

*If you have the 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:**

*If you have used more than you should use from **MAXIMUS**, talk to a doctor or pharmacist.*

If you have taken an overdose of **MAXIMUS**, drowsiness, nausea, vomiting and abdominal pain usually occur. In this case, appropriate treatment should be applied in the emergency department of the hospital. It is useful to use activated carbon within 4 hours of taking **MAXIMUS**. Your doctor or pharmacist will help you in this regard.

If you forget to use **MAXIMUS**

Do not take a double dose to make up for forgotten doses.

If you forget to take your tablets on time, take them when you remember. If the time to take your next tablets is approaching, continue your normal treatment without taking an additional dose.

If you forget to take more than one dose, tell your doctor.

4. What are the possible Side Effects?

Like all medicines, there may be side effects in people who are sensitive to the substances contained in **MAXIMUS**.

Side effects are listed as shown in the following categories:

Very common: may occur in at least 1 in 10 patients.

Common: less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: less than 1 in 100 patients, but more than 1 in 1,000 patients.

Rare: less than 1 in 1,000 patients, but more than 1 in 10,000 patients

Very rare: less than 1 in 10,000 patients.

Not known: Cannot be estimated from the available data.

If any of the following occur, stop using MAXIMUS and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:

- Hypersensitivity (allergic) reactions (such as skin rash, mucous membrane disorders or any other manifestation of hypersensitivity)

These are all very serious side effects. If you have one of these, it means you are allergic to **MAXIMUS**. You may need emergency medical attention or hospitalization.

All of these very serious side effects are very rare.

Common:

- *Nose inflammation (rhinitis)*
- *Urinary tract infection*
- *Changes in body weight*
- *Inner restlessness (anxiety)*
- *Depression*
- *Insomnia*
- *Irritability*
- *Forgetfulness (amnesia)*
- *Dizziness (vertigo)*
- *Headache*
- *Increase in reflexes*
- *Sleepiness (somnolence)*
- *tremor*
- *Changes in vision*
- *Tinnitus (tinnitus)*
- *Stomach ache*
- *Constipation*
- *Diarrhea*
- *Indigestion (dyspepsia)*
- *Gas*

- *Stomach and intestinal bleeding (gastrointestinal bleeding)*
- *Nausea*
- *Vomiting*
- *Skin rash*
- *Fatigue (asthenia)*
- *Fluid accumulation in the body, for example swelling in the ankles (edema)*
- *Weakness, feeling sick*
- *Elevated liver enzymes*

Uncommon:

- *Anemia (iron deficiency anemia)*
- *Kanda ürik asit seviyesinin artması (hiperürisemi)*
- *Fluid retention (fluid retention)*
- *Blurring of consciousness (confusion)*
- *Muscle coordination disorder (ataxia)*
- *Decreased blood flow to the brain (cerebrovascular ischemia)*
- *Numbness (paresthesia)*
- *Disorder of smell (parosmia)*
- *Eye inflammation (conjunctivitis)*
- *Heart failure*
- *Vascular diseases*
- *Dilation of blood vessels (vasodilation)*
- *High blood pressure (hypertension)*
- *Asthma*
- *Nose bleeding (epistaxis)*
- *Bloody diarrhea*
- *Esophageal disease*
- *Stomach inflammation (gastritis)*
- *Vomiting blood (hematemesis)*
- *Wound in the stomach or duodenum (peptic ulcer)*
- *Mouth inflammation (stomatitis)*
- *Wound in the gastrointestinal tract (gastrointestinal ulcer)*
- *Liver inflammation (hepatitis)*
- *A kind of allergic condition (angioedema)*

- *Eczema*
- *Itching*
- *Hives (urticaria)*
- *Twitch*
- *Blood in the urine (hematuria)*
- *Kidney failure*
- *chills*
- *Fever*
- *Changes in some test results (decrease in hemoglobin and hematocrit levels)*

Rare:

- *Serious allergic reactions (anaphylactic reactions)*
- *Heart attack (myocardial infarction)*
- *Perforation in the gastrointestinal tract (gastrointestinal perforation)*
- *Inflammation in the kidney (glomerulonephritis)*
- *Tissue death in the kidney (renal papillary necrosis)*
- *Defect in nephrons, the smallest structural unit of the kidney (nephrotic syndrome)*

Unknown:

- *Inhibition of blood coagulation (platelet aggregation inhibition)*

The following side effects are mainly derived from worldwide post-marketing experience and literature. Precise frequency estimation is often not possible.

- *Anemia (aplastic anemia, hemolytic anemia)*
- *Decreased platelet level in the blood (thrombocytopenia)*
- *Allergic shock (Anaphylaxis)*
- *Inflammation of the large intestine (colitis)*

- *Exacerbation of inflammatory bowel disease*
- *Small intestine inflammation with loss of blood and protein*
- *Icterus*
- *A type of skin inflammation (exfoliative dermatitis)*
- *Light sensitivity (photosensitivity)*
- *Skin diseases (Stevens-Johnson syndrome, toxic epidermal necrosis)*
- *Inflammation of the meninges (aseptic meningitis)*
- *Kidney inflammation with vomiting (interstitial nephritis)*

If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. Storage of MAXIMUS

Keep **MAXIMUS** out of the sight and reach of children and in its package. It should be stored at room temperature below 25°C, protected from light.

Use in accordance with expiration dates.

*Do not use **MAXIMUS** after the expiry date stated on the package.*

Do not use **MAXIMUS** if you notice any defects in the product and/or its packaging.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorisation Holder:

Drogsan İlaçları San. ve Tic. A.Ş.

Oğuzlar Mah. 1370. sok. 7/3, 06520 Balgat-ANKARA

Manufacturer:

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