PACKAGE LEAFLET: INFORMATION FOR THE USER

EFAMAT 1 g/2 ml Solution for IM Injection
Administered into muscle
Sterile

***Active substance*:** Each ampoule of 2 ml (total volume) solution for injection contains 1 g etofenamate.
Excipient(s): Medium-chain triglyceride.

Read all of this PACKAGE 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 any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this Medicine, when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take this medicine in either* ***higher*** *or* ***lower*** *dose other than recommended to you.*

In this leaflet:

1. WHAT EFAMAT IS AND WHAT IT IS USED FOR

EFAMAT is a medicine containing 1 or 3 colorless ampoules for administration into the muscle tissue.
EFAMAT contains etofenamate as the active substance.
Etofenamate is an active substance belonging to the group of non-steroidal analgesic/anti-rheumatic agents and has anti-inflammatory and pain-relieving (analgesic) properties. It is used for the treatment of the following conditions:
- Degenerative joint disease, joint calcification (osteoarthritis)
- Rheumatic disease with joint inflammation (rheumatoid arthritis)
- A rheumatic disease that is seen especially with the fusion of the spine joints and loss of movement (ankylosing spondylitis)
- Joint inflammation that occurs suddenly at times, often manifested by inflammation of the big toe, causing severe pain, tenderness, redness and swelling of the joints (acute gouty arthritis)
- Acute musculoskeletal pain
- Postoperative inflammation, swelling and soft tissue damage (postoperative pain)
- Menstrual pain (dysmenorrhea)

Note: This solution for injection is used only when topical administration of etofenamate is not beneficial or appropriate. As a rule, the treatment should be limited to a single injection.

Due to the slow release of the active substance of EFAMAT from the administration site, it is not

suitable for starting treatment in diseases where rapid onset of action is required.

Due to the slow release of the active substance from the oily formulation, the duration of action may be extended up to 24 hours after EFAMAT administration.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE EFAMAT

Consult your doctor or pharmacist before using any medicine.

DO NOT use EFAMAT in the following situations

Cardiovascular system risk:
NSAIDs or pain relievers may increase the risk of stroke, heart attack and cardiovascular thrombotic events, which can be fatal. This risk may increase with duration of use. People with or at risk for cardiovascular disease may have an increased risk. EFAMAT should not be used for pain management in preparation for coronary artery bypass graft surgery.
Gastrointestinal system risk:
NSAIDs or pain relievers cause an increased risk of serious gastrointestinal side effects, such as perforation, ulceration and bleeding in the gastrointestinal tract, which can be fatal. These side effects may occur at any time during treatment and without warning symptoms. Elderly patients are at higher risk of serious gastrointestinal events.

- If you are hypersensitive to etofenamate or any of the other ingredients in EFAMAT,
- If you have experienced asthma, wheezing, runny nose, urticaria, or allergic-type reactions after previous use of aspirin or another non-steroidal anti-inflammatory drug,
- If you have or have ever had ulcers or bleeding in your stomach or intestines,
- If you are going to have a surgery on your vessels that supply blood to the heart (coronary arteries),
- If you are taking medication that prevents blood clotting, or blood thinners (anticoagulants or antithrombotics),
- If you have severe heart failure,
- If you have liver or kidney failure,
- If you are in the late stage of pregnancy (after the sixth month),
- If you are breastfeeding,
- If you are under the age of 18.

TAKE SPECIAL CARE with EFAMAT in the following situations

Situations where EFAMAT should only be used after careful assessment of the risk-benefit ratio:

- If you have acute porphyria (congenital or acquired defect in the production of the substance that gives color to the blood; acute attacks of this disease can be triggered by some substances).

Situations where EFAMAT should only be used with careful medical observation:

- If you have ever had gastrointestinal bleeding or perforation related to NSAIDs or pain relievers,
- If you have or have ever had ulcers or bleeding in your stomach or duodenum (one or two proven episodes of bleeding or ulcers),
- If you have or have ever had inflammatory bowel disease (ulcerative colitis or Crohn's disease),
- If you have a problem with your cardiovascular system,
- If you suffer from high blood pressure (hypertension),
- If you have heart disease or edema,

- If you have had stroke before,
- If you have recently had a surgery,
- If you are over the age of 65 or have a condition that weakens your body resistance.

Please consult your doctor, even if these warnings were applicable to you at any time in the past.

Using EFAMAT with food and drink
There is no interaction with food or drinks due to its method oadministration.

Pregnancy
Consult your doctor or pharmacist before taking this medicine.
EFAMAT should not be used after the sixth month of pregnancy. In addition, it should not be used before this period unless your doctor tells you to use it.

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

Breast-feeding
Consult your doctor or pharmacist before taking this medicine.
Do not use EFAMAT during breastfeeding.

Driving and using machines
EFAMAT may affect your vigilance, especially at the beginning of your treatment or when your treatment dose is increased.

If you are taking EFAMAT, do not drive or operate machinery.

Important information about some of the ingredients of EFAMAT
It does not contain any excipients that require warning.

Taking other medicines
Do not use EFAMAT with the following medicines:
- Aspirin and other NSAIDs

EFAMAT should be used with caution with the following medicines:
- Angiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure)
- Furosemide and diuretic (urinative) medicines
- Antihypertensives (medications that lower high blood pressure)
- Lithium (used to treat mania and depression)
- Methotrexate (used to treat rheumatoid arthritis and some types of cancer)
- Warfarin and similar medicines that prevent blood clotting or thin the blood
- Digoxin (used to treat heart failure)
- Phenytoin (used to treat epilepsy)
- Corticosteroids (a group of medicines used for multiple purposes in inflammation, allergy, or organ transplantation)
- Potassium-sparing diuretics
- Selective serotonin reuptake inhibitors (SSRIs) (used to treat depression)
- Probenecid or sulfinpyrazone (used to lower increased levels of uric acid in the blood)

- Alcohol
- Cyclosporine (used to prevent tissue rejection)
- Antidiabetic medications (used to lower blood sugar)

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 EFAMAT

Instructions for proper use and dose/administration frequency
Depending on your disease, your doctor will determine the dose of EFAMAT and apply it to you. The general dose is 1 ampoule of EFAMAT by deep injection into the muscle.

If etofenamate treatment is considered to be continued, you may be told to continue the treatment with etofenamate gel, which can be applied locally after EFAMAT application.

Route and method of administration
EFAMAT IM ampoules are for use into the muscle tissue only. After breaking the ampoule, the solution for injection is drawn into a syringe and injected deeply into the muscle with an injection needle of sufficient length. Before injecting the solution, the plunger of the syringe is pulled back slightly to ensure that no blood vessels are damaged.

You may need to be monitored for at least 1 hour after EFAMAT injection due to the possibility of anaphylactic reactions (sudden severe allergy).

Different age groups

Use in children
As there is no experience with EFAMAT in children and adolescents, it should not be used in patients under 18 years of age.

Use in the elderly (65 years and above)
Due to the possible undesirable effects, EFAMAT should be used under close supervision in elderly patients.

Use in special conditions

Kidney/Liver failure
Do not use EFAMAT if you have kidney and/or liver failure.

Please talk your doctor or pharmacist if you have an impression that the effect of EFAMAT is too strong or too weak.

If you take more EFAMAT than you should
If you have used more EFAMAT than you should, talk to a doctor or pharmacist.
If more EFAMAT is used than necessary, the undesirable effects and their severity may increase. If EFAMAT has been administered in excessive doses, it can cause central nervous system disorders such as headache, dizziness, drowsiness and confusion, as well as symptoms such as nausea, vomiting and abdominal pain. In addition, bleeding in your gastrointestinal tract, deterioration in liver and kidney functions may occur. If you experience these symptoms, your doctor or pharmacist will help you.

If you forget to use EFAMAT
Do not take a double dose to make up for a forgotten dose.

Effects that may occur when treatment with EFAMAT is stopped
No effects are expected.

4. POSSIBLE SIDE EFFECTS

Like all medicines, EFAMAT can cause side effects in patients who are sensitive to its ingredients.

Very common (≥ 1/10) : may be seen in at least 1 in 10 patients.
Common (≥ 1/100 to < 1/10) : may be seen in less than 1 in 10 but more than 1 in 100 patients.
Uncommon (≥ 1/1,000 to < 1/100): may be seen in less than 1 in 100 but more than 1 in 1,000 patients.
Rare (≥ 1/10,000 to < 1/1,000): may be seen in less than 1 in 1,000 but more than 1 in 10,000 patients.
Very rare (< 1/10,000): may be seen in less than 1 in 10,000 patients.
Not known: The frequency cannot be estimated from the available data.

If any of the following occur, stop using EFAMAT and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:
- Severe forms of skin reactions (Stevens-Johnson syndrome, Lyell syndrome)
- Serious hypersensitivity reactions are possible and the following may occur:
  Severe allergic reaction-like symptoms such as swelling on the face, tongue and throat, skin rash, wheezing, difficulty breathing, laryngeal edema that narrows the airway, difficulty breathing which may progress to an asthma crisis, increase in heart rate, decrease in blood pressure which may cause potentially a fatal shock, fever or shock.

These reactions may appear during first use of the medicine.
These are all very serious side effects.

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

It should be noted that the following undesirable reactions are dependent to the dose and may differ between individuals.

In general, the most common side effects are related to the digestive system. Especially in elderly patients, gastrointestinal tract ulcer (peptic ulcer), perforation or gastric or intestinal bleeding which may be fatal may appear. Nausea, vomiting, diarrhea, flatulence, constipation, digestion problems, abdominal pain, dark stool, vomiting blood, oral ulcers, colitis and exacerbation of Crohn's disease were reported following injection. Gastric inflammation is observed rarely. In general, the risk of gastrointestinal bleeding depends on duration and dose of NSAIDs.

NSAID-associated edema, high blood pressure and heart failure were reported.
Medicines such as EFAMAT may be associated with a slight increase for risk of heart attack (myocardial infarction or stroke).

Undesirable effect reported for etofenamate:
Common side effects:
Complaints such as nausea, vomiting, diarrhea, and slight bleeding in the gastrointestinal tract that may lead to anemia in exceptional cases.

Uncommon side effects:
Headache, excitation, irritability, tiredness, drowsiness and dizziness
Digestion disorders, flatulence, abdominal cramp, loss of appetite, gastric and duodenal ulcers (with bleeding and perforation in some cases)
Hypersensitivity reactions such as skin rash and itching
Elevated blood liver enzymes (serum transaminases)

Rare side effects:
Blood production disorders (anemia, leukopenia, agranulocytosis, and thrombocytopenia). Initial symptoms include fever, throat pain, and superficial lesions in the mouth, flu-like symptoms, severe fatigue, nasal bleeding and dermal bleeding. Blood levels of patients undergoing prolonged treatment should be monitored regularly.
Blood in vomit, stool or diarrhea
Urticaria and/or hair loss
Liver damage (hepatitis with or without jaundice, in very rare cases with fulminant course, rarely without prodromal symptoms). Therefore, the patient's liver enzymes should be monitored regularly.
Edema (peripheral edema) may develop especially in patients with high blood pressure (hypertensive) or impaired renal function.

Very rare side effects:
Palpitations, chest pain, high blood pressure and circulatory collapse.
Heart failure
Hemolytic anemia
Sensory disorders, taste disorders, ringing in the ears and transient impaired hearing, impaired memory, disorientation, convulsions, state of anxiety, nightmares, tremors, depression and other psychotic reactions.
Inflammations of the oral mucosa and tongue, esophageal lesions, complaints in the lower abdomen (e.g. exacerbation of bleeding colitis or Crohn's disease/ulcerative colitis) and constipation.
Vision disorders (blurred vision and/or double vision)
Fluid-filled blistering rash on the skin, eczema, redness, photosensitivity, blistering (also allergic purpura)
In rare cases: Kidney damage (interstitial nephritis, papillary necrosis), protein in the urine (proteinuria) and/or blood in the urine (hematuria), which may be accompanied by acute kidney failure.
In isolated cases, nephritic syndrome may develop. Therefore, kidney function should be checked regularly.
In isolated cases, pancreatic inflammation has been reported.
In isolated cases, allergy-related inflammations have been observed in the blood vessels and lungs.
In isolated cases, infection-related inflammation (development of necrosis fasciitis) may worsen as soon as non-steroidal anti-inflammatory drugs are administered. This is probably related to the mechanism of action of non-steroidal anti-inflammatory drugs. Therefore, if symptoms develop due to a new infection or if your existing symptoms worsen when you use EFAMAT, consult your doctor immediately. The need for any antibiotic or anti-infectious treatment should be considered.
After intramuscular administration, uncommon local side effects (burning sensation) or tissue damage (such as the formation of sterile abscesses, fatty tissue or skin necrosis) may be seen at the injection site.
Follow the recommendations listed for the side effects mentioned above.

<u>Reporting of side effects</u>
If you get any side effects including any possible side effects not listed in this leaflet, talk to your

doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

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

5. HOW TO STORE EFAMAT

Keep EFAMAT out of the reach and sight of children and in its original package.

Keep at room temperature below 25°C.

Use it in accordance with the expiry date.

Do not use EFAMAT after the expiry date, which is stated on the package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Marketing Authorization Holder
DEVA Holding A.Ş.
Küçükçekmece - İSTANBUL/TÜRKİYE

Manufacturing Site:
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