

PATIENT INFORMATION LEAFLET

SANTAFENAMAT gel

Applied onto the skin.

- **Active substance:** 1 g gel contains 50 mg of etofenamate.
- **Excipients:** Eucalyptus essential oil, pine essential oil, polyethylene glycol 400, emulgin M8, carbomer, triethanolamine, isopropyl alcohol and deionized water.

Read all of this PATIENT INFORMATION LEAFLET carefully before you start using this medicine, because it contains useful 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 for you personally and you should not pass it on to others.*
- *When you see a doctor or go to hospital while you are on the drug, tell your doctor that you are using this medicine.*
- *Precisely follow the instructions included in this leaflet. Do not use any dose **higher or lower** than what was prescribed for you.*

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1. What SANTAFENAMAT is and what it is used for

SANTAFENAMAT is presented in metal tubes with plastic screw caps, containing 40 g of gel packed in a boxes. Colorless or slightly yellow, transparent gel.

SANTAFENAMAT contains etofenamate as the active substance.

Etofenamate is an active substance belonging to the group of nonsteroidal (non-cortisone) anti-rheumatic (rheumatic therapy) drugs and has inflammation relieving (anti-inflammatory), pain relieving (analgesic) properties.

SANTAFENAMAT is used in the treatment of the following conditions:

- Painful conditions due to acute contusion, sprains and strains of joints following blunt trauma such as those caused by sport injuries.
- Painful conditions of periarticular soft tissues (bursa, tendons, ligaments and joint capsule) in cases of inflammation of the knee joint.

2. What you need to know before you use SANTAFENAMAT

Consult your doctor or pharmacist before taking any medicine.

Do NOT use SANTAFENAMAT in case of the following conditions

- If you are hypersensitive (allergic) to etofenamate or to any of the ingredients contained in SANTAFENAMAT, or to other pain relievers or anti-rheumatic drugs (non-steroidal anti-inflammatory drugs).
- If there is eczema, open wounds, inflammation or infection on the skin area you need to apply the gel.
- Do not apply on the mucous membranes such as the lips, inside the nose and eyes.
- If you are in the late stages of pregnancy (after sixth month).
- If you are under 18 years of age.

Take SPECIAL CARE with SANTAFENAMAT in case of the following conditions

- If you have asthma, hay fever, chronic swelling of the nasal mucosa (also called nasal adenoids), chronic obstructive airways disease or chronic respiratory tract infection, especially if they are accompanied by hay fever-like clinical symptoms.
- If you experience allergic reactions to other substances, manifested by skin reactions, itching or hives.

SANTAFENAMAT can lead to damage and discoloration on polished furniture or plastic surfaces. Therefore, wash your hands after applying SANTAFENAMAT or avoid contact with the above material.

Please consult your doctor if any of the above applies to you, even at any time period in the past.

Using SANTAFENAMAT with food and drink

There is no interaction with food and drink regarding method of administration.

Pregnancy

Consult your doctor or pharmacist before using this medicine.

SANTAFENAMAT is not used after the sixth month of pregnancy. Before this period also, do not use SANTAFENAMAT unless your doctor tells that you must use it.

Consult your doctor or pharmacist immediately if you find out you are pregnant during your treatment.

Breastfeeding

Consult your doctor or pharmacist before using this medicine.

Because etofenamate passes into breast milk in small amounts, do not use SANTAFENAMAT for a prolonged period and certainly do not exceed the daily dose. To avoid exposure of your baby to the drug, do not apply SANTAFENAMAT to your chest area during breastfeeding your baby.

Driving and using machines

There is no data that SANTAFENAMAT influences your ability to drive and use machines.

Important information about some of the ingredients of SANTAFENAMAT

If you do not have any hypersensitivity to the ingredients of SANTAFENAMAT, no adverse effects are observed due to these substances.

Concomitant use with other medicines

No drug interactions have been reported in the use of etofenamate on the skin as recommended.

Please tell your doctor or pharmacist about any medicines, prescription or non-prescription, you are currently taking or have recently taken.

3. How to use SANTAFENAMAT

Instructions for proper use and dosage/frequency of administration:

Your doctor will tell you the dose of SANTAFENAMAT, depending on your illness. Unless indicated otherwise by your doctor, follow the instructions below.

Apply SANTAFENAMAT three times a day. Depending on the size of the painful site, applying about a 10 cm strip (equivalent to about 3 g of gel and 150 mg of etofenamate) will be sufficient. In blunt traumas maximum daily dose of SANTAFENAMAT is 9 g of gel, equivalent to 450 mg of etofenamate.

Route and method of administration:

SANTAFENAMAT is only for external application to the skin. Never swallow it!

Apply SANTAFENAMAT in a thin layer to the affected areas of your body and massage gently into the skin.

After applying SANTAFENAMAT, allow it to dry on the skin for a few minutes. Do not cover treated skin areas with a bandage unless your doctor has told you to.

Your doctor will tell you the duration of your treatment with SANTAFENAMAT. In blunt traumas such sports injuries, one week of treatment is usually sufficient.

For rheumatic diseases, 3-4 weeks of treatment is sufficient in most cases. If your complaints persist, consult your to determine whether you need further treatment.

Different age groups

Use in children:

Since there is no experience with etofenamate in children and adolescents, SANTAFENAMAT should not be used in patients under 18 years of age.

Use in the elderly:

No dosage adjustment is necessary.

Special use conditions:

Renal/hepatic impairment:

No dosage adjustment is necessary.

Talk to your doctor or pharmacist if you have an impression that the effect of SANTAFENAMAT is too strong or too weak.

If you use more SANTAFENAMAT than you should

If you use more than the recommended dose of SANTAFENAMAT on the skin, remove it from the skin and rinse with water.

Contact a doctor or pharmacist if you use more SANTAFENAMAT than you should.

If you forget to use SANTAFENAMAT

Do not use a double dose to make up for a forgotten dose.

The effects that may occur if treatment with SANTAFENAMAT is stopped.

Not applicable.

4. Possible side effects

Like all medicines, side effects may occur in persons who are sensitive to the ingredients of SANTAFENAMAT.

The assessment of undesirable effects is based of the following frequencies:

- Very common: May affect at least 1 in 10 patients.
- Common: May affect less than 1 in 10 patients, but more than 1 in 100 patients.
- Uncommon: May affect less than 1 in 100 patients, but more than 1 in 1.000 patients.
- Rare: May affect less than 1 in 1,000 patients, but more than 1 in 10.000 patients.
- Very rare: May affect less than 1 in 10.000 patients.
- Not known: Frequency cannot be estimated from the available data.

If SANTAFENAMAT is applied on a large area of skin and for a prolonged period, development of side effects that may affect specific organ systems or the entire body is likely, as seen after systemic use of drugs containing etofenamate.

Undesirable effects reported for SANTAFENAMAT

Uncommon:	- Redness of the skin - Itching - Burning sensation - Skin rash - Sometimes local skin reactions like blisters or urticaria
Rare	- Allergic reactions - Local allergic reactions (contact dermatitis)

When you stop using this medicine, skin reactions will disappear quickly. Therefore, no other specific applications are necessary.

If you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

Please tell your doctor, pharmacist or nurse if any side effects listed or not listed in this leaflet occur. In addition, please report the side effects you experience to Turkish Pharmacovigilance Center (TUFAM) by clicking on the icon, “Reporting of Drug Side Effects” at www.titck.gov.tr or by calling the side effects reporting line on 0 800 314 00 08. By reporting the side effects occurred, you will contribute to the acquisition of further information about the safety of the drug you are using.

5. How to store SANTAFENAMAT

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

Store at room temperature below 25°C.

Use in line with the expiry date.

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

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This Patient Information Leaflet is approved on --/--/--