PATIENT INFORMATION LEAFLET

SERTOFEN 1.25% Gel

External Use

- ***Active Substance:*** 1 g gel contains 18.45 mg Dexketoprofen trometamol equivalent to 12.5 mg Dexketoprofen.
- ***Excipients:*** Carbomer homopolymer, Menthol, Lavender oil, Ethanol (96%), Sodium hydroxide, purified water.

Read all of this LEAFLET carefully before you start using this medicine because it includes special 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.*
- *If you go to doctor or hospital at the time of using this medicine, Please tell your doctor.*
- *Please follow the instructions exactly. Do not use another **high or low doses** out of recommended.*

In this leaflet:

1. What SERTOFEN is and what it is used for?

2. Before you use SERTOFEN

3. How to use SERTOFEN?

4. Possible side effects

5. How to store SERTOFEN?

1. What SERTOFEN Is And What It Is Used For?

Sertofen is a pain killer from the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

SERTOFEN is used in the treatment of traumatic or degenerative origin painful and inflammatory conditions on joints, tendons (the structure that connects muscles to bones), ligament (rigid connective tissue holding the bones together) and muscles.

SERTOFEN shows its effect by inhibition or decrease the formation of substances causing pain and inflammation in damaged areas on joints, tendons, ligaments and muscles. When gel is administered regionally, it decreases pain and swelling on administered area.

SERTOFEN gel contains Dexketoprofen (as trometamol) as an active substance and is presented in aluminum tube containing 60 g gel.

2. Before You Use SERTOFEN

Do not use SERTOFEN in the following situations:

If,

- you are allergic (hypersensitive) to Dexketoprofen trametamol or to any of the other excipients of SERTOFEN;
- you are allergic to acetylsalicylic acid (aspirin) or to other non-steroidal anti-inflammatory medicines;
- you have asthma or attacks of asthma, acute allergic rhinitis (a short period of inflamed lining of the nose), nasal polyps (lumps within the nose due to allergy), urticaria (skin rash), swelling of face and throat (swelling in face, eyes, lips, or tongue, or respiratory distress) as a result of allergy or wheezing in the chest occur after using acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory medicines in the past;
- you are in the third trimester of pregnancy or breast feeding;
- It should not be administered to open wounds or permanent existing lesions of the skin.
- It should not be administered to mucosa, eye, anal or genital regions.
- SERTOFEN should not be administered with occlusive or obstructive dressings.

Use SERTOFEN CAREFULLY in the following situations

- Specifically, products used for a long time topically may cause sensitivity and regional irritation.
- For the prevention of light sensitivity or hypersensitivity cases that may occur, should not be exposed to direct sunlight, UV and solarium during treatment and up to two weeks after treatment.
- Although its systemic effect is minimal, it should be used with caution in patients with severe renal and hepatic impairment.
- Treatment should be discontinued immediately upon development of any skin reaction after administration of SERTOFEN.

If any of these warnings applies to you or even if any time in the past, please consult your doctor.

Using SERTOFEN with food and drink

As it is administered by rubbing on the skin, interaction with food and drink is not expected.

Pregnancy

Consult your doctor or pharmacist before using this medicine.

Use of SERTOFEN during the third trimester of your pregnancy is not recommended.

Use SERTOFEN carefully during the first or second trimester of pregnancy.

Consult your doctor if you are pregnant or if you are planning to become pregnant before use SERTOFEN.

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 medicine.

If you are breastfeeding your baby, consult your doctor before using SERTOFEN.
Use of SERTOFEN during breastfeeding is not recommended.

Driving and using machines

There are no known effects on driving and using machines.

Using with other medicines

Since Dexketoprofen slightly diffuses to systemic circulation after topical administration, drug and other interactions are almost not observed.

Use of non-steroidal anti-inflammatory drugs (NSAIDs) may lead to an increase in the risk of side effects.

Please inform your doctor or pharmacist if you are using at present or have recently used any medicine with or without a prescription.

3. HOW TO USE SERTOFEN?

Instructions for proper using and dose/administration frequency:

It can be rubbed on the painful area 2-3 times a day.
Treatment time should not be more than 7 days.
Use the indicated doses unless advised by a doctor in any other way.

Administration route and method:

SERTOFEN is administered externally.
Ensure absorption of gel completely by gently rubbing.
After the use of SERTOFEN, the hands should be thoroughly washed.

Different age groups:

Using in children:

Because no indication or dose is determined in children under 6 years of age, usage in this age group is not recommended.

Using in Elderly:

Dose adjustment is not necessary for elderly patients.

Special usage cases:

Kidney/liver failure:

Although its systemic effect is minimal, it should be used carefully in patients with severe renal or severe hepatic impairment.

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

If you use more SERTOFEN than you should:

Do not use SERTOFEN more than 7.5 g (approximately 14 cm of gel) per day.

In case of accidental oral ingestion, inform your doctor immediately or contact the emergency department of your nearest hospital.

If you use more SERTOFEN than you should, talk to a doctor or pharmacist.

If you forget to use SERTOFEN

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

The effects that can occur when treatment with SERTOFEN is terminated:

Not available.

4. Possible Side Effects

Like all medicines, side effects on patients, who are sensitive to the ingredients of SERTOFEN, may occur.

Rare side effects (seen in at least 1 in 10,000 patients, up to 1 in 1,000 patients)

- Dermatitis (Redness in skin, severe itching, swelling, watering, incrustation, dandruff)

Very rare side effects seen in at least 1 in 10,000 patients)

- Hypersensitivity reactions (hives, swelling on the face, eyes, lips or tongue or difficulty in breathing)

Unknown side effects

- Photosensitivity (sensitivity to light) reactions (fluid-filled blisters on the skin, redness)

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

5. How To Store SERTOFEN

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

Store below 30°C at room temperature.

Use in accordance with expiry date.

Do not use SERTOFEN after expiry date on the package.

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

Manufacturing Site:	World Medicine İlaç San. ve Tic. A.Ş. Bağcılar/İstanbul, Turkey