LEAFLET
ON DRUG ADMINISTRATION

SERTOFEN

TRADE NAME
Sertofen

INTERNATIONAL NONPROPRIETARY NAME
Dexketoprofen

PHARMACEUTICAL FORM
Gel 1.25%.
Description: opaque, greyish-white colored, homogenous gel with odour of lavender, mint and spirit.

COMPOSITION
1 g of gel contains:
Active ingredient: dexketoprofen (as dexketoprofen trometamol) 12.5 mg.
Excipients: carbomer homopolymer, ethanol 96%, lavender oil, menthol, sodium hydroxide, purified water.

ATC CODE M01AE17

PHARMACOTHERAPEUTIC GROUP
Nonsteroidal anti-inflammatory drugs (NSAIDs) for external use. Propionic acid derivatives.

PHARMACOLOGICAL PROPERTIES
PHARMACODYNAMICS
Sertofen is a nonsteroidal anti-inflammatory drug (NSAID), a propionic acid derivative. It has an analgesic and anti-inflammatory action. The mechanism of action is related to the inhibition of cyclooxygenase-1 and cyclooxygenase-2 activity and the biosynthesis decrease of prostaglandins that play an important role in the pathogenesis of the inflammation, pain and fever.

PHARMACOKINETICS
When the drug in form of gel is topically applied it is slowly absorbed and practically doesn’t accumulate in the body. The bioavailability is 5% that conditions the local character of the exposure and the absence of systemic effects.
When Sertofen gel is topically applied the maximum concentration in the blood plasma is reached in 4 hours. The drug is completely eliminated in 24 hours.
The therapeutic level of dexketoprofen, equivalent to 2.5% gel of dexketoprofen, is observed in synovial liquid.

THERAPEUTIC INDICATIONS
The mild and moderate pain syndrome in the following diseases and conditions:
- in acute and chronic inflammatory, inflammatory-degenerative and metabolic diseases of the musculoskeletal system (including reumatoidal arthritis, spondiloarthritis, arthrosis, osteochondrosis);
- in rheumatic diseases of soft tissues (peritendinitis, bursitis and etc.);
- in post-traumatic inflammation of soft tissues and joints (due to sprains, overexertions, contusion, displacement and etc.).

METHOD OF ADMINISTRATION AND DOSAGE
Sertofen gel is for external use. The applied drug amount depends on the extensity of the inflammatory process and pain syndrome.
In adults and children older 6 years old Sertofen gel is applied 2-3 times per day. The daily dose shouldn’t be more than 7.5 g that corresponds to about 14 cm of gel. Apply the gel on the intact skin area and rub it until complete absorption. To apply the drug under occlusive dressing is not allowed.

It is necessary to wash the hands after the application of Sertofen gel.
The drug should be applied for not longer than 7 days without consultation with doctor.

**CONTRAINDICATIONS**
- hypersensitivity to dexketoprofen, acetylsalicylic acid or other NSAIDs, or to any of the excipients of the drug;
- history of the asthma attacks, bronchospasm, acute rhinitis, urticaria or angioneurotic edema, appeared due to the administration of substances with similar mechanism of action (acetyl salicylic acid and other NSAIDs);
- integrity damage of cutaneous integuments;
- III trimester of pregnancy.

**SIDE EFFECTS**
Sertofen gel causes the following side effects:
- rarely: dermatitis, erythema, itch, edema, desquamation;
- very rarely: hypersensitivity reactions (rash, nettle rash, bronchial asthma, edema of face, eyes, lips, tongue);
- often: photosensitization.

**SPECIAL WARNINGS**
Sertofen gel should be applied only on the intact skin avoiding the penetration into the open wounds. It is necessary to avoid the continuous drug administration on the extensive skin areas. One should also to avoid the drug penetration into the eyes and mucous membranes. It is necessary to avoid the exposure to the direct sun lights or to suspend the visits to solarium during the treatment or during the following two weeks.

Sertofen gel should be prescribed with caution in case of liver and kidney dysfunction.

**EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**
Sertofen doesn’t influence on ability to drive or to perform activities requiring rapid psychomotor reactions.

**USE DURING PREGNANCY AND LACTATION**
Sertofen is contraindicated in III trimester of pregnancy. The drug administration in I and II trimesters of pregnancy is possible only in the case when the benefit to the mother exceeds the potential risk to the fetus.

It is not recommended to use the drug during breastfeeding.

**PEDIATRIC USE**
The drug administration is not recommended in children under 6 years old due to the insufficiency of data.

**DRUG INTERACTIONS**
It is very difficult to evaluate the interaction with other drugs due to the very low absorption of Sertofen gel.

**OVERDOSE**
The overdose is unlikely because the systemic absorption of dexketoprofen for the external administration is extremely low.

**RELEASE FORM**
Gel 60 g in aluminum tube.
1 aluminum tube together with a leaflet in a carton box.
**STORAGE CONDITIONS**
Store at temperature not exceeding 25°C.
Keep out of reach of children!

**SHELF LIFE**
3 years from the date of manufacture.
Do not apply after the shelf-life expiration.

**CONDITIONS OF SALES IN DRUGSTORES**
Sold under prescription.

**MANUFACTURER**
The holder of Marketing Authorization is
**“DR SERTUS İLAÇ SANAYİ VE TİCARET LİMİTED ŞİRKETİ”, TURKEY.**
Manufactured by
**“Münir Şahin İlaç San. ve Tic. A.Ş.”, Turkey**
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