INSTRUCTIONS FOR USE

DEXENJE Ampoule containing 50 mg/2 ml solution for injection
Sterile
It is applied intramuscularly or intravenously

- ***Active ingredient:*** 73.8 mg dexketoprofen trometamole equivalent to 50 mg of dexketoprofen

- ***Excipients:*** Ethanol (96 percent), Sodium chloride, Sodium hydroxide (for adjustment of pH), Water for injection

Read this INSTRUCTIONS for USE carefully before you start **using** this **medicine because it** contains **very important information** for **you.**

- *Keep this instruction* for *use. You* may *need to read it again later.*
- *If you have additional questions , please consult your doctor or pharmacist .*
- *This medicine is personally prescribed for* you, *do not give it to others.*
- *When you go to the doctor or hospital during the use of this medicine, tell your* doctor *that you are using this medicine.*
- *Follow exactly what is written in this instruction. About the drug outside of the dosage you are advised to*

In this instruction for use :

Headings are included .

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

DEXENJE is a painkiller from a group of drugs called non-steroidal anti-inflammatory drugs (NSAIDs) (anti-inflammatory).

Treatment of signs and symptoms of osteoarthritis (destruction and calcification of the joints), rheumatoid arthritis (inflammatory joint disease) and ankilousozan spondylitis (painful progressive rheumatism, more often with stiffness in the joints of the spine) and acute gouty arthritis (due to gout) painful joint inflammation), acute musculoskeletal pains (eg. low back pain), postoperative pain (pain after surgery), dysmenorrhea (painful menstrual periods) and renal colic (severe kidney pain).

DEXENJE contains 50 mg of dexketoprofen (trometamol) and is available in a package of 6 ampoules, each containing 2 ml of clear and colorless solution.

2. Things to consider before using DEXENJE

DO NOT use DEXENJE in the following situations

If

- If you are allergic (hypersensitive) to any of the excipients in Dexketoprofen trometamole or DEXENJE;
- If you are allergic to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs ;
- Asthma attack if you have asthma or after using aspirin or other non-steroidal anti-inflammatory drugs in the past, acute allergic rhinitis (short-term inflammation in the nose due to allergies), nasal polyps (masses that form in the nose due to allergies), urticaria (skin rash), swelling of the face and throat (swelling of the face, eyes, lips or tongue or difficulty breathing) or wheezing in the chest (wheezing) as a result of allergies ;
- If you complain of photoallergic or phototoxic (typical redness and speckle form on skin exposed to the sun) during treatment with ketoprofen (non-steroidal anti-inflammatory drugs) or fibrates (drugs used to lower the amount of fat in the blood);
- If you have a peptic ulcer (gastrointestinal wound) or bleeding, ulceration or perforation in the stomach or large intestine, or if you have previously complained;
- If gastric or intestinal bleeding or perforation has occurred due to previous use of non-steroidal anti-inflammatory drugs (NSAIDs) or if you have had such a complaint in the past;
- If you have ongoing digestive problems (e.g. indigestion, burning in the chest);
- If you have ongoing inflammatory bowel disease (Crohn's disease or ulcerative colitis);
- If you have severe heart failure, moderate or severe kidney problems, or serious liver problems;
- If you have a bleeding disorder or blood clotting disorder;
- If you have severe dehydration due to vomiting, diarrhea or insufficient fluid intake (loss of a large amount of fluid from the body);
- If you are in the third trimester of your pregnancy or breastfeeding;
- Do not use in the treatment of pain before, during and after surgery in the case of coronary artery surgery (Coronary artery by-pass graft).

USE DEXENJE CAREFULLY IN THE FOLLOWING SITUATIONS

If

- If you have had ongoing inflammatory bowel disease from the past (ulcerative colitis, Crohn's disease);

- If you have stomach and bowel problems or have had complaints in the past;

- Other medications that will increase the risk of peptic ulcers or bleeding, eg. oral steroids, certain antidepressants (SSRI-type medications, such as Selective Serotonin Reuptake Inhibitors), anticoagulants such as warfarin, or blood clotting agents such as acetyl salicilic acid, such as in durum, before taking DEXENJE consult your doctor. Your doctor may ask you to take an additional medication to protect your stomach (e.g., your stomach). misoprostol or drugs that inhibit the production of stomach acid).

- If you have heart problems, have had a stroke before, or think you're at risk (for example, if you have high blood pressure, diabetes or high cholesterol, or if you smoke), ask your doctor or pharmacist about your treatment. Medications such as DEXENJE may be associated with a slight increase in the risk of heart attack ("myocardial infarctionoutset") or stroke. With high doses and long-term treatment, any kind of risk is more likely. Do not exceed the recommended dose or duration of treatment.

- If you're older: you're more likely to experience side effects (see Section 1.c.). Section 4). Ifany of these things occur, contact your doctor immediately;

- If you have allergies or have had allergic problems in the past;

- If you have kidney, liver or heart problems (high blood pressure and/or heart failure) as well as fluid retention or have suffered from any of these problems in the past ;

- If you are taking diuretic (diuretic) medications or have problems with dehydration and decreased blood volume due to excessive fluid fluid (e.g. excessive urination, diarrhea or vomiting);

- If you have fertility problems (DEXENJE can adversely affect fertility, so do not use this medicine if you plan to become pregnant or have a fertility test);

- If you are in the first or second trimester of your pregnancy;

- If you complain of an irregularity in the production of blood or blood cells;

- If you have systemic lupus erythematosus (a disease manifested by diffuse flaking of the skin) or mixed connective tissue disease (immune system disorders that can affect connective tissue);

- Because you have a higher risk of allergy to acetylsalicylic acid and/or NSAIDs than the rest of the population, you suffer from asthma, chronic rhinitis , chronic sinusitis, and/or nasal polyps as a result of intake of acetylsalicylic acid or other NSAIDs. If. The use of this drug can cause asthma attacks or bronchospasm (narrowing of the airways), especially in patients who are allergic to acetylsalicylic acid or NSAIDs.

- Exceptionally, since NSAIDs can increase infection, if you have varicella (chickenpox);

- NSAIDs cause serious gastrointestinal side effects that can be fatal, such as anama, gastrointestinal wounds or perforations. These side effects can occur at any time, with or without any precautionary signs. Elderly patients have a higher risk of serious gastrointestinal side effects.

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

Use of DEXENJE with food and beverage
No warning is required due to the application path.

Pregnancy
Consult your doctor or pharmacist before using the drug.

Do not use DEXENJE during the third trimester of pregnancy.

If you are pregnant, tell your doctor. If you are planning to become pregnant, using DEXENJE may not be right for you.

Those who are planning to become pregnant or who are pregnant should not use DEXENJE. Treatment at any stage of pregnancy should be managed by the doctor.

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

Lactation
Before using the drug, *you should consult* your *doctor or pharmacist.*

Do not use DEXENJE if you are breastfeeding.

Use of vehicles and machinery
DEXENERGE may slightly affect your ability to drive vehicles and machinery, due to the possibility of dizziness or drowsiness as a side effect of treatment. If you notice these effects, do not use vehicles or machinery until the symptoms have passed. Consult your doctor for advice .

Important information about some of the excipients contained in DEXENJE
Each ampoule of DEXENJE contains 200 mg of ethanol, equivalent to 5 ml of beer or 2.08 wines per dose. It can be harmful for those with alcohol dependence. It should be considered for pregnant or lactating women, children, and high-risk patients with liver disease or epilepsy.

This medicinal product contains less than 1 mmol (23 mg) of sodium in each dose; that is, it is essentially "sodium-free".

Concomitant use with other drugs

If you are taking any of the following medications alongside DEXENJE, be sure to inform your doctor, dentist or pharmacist. Some drugs may not be used in a row or their doses may need to be adjusted if they are used.

Not recommended combinations:

- Acetylsalicylic acid (aspirin), corticosteroids (cortisone), or other anti-inflammatory drugs
- Warfarin, heparin, or other medications used to prevent blood clots
- Lithium used to treat certain mood disorders
- Methotrexate, which is used to treat rheumatoid arthritis (a persistent disease that causes pain and deformity in the joints) and cancer
- Hydantoins and phenytoin used for epilepsy (sara)
- Sulfamethoxazole , which is used for bacterial infections (inflammatory microbial disease)

Combinations that require precautions:

- ACE inhibitors, diuretics, beta blockers and angiotensin II antagonists used in high blood pressure and heart problems
- Pentoxifylline and oxpentiphylline, which are used to treat ongoing venous ulcers (vein wounds)
- Zidovudine used in the treatment of viral infection
- Aminoglycoside antibiotics used in the treatment of bacterial infection (gentamine, amicacin, etc.)
- Chlorpropamide and glibenclamide used for diabetes

Combinations to look out for:

- Quinolone antibiotics used for bacterial infections (e.g. ciprofloxsasin, levofloxacin)
- Cyclosporine or tacrolimus used in the treatment of immune system diseases and organ transplantation
- Streptokinase and other thrombolytic or fibrinolytic drugs , i.e. drugs used to dissolve blood clots
- Probenecid used in the treatment of gout
- Digoxin used in the treatment of ongoing heart failure
- Mifepristone used to terminate pregnancy
- Antidepressants (SSRIs) in the form of selective serotonin reuptake inhibitors
- Anti-platelet agents used for platelet aggregation (clustering of blood scales) and reducing blood clot formation

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

3. How to use DEXENJE?

Instructions for proper **use and frequency of dosage/administration:**
Always take DEXENJE exactly as directed by your doctor. When you are not sure , consult your doctor .
Depending on the duration, type, and severity of your disease's symptoms, your doctor will determine the dose of DEXENJE you need . The recommendeddose is usually 1 ampoule (50 mg) of DEXENJE every 8-12 hours. In no case do not exceed a daily dose of 150 mg of DEXENJE (3 ampoules).
Use injection therapy only in the acute period (i.e., do not use it for more than two days).
Switch to oral painkillers whenever possible .

Ways and methods of application:
DEXENJE can be administered intravenously or intramuscularly (technical information on intra-mar injection "The following information is for the medical personnel who will administer this drug." section).

When DEXENJE is administered intramuscularly, the solution should be administered by slow injection into the deep muscle immediately after removal from the colored ampoule.
Only clear and colorless solution should be used.

Different age groups

Use in children and adolescents :
The use of DEXENJE in children and adolescents (under 18 years of age) has not been studied. Therefore, DEXENJE should not be used in children and adolescents because safety and efficacy have not been demonstrated.

Use in the elderly :
Elderly persons with impaired renal function should not exceed a total daily dose of 50 mg of DEXENJE (1 ampoule).
Special use cases Kidney/liver failure:

Patients with kidney or liver disorders should not exceed a total daily dose of 50 mg of DEXENJE (1 ampoule).

If you have the impression that the effect of DEXENJE *is too strong or too weak, talk to your doctor or pharmacist .*

If you've used more DEXENJE than you should:
If you have used more *of* DEXENJE *than you should, talk to a doctor or pharmacist*.
Please do not forget to take the packaging or instructions for use of the medicine with you.

If you forget to use DEXENJE:
Please do not take double doses to offset forgotten doses.

Take the next dose when the time is right (in chapter 3 "How to Use DEXENJE?" according to a).

If you have further questions about the use of this product, ask your doctor or pharmacist.

4. What are the possible side effects?

Like all medications, DEXENJE can cause side effects, although it is not seen in everyone, and people who are sensitive to the substances contained in DEXENJE may also have side effects.

Possible side effects are listed below according to how often they occur. This table shows how many patients these side effects can occur:

Prevalent	More than 1 in 100 patients and less than 1 in 10 patients
Uncommon	More than 1 in 1000 patients and less than 1 in 100 patients
Rare	More than 1 in 10,000 patients and less than 1 in 1,000 patients
Very sparse	less than 1 in 10,000 patients, including isolated reports

Common side effects include:
- Nausea and/or vomiting
- Pain at the injection site
- Reaction at the injection site, including inflammation, bruising and redness (bleeding)

Uncommon side effects:
- Bloody vomiting
- Low blood pressure
- Fire
- Blurred vision
- Dizziness
- Drowsiness
- Sleep disorders
- Headache
- Anemia
- Abdominal pain
- Constipation
- Digestive disorders
- Diarrhea
- Dry mouth
- Forehead flushing (facial flushing)
- Rash
- Dermatitis
- Itch
- Excessive sweating

- Fatigue
- Pain
- Chills

Infrequent side effects:

- Perforation of the stomach or intestine due to peptic ulcer, peptic ulcer bleeding or peptic ulcer
- High blood pressure
- Faint
- Breathing too slowly
- Inflammation of the superficial veins due to a blood clot (superficial thrombophlebitis)
- Isolated heart rhythm disturbance (extrasystole)
- Rapid heartbeat
- Peripheral edema (swelling in the legs and arms)
- Laryngeal edema (swelling in the area of the vocal cords)
- Abnormality in the senses
- Feeling of fever rising and chills
- Ringing in the ears (tinnitus)
- Itchy rash
- Jaundice
- Acne
- Back pain
- Kidney pain
- Frequent urination
- Menstrual irregularities
- Prostate problems
- Muscle stiffness
- Joint stiffness
- Muscle cramping
- Abnormal liver tests (blood tests), elevation in blood sugar level (hyperglycemia), decrease in blood sugar level (hypoglycemia), increase in the concentration of triglyceride fats in the blood (hypertriglyceridemi), ketone bodies (ketonuria) in the urine, prot ein in the urine (proteinuria))
- Inflammation of the liver cells (hepatitis)
- Acute renal failure

Very sparse

- Anaphylactic reaction (hypersensitivity reaction that can lead to collapse)
- Formation of ulcers in the skin, mouth, eyes and genital areas (Stevens Johnson and Lyell syndromes),
- Swelling of the face or swelling of the lips and throat (angioedema)
- Breathlessness due to contraction of the muscles around the airways (bronchospasm)
- Shortness of breath
- Pancreatitis
- Skin sensitivity reactions and skin hypersensitivity to light
- Kidney damage

- Decrease in white blood cell count (neutropenia)
- Decrease in the number of blood scales (thrombocytopenia)

If you notice any gastrointestinal side effects at the beginning of treatment (e.g., stomach pain, heartburn or bleeding), tell your doctor immediately if any side effects have already occurred due to long-term use of anti-inflammatory drugs, and especially if you are elderly.

Discontinue the use of DEXENJE as soon as you notice the appearance of any skin rash or lesions on mucous surfaces (for example, in the mouth) or any allergy symptoms.

During treatment with non-steroidal anti-inflammatory drugs, fluid retention and swelling (especially in the wrists and legs), elevated blood pressure, and heart failure have been reported.

Medications such as DEXENJE may be associated with a heart attack ("myocardial infarction") ora slight increase in stroke skin.

Anti-inflammatory drugs in patients with systemic lupus erythematosus (a disease manifested by diffuse flaking of the skin) or mixed connective tissue disease (immune system disorders affecting connective tissue), rarely fever, head they can lead to pain and stiffness in the neck.

If signs of infection occur or if symptoms worsen while using DEXENJE, report this to your doctor immediately.

If the side effects worsen or you notice that side effects that are not listed in this instructions for use occur, please contact your doctor or pharmacist.

If you encounter any side effects that are not mentioned in this instructions *for use,inform your grandchild or pharmacist.*

Reporting of side effects
Talk to your physician, pharmacist or nurse if any side effects occur that may or may not be included in the Instructions for Use . In addition, report the side effects you encounter to the Turkish Pharmacovigilance Center (TÜFAM) by clicking on the "Drug Side Effect Notification" icon on the www.titck.gov.tr site or by calling the side effect notification line at 0 800 314 00 08 . By reporting any side effects that occur, you will contribute to learning more about the safety of the medication you are using.

5. Storage of DEXENJE

Keep DEXENJE out of the reach of *children and in its packaging.*
Store at room temperature at 25°C, protect from light. Store the bulbs in the original cardboard boxes .

Each box contains 6 x 2 ml clear colorless solution type I glass colored bulbs.

Use in accordance with the expiration date.

Do not use DEXENJE *after* the *expiration date indicated on the* packaging.

If you notice defects in the product and/or its packaging, do not use DEXENJE.

If you notice that the solution is not clear and colorless and shows signs of deterioration (for example, the formation of particles), do not use DEXENJE. DEXENJE is disposable and should be used immediately after opening. Discard the unused part of the product.

Medicines should not be diverted away through wastewater or household waste. Ask your pharmacist how to dispose of medications that you no longer use or the appropriate ways of excreting used needle tips and injectors. These measures will help protect the environment.

***Licensee*:** Si Pharma İlaç San. Ve Tic. Ltd.Sti.
Haliç Sokak No: 31/56
Ümraniye/Istanbul/TURKEY

Manufacturer: Mefar İlaç Sanayi A.Ş.
Ramazanoglu Cad.No:20 Pendik/Istanbul

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THE FOLLOWING INFORMATION IS FOR HEALTH PERSONNEL WHO WILL ADMINISTER THIS MEDICINE

Intravenous use:

Intravenous infusion: The contents of one ampoule (2 ml) of DEXENJE should be diluted in Normal Saline in a volume of 30 to 100 ml, in a solution of 5% glucose or ringer's lactate. The diluted solution should be given in the form of a slow infusion over a period of 10 to 30 minutes . The solution should always be protected from natural sunlight.
Intravenous injection: If necessary, one ampoule (2 ml) of DEXENJE can be injected directly into the vein for a period of not less than 15 seconds.

Due to the fact that it contains ethanol, the administration of DEXENJE by neural (intrathecal or epidural) route is contraindicated.
Product usage instructions:
When DEXENJE is administered in the form of an intravenous injection, the solution should be injected immediately after withdrawal from the colored ampoule.
In application in the form of intravenous infusions, the solution must be diluted in an aseptic way and protected from natural sunlight.
Only rrak and colorless solution should be used.

Substances in which he is compatible :

When mixe**d** in low volumes (e.g. **in** an injector), DEXENJE has been shown to be compatible with injectable solutions of heparin, lidocaine, morphine and theophylline.

The solution for injection, diluted as indicated, is a clear solution. DEXENJE, diluted in a normal saline or glucose solution with a volume of 100 ml, has been shown to be compatible with the following solutions for injection: Dopamine, heparin, hydroxyserine, lidocaine, morphine , petidine and theophylline.

When diluted DEXENJE solutions are stored in plastic packaging or in application utensils made of Ethyl Vinyl Acetate (EVA), Cellulose Propionate (CP), Low Density Polyethylene (LDPE) and Polyvinyl Chloride (PVC), "the active substance was found not to be absorbed.