

PATIENT INFORMATION LEAFLET

DEKSIT 25 mg / 8 mg Tablet

Taken by oral way.

- **Active substances:** Each tablet contains 36.90 mg dexketoprofen trometamol equivalent to 25 mg dexketoprofen and 8 mg thiocolchicoside.
- **Excipients:** Partial pregelatinized corn starch, sodium starch glycollate Type A, microcrystalline cellulose PH 102, microcrystalline cellulose PH 101, magnesium stearate and pure water.

Please read this LEAFLET carefully before you start using this medicine because it contains important information for you.

- *Keep these leaflet. You can need to read again.*

- *If you have other questions, please talk your doctor or pharmacist.*

- *This medicine has been prescribed for you personally, do not give it to others.*

- *During the use of this medicine, tell your doctor that you are using this medicine when you go to the doctor or hospital.*

- *Follow exactly what is written in this leaflet. Do not use **high or low doses** other than the dose recommended for you about the drug.*

In this leaflet:

- 1. What is DEKSIT and what is it used for?***
- 2. Things to consider before using DEKSIT***
- 3. How to use DEKSIT?***
- 4. What are the possible side effects?***
- 5. Storage of DEKSIT***

Headlines are included.

1. What DEKSIT is and what it is used for

DEKSIT tablet contains dexketoprofen and thiocolchicoside as the active substance.

DEKSIT is in the form of a yellowish, round, flat notched tablet.

DEKSIT is presented in blister packs containing 14 tablets.

Dexketoprofen trometamol in DEKSIT, is an analgesic drug belong a drug group called a non-steroidal anti-inflammatory drugs (NSAIDs). The thiocolchicoside in DEKSIT has mainly muscle relaxant activity. Thiocolchicoside is used for the treatment of symptoms of painful muscle cramps.

DEKSIT is used in the treatment of osteoarthritis (calcification), painful syndromes of the vertebral column (spine), extra-articular rheumatism, painful muscle contractions symptoms, and in the treatment of post-operative pain and trauma.

2. Things to consider before using DEKSIT

Risks related to the cardiovascular system

NSAIDs can cause an increased risk of coagulation related (thrombotic) events, heart attack and stroke in the cardiovascular system, which may be fatal. This risk may increase depending on the duration of use. Patients with cardiovascular disease or cardiovascular disease risk factors may have a higher risk.

- DEKSIT should not be used in the treatment of pain before cardiovascular (coronary artery bypass) surgery.

Risks related to digestive system

NSAIDs cause serious undesirable effects such as bleeding, wound formation, stomach or intestinal perforation. These undesirable effects can occur at any time, with or without prior warning.

DO NOT USE DEKSIT in the following cases

- If you are allergic (hypersensitive) to dexketoprofen trometamol, thiocolchicoside or any of the excipients in DEKSIT,
- If the muscle or muscles failure to serve their function (contraction),
- If you are allergic to acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs.
- If you have asthma, or after taking acetylsalicylic acid or other non-steroidal anti-inflammatory drugs in the past, asthma attack, acute allergic rhinitis (short-term inflammation in the nose due to allergies), polyp in the nose (allergy-induced masses in the nose), urticaria (skin rash), allergy result swelling of face and throat (swelling of the face, eyes, lips or tongue or difficulty breathing) or wheezing in the chest,
- If you have peptic ulcer, stomach or intestinal bleeding, or ongoing digestive problems (e.g. indigestion, burning in the chest), or if you have had it before,
- If you have had stomach or intestinal bleeding or perforation in the past due to the use of non-steroidal anti-inflammatory drugs (NSAIDs) used as pain relievers,
- If you have ongoing inflammatory bowel disease (Crohn's disease or ulcerative colitis),
- If you are taking medicines that prevent blood clotting,
- If you have serious heart failure, moderate or severe kidney problems, or severe liver problems,
- If you have bleeding problems or blood clotting disorders,
- If you are pregnant,
- If you are breastfeeding,
- If you are likely to become pregnant and do not use an effective contraceptive method,
- If you are in the period before coronary artery bypass graft surgery and need to treat pain before surgery.

DEKSIT should not be used in children younger than 18 years old.

USE DEKSIT CAREFULLY in the following cases

- If you are epilepsy patient or have a risk of seizures of epilepsy,
- If you are allergic or have had allergic problems in the past,
- If you have kidney, liver or heart problems (high blood pressure and / or heart failure) including fluid retention, or if you have had any of these problems in the past,
- If you are taking diuretic (diuretic) medications, or if you are experiencing fluid deficiency and decreased blood volume due to excessive fluid loss (eg excessive urination, diarrhea or vomiting),
- Consult your doctor or pharmacist about your treatment if you have heart problems, have had a stroke before or think you are at risk (eg if you have high blood pressure, diabetes or high cholesterol, or if you smoke). Drugs such as DEKSIT can be associated with a slight increase in the risk of heart attacks (“myocardial infarction”) or the risk of serious cardiovascular diseases such as stroke. These serious diseases can occur without any symptoms. Inform your doctor if you experience any of the signs and symptoms such as chest pain, shortness of breath, slurred speech, and weakness. Any risk is more likely with high doses and long-term treatment. Do not exceed the recommended dose or duration of treatment.
- If you are elderly: you are more likely to experience undesirable effects, especially peptic ulcer bleeding and puncture can be life-threatening (see Chapter 4). If any of these occur, consult your doctor immediately,
- If you are a woman with reproductive problems (DEKSIT may adversely affect reproduction, so do not use this drug if you have a conception plan or are going to have an infertility test),
- If you have a blood or blood cell building disorder,
- If you have systemic lupus erythematosus (a disease manifested by extensive scaly skin) or mixed connective tissue disease (immune system disorders that can affect connective tissue),
- If you have had long-term inflammatory bowel disease in the past (ulcerative colitis, Crohn's disease),
- If you have another stomach and bowel disease or have had it before,
- If you use oral steroids, some antidepressants (SSRI-type drugs, such as Selective Serotonin Reuptake Inhibitors), anticoagulants such as warfarin, or anticoagulants such

as acetylsalicylic acid that increase the risk of peptic ulcer or bleeding. In such cases, consult your doctor before taking DEKSIT. Your doctor may recommend that you take an additional medicine to protect your stomach (eg. misoprostol or medications that inhibit stomach acid production).

- As with the use of other NSAIDs, DEKSIT can cause gastrointestinal (GI) discomfort and rarely serious GI side effects such as ulcers (wounds) and bleeding, which may result in hospitalization or death. If you experience any of the following during your treatment, stop taking the medicine and seek medical help immediately: blood coming out of the stool, dark color stools like black tar, blood vomiting or coming pieces like coffee grounds,
- If you have indigestion or a burning sensation in the chest, abdominal pain, or other abnormal abdominal symptoms, stop taking the medicine and consult your doctor.
- Inform your doctor when you gain unexplained weight or if edema (swelling) occurs in your body.
- If you experience one of the signs and symptoms of hepatotoxicity (liver poisoning), such as nausea, weakness, fatigue, jaundice, itching, right upper quadrant sensitivity, flu-like symptoms, stop treatment and seek medical treatment immediately.
- As with the use of other NSAIDs, DEKSIT can cause serious skin reactions such as exfoliative dermatitis (skin disease that causes skin peeling and flaking), Stevens-Johnson syndrome (inflammation associated with skin swelling and redness) and toxic epidermal necrolysis (a serious disease on the skin with fluid-filled blisters), may also result in hospitalization or death. These serious skin reactions can also occur without any symptoms. If any of the symptoms such as itching, fever, rash, blisters occur, stop using your medicine and inform your doctor as soon as possible.
- One of the substances occurring in the body when using DEKSIT can cause damage (abnormal number of chromosomes) in some cells when DEKSIT is used in high doses. This has been demonstrated in animals and laboratory studies. This damage that can occur in cells in humans creates a risk factor for cancer, can harm the unborn child and cause infertility in men. Therefore, strictly comply with the dosage and duration of treatment specified in the "instructions for proper use and dose / frequency of administration". Do not use the drug in higher doses and more than 7 days. If you have any other questions, please consult your doctor.
- Liver problems may occur during treatment with DEKSIT. If any of the following symptoms occur, tell your doctor immediately: pain or discomfort in the stomach

(abdomen) area, loss of appetite, nausea, vomiting, yellowing of the skin or eye (jaundice), urine being darker than normal, itching, as well as fever and fatigue (especially if the previously mentioned symptoms are together). These may be symptoms of liver problems.

- As with other NSAIDs, Dexketoprofen can mask the symptoms of infection (inflammatory microbial disease).
- If diarrhea occurs during treatment, discontinue treatment with DEKSIT.
- Using the lowest dose, which is effective in relieving the symptoms of your disease, for the shortest period of time will minimize the possibility of adverse effects of the drug.

Please consult your doctor if these warnings are valid for you, even at any time in the past.

Using DEKSIT with food and drink

Take the tablets with sufficient amount of water. Taking DEKSIT with food helps reduce the risk of side effects that may occur in the stomach or intestine. However, if you have acute pain, take the tablets on an empty stomach. Taking the medicine at least 30 minutes before meals helps the medicine work a little faster.

Pregnancy

Consult your doctor or pharmacist before using this medication.

Women with childbearing potential must have effective contraception during treatment.

Do not use DEKSIT if you are pregnant.

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 medication.

Do not use DEKSIT if you are breastfeeding.

Driving and using machines

DEKSIT treatment may cause dizziness, drowsiness, giddiness or hypokinesia as side effect, thus it may affect your ability to drive and use machines a little. If you notice these effects,

do not drive or operate machinery until the symptoms disappear. Consult your doctor for advice.

Important information about some of the ingredients of DEKSIT

Sodium warning;

Each dose of DEKSIT contains less than 1 mmol (23 mg) sodium; no sodium-related side effects are expected at this dose.

Concomitant use with other drugs

If you are using any of the following medicines at the same time with DEKSIT, you should definitely inform your doctor, dentist or pharmacist. Some medicines may not be used together or their dosage may need to be adjusted.

Not recommended combinations:

- Taking DEKSIT with other drugs that have a muscle relaxant effect on the musculoskeletal system is not recommended because they can increase the effect of each other. For the same reason, caution should be exercised against the possibility of increasing the frequency of undesirable effects if used with another drug acting on smooth muscles.
- Acetylsalicylic acid (aspirin), corticosteroids or other anti-inflammatory drugs (drugs used to treat inflammation)
- Warfarin, heparin or other anticoagulant drugs (drugs used to prevent blood clotting)
- Lithium (a medicine used to treat some mood disorders)
- Methotrexate (drug used to treat cancer and rheumatoid arthritis [a persistent disease that causes pain and deformities in the joints] when used at doses of 15 mg or more per week)
- Hidantoins and phenytoin (a medicine used to treat epilepsy)
- Sulfamethoxazole (drug used for bacterial infections [inflammatory microbial diseases])

Combinations requiring precautions:

- ACE inhibitors, diuretics, beta-blockers and angiotensin II antagonists (drugs used in high blood pressure and heart problems.)
- Furosemide (used to treat fluid retention (edema) in people with kidney disease such as congestive heart failure, liver disease, and nephrotic syndrome)
- Methotrexate (drug used to treat cancer and rheumatoid arthritis [a persistent disease that causes pain and deformities in the joints] when used at doses of 15 mg or less per week)
- Pentoxifylline and oxpentifiline (medicines used to treat ongoing venous ulcers)
- Zidovudine (drug used to treat viral infections)
- Chlorpropamide, sulfonylurea and glibenclamide (drugs used to treat diabetes)
- Aminoglycoside antibiotics (drugs used for bacterial infections)

Combinations requiring attention:

- Quinolone antibiotics (ciprofloxacin, levofloxacin; drug used for bacterial infections)
- Cyclosporine and tacrolimus (drugs used in organ transplantation or in the treatment of immune system diseases)
- Streptokinase and other thrombolytic or fibrinolytic drugs (drugs used to dissolve blood clots)
- Probenecid (drug used to treat gout)
- Digoxin (a medicine used to treat ongoing heart failure)
- Mifepristone (drug used to end pregnancy)
- Antidepressants (SSRIs) such as selective serotonin reuptake inhibitors (drugs used to treat depression)
- Anti-platelet agents (drugs used to reduce aggregation of platelets [clustering of blood flakes] and blood clot formation)

Please note that these warnings may also apply to products that have been used a while ago or will be used in the future.

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

3. How to use DEKSIT?

Instructions for proper use and dose / frequency of administration:

Always take DEKSIT exactly as your doctor has told you. If you are not sure, consult your doctor or pharmacist.

The recommended and daily maximum dose is one tablet, provided that it is taken every 12 hours (12 hours interval) 2 times a day). In other words, do not use more than 2 tablets of DEKSIT in one day (total 50/16 mg dexketoprofen / thiocolchicoside / day) .

Normally, the duration of treatment with DEKSIT is 5-7 days. Do not use the drug for more than 7 consecutive days.

Do not exceed the recommended dosage and avoid prolonged use. Do not forget to take your medicine on time.

Your doctor will tell you how long your treatment will last with DEKSIT. Do not interrupt treatment early because you cannot get the desired result.

Application way and method:

DEKSIT is for oral use only.

DEKSIT should be taken on a full stomach.

Different age groups

Use in children:

DEKSIT should not be used in children under 18 years of age.

Elderly usage:

The safety and efficacy of DEKSIT in elderly patients has not been studied..

Special use cases:

Kidney / Liver failure:

DEKSIT should not be used in patients with moderate and severe renal dysfunction and / or severe liver dysfunction.

The safety and efficacy of DEKSIT in patients with kidney / liver failure has not been studied.

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

If you have used more DEKSIT than you should

If you have used more than you should use from DEKSIT, talk to a doctor or pharmacist.

If you forget to use DEKSIT

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

Skip the dose you forgot to take and take the next dose as usual. Tell your doctor if you forget to take more than one dose.

Effects that may occur when treatment with DEKSIT is terminated

If you encounter any problem about using DEKSIT, consult your doctor or pharmacist.

You can stop using DEKSIT by consulting your doctor..

4. What are the possible side effects?

Like all medicines, side effects can occur in people sensitive to DEKSIT.

If any of the following occurs, stop using DEKSIT and tell your doctor IMMEDIATELY or contact the emergency department of the nearest hospital:

- Swelling of the hands, feet, wrists, face, lips, or swelling of the mouth or throat making it difficult to swallow or breathe,
- Very severe response of the body to allergic substances, sudden hypersensitivity (Anaphylactic reaction),
- Itching, swelling of the skin and mucous membranes, face or lips and throat (angioneurotic edema),

- Swelling, redness, open wounds in the skin, mouth, eyes and genital areas (Stevens Johnson syndrome),
- Swoon (vasovagal syncope), fainting,
- Having convulsions (seizure),
- Toxic epidermal necrolysis (a serious disease characterized by fluid-filled blisters on the skin)
- Skin rashes
- Peptic ulcer perforation or bleeding, manifested by blood vomiting or black stool,
- Palpitation,
- Breathlessness due to narrowing of the airways (bronchospasm).

These are all very serious side effects.

If you have one of these, you have a serious allergy to DEKSIT.

You may need an emergency medical intervention or hospitalization. All of these very serious side effects are very rare.

Side effects are defined as shown in the following categories:

Very common: seen in at least 1 in 10 patients.

Common: Less than one in 10 patients, but more than one in 100 patients.

Uncommon: Less than one in 100 patients, but more than one in 1000 patients.

Rare: Less than one in 1,000 patients, but more than one in 10,000 patients.

Very rare: Less than one in 10,000 patients can be seen.

Unknown: It cannot be estimated from the available data.

Common:

- Diarrhea
- Digestive problems (indigestion),
- Puffiness,
- Nausea and / or vomiting,
- Abdominal pain,
- Sleepiness,
- Stomache ache,

Uncommon:

- Sleep disturbances - insomnia,
- Irritability,
- Headache,
- Flushing,
- Stomach pain, stomach problems,
- Constipation,
- Dry mouth,
- Pain,
- General malaise, indisposition
- Dizziness (vertigo),
- Giddiness
- Drowsiness,
- Skin rashes,
- Fast heartbeat, heart palpitations,
- Anxiety,
- Weakness,
- Tiredness,
- Itching,
- Allergic skin reaction,

Rare:

- Acne,
- Increased sweating,
- Back pain,
- Frequent urination,
- Menstrual irregularities,
- Bleeding or perforation of the stomach or intestines,
- High blood pressure,
- Breathing very slowly,

- Kidney problems (acute kidney failure),
- Prostate problems,
- Liver function test abnormality,
- Hepatitis (Liver inflammation)
- Throat edema,
- Anorexia,
- Numbness - fainting,
- Urticaria,
- Regional (peripheral) edema,
- Low blood pressure (hypotension),
- Nausea, vomiting,

Very rare:

- Blurred vision,
- Ringing in the ears (tinnitus),
- Sensitivity to the skin,
- Stevens-Johnson syndrome (inflammation with blood accumulation, swelling and redness in the skin and around the eyes) and toxic epidermal necrolysis (a serious disease with fluid-filled blisters on the skin)
- Sensitivity to light,
- Water retention and swelling of the body away from the body (eg swelling of the ankles),
- Abnormality in the senses,
- Abnormal liver function tests (blood tests),
- Shortness of breath (dyspnea),
- Inflammation in the pancreas (pancreatitis),
- Liver cell damage (hepatitis),
- Low white blood cell count (neutropenia), low number of blood flakes (thrombocytopenia),
- Low blood pressure,
- Kidney inflammation (nephritis) or kidney damage,

- Pain or discomfort in the stomach (abdomen) area, loss of appetite, nausea, vomiting, yellowing of the skin or eye (jaundice), urine being darker than normal, itching, fever and fatigue (these may be signs of liver problems),
- Reactions, including shock, due to the body's hypersensitivity to allergens,
- The number of heart beats per minute exceeds normal (tachycardia)
- Sudden and involuntary contraction of the smooth muscles in the branches of the trachea (bronchi) leading to the lungs

Unknown:

- Temporarily blurred consciousness, exuberance, having convulsions,
- Angioneurotic edema (itching, swelling on the skin and mucous membranes, face or lips and throat)
- Serious allergic reactions (anaphylactic shock) that may occur against allergen substances in the body,
- Severe itching,

If you have had a side effect due to long-term use of anti-inflammatory drugs and especially if you are elderly, if you notice any abdominal / intestinal side effects at the beginning of treatment (eg abdominal pain, burning, bleeding).

Stop using DEKSIT as soon as you notice any skin rash or any lesions in the mouth or genital area or any signs of allergy.

Fluid retention and swelling (especially in the ankles and legs), elevated blood pressure and heart failure have been reported during treatment with nonsteroidal anti-inflammatory drugs.

Drugs like DEKSIT can be associated with a heart attack ("myocardial infarction") or a slight increase in stroke risk.

In patients with immune system disorders affecting connective tissue (systemic lupus erythematosus or mixed connective tissue disease), anti-inflammatory drugs may rarely cause fever, headache and neck stiffness.

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

5. Storage of DEKSIT

Keep DEKSIT in places where children cannot see, cannot reach and in its packaging.

Store at room temperature below 25°C, protected from moisture and light.

Use in accordance with expiration dates.

Do not use DEKSIT after the expiration date on the packaging..

Eğer üründe ve/veya ambalajında bozukluklar fark ederseniz DEKSIT'i kullanmayınız.

Do not dispose of expired or unused drugs! Give to the collection system determined by the Ministry of Environment and Urbanization.

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