

## PATIENT INFORMATION LEAFLET

### DEKSIT 25 mg / 4 mg Tablet

Taken by oral way.

- **Active substances:** Each tablet contains 36,90 mg dexketoprofen trometamol equivalent to 25 mg dexketoprofen and 4 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 20 tablets.

Dexketoprofen trometamol, contained in DEKSIT, is a painkiller of pharmaceutical drugs known as non-steroidal anti-inflammatory systems (NSAIDs). Thiocolchicoside, contained in DEKSIT, has mainly muscle relaxant activity. Thiocolchicoside is used to treat painful muscle cramps. DEKSIT is used in the symptomatic treatment of osteoarthritis (calcification), painful syndromes of the vertebral column (spine), extra-articular rheumatism, painful muscle contractions, and in the treatment of pain occurring after trauma and surgery.

## 2. Things to consider before using DEKSIT

### **Risks related to the cardiovascular system:**

NSAIDs may cause an increased risk of heart attack and stroke, which can be fatal due to clotting (thrombotic) events in the cardiovascular system. This risk may increase depending on duration of use. The risk may be higher in patients with cardiovascular disease or risk factors for cardiovascular disease.

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

### **Risks related to the digestive system**

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

Elderly patients are at higher risk of these serious undesirable effects.

## **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 there is a condition in which the muscle or muscles cannot function (contract),
- If you are allergic to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs,

- If you have asthma or have used acetylsalicylic acid or other non-steroidal anti-inflammatory drugs in the past, you may experience an asthma attack, acute allergic rhinitis (short-term inflammation in the nose due to allergies), nasal polyps (masses formed in the nose due to allergies), urticaria (skin rash), face rash due to allergies and if you experience swelling of the throat (swelling of the face, eyes, lips or tongue or difficulty breathing) or wheezing in the chest,
- If you have or have ever had a peptic ulcer, stomach or intestinal bleeding, or ongoing digestive problems (e.g. indigestion, heartburn),
- 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 for pain relief.
- If you have an ongoing inflammatory bowel disease (Crohn's disease or ulcerative colitis),
- If you use medications that prevent blood clotting,
- if you have severe heart failure, moderate or severe kidney problems or serious 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 are not using an effective birth control method,
- If you are in the period before coronary artery bypass graft surgery and need pain management during surgery.

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

**USE DEKSIT CAREFULLY in the following cases**

- If you have epilepsy or are at risk of epileptic seizures,
- If you are allergic or have had allergic problems in the past,
- If you have kidney, liver or heart problems, including fluid retention (high blood pressure and/or heart failure), or have had any of these problems in the past.
- If you are taking diuretic medicines or if you have problems with fluid deficiency and decreased blood volume due to excessive fluid loss (e.g. excessive urination, diarrhea or vomiting),

- If you have heart problems, have had a stroke before, or think you may be at risk (e.g. if you have high blood pressure, diabetes or high cholesterol, or if you are a smoker), consult your doctor or pharmacist about your treatment. Medicines such as DEKSIT may be associated with a slightly increased risk of heart attack (“myocardial infarction”) or serious cardiovascular disease such as stroke. These serious diseases can occur without any symptoms. If you experience any of the signs and symptoms such as chest pain, shortness of breath, slurred speech, or fatigue, inform your doctor. Any risks are more likely with high doses and long-term treatment. Do not exceed the recommended dose or treatment duration.
- If you are elderly: you are more likely to experience undesirable effects, especially bleeding and perforation of peptic ulcers, which can be life-threatening (see Section 4). If any of these occur, consult your doctor immediately,
- If you are a woman with reproductive problems (DEKSIT may negatively affect fertility, so do not use this medicine if you are planning to become pregnant or if you are going to have an infertility test).
- If you have a blood or blood cell production disorder,
- If you have systemic lupus erythematosus (a disease characterized by widespread flaking of the skin) or mixed connective tissue disease (immune system disorders that can affect connective tissue),
- if you have had long-term inflammatory bowel disease (ulcerative colitis, Crohn's disease) in the past,
- If you have or have ever had another stomach and intestinal disease,
- If you are taking oral steroids, certain antidepressants (SSRI-type drugs, e.g. Selective Serotonin Reuptake Inhibitors), anticoagulants such as warfarin, or agents that prevent blood clotting such as acetylsalicylic acid, which may increase the risk of peptic ulcers or bleeding. In such cases, consult your doctor before taking DEKSIT. Your doctor may recommend that you take an additional medication to protect your stomach (e.g. misoprostol or medications that inhibit stomach acid production).
- As with other NSAIDs, DEKSIT may cause gastrointestinal (GI) upset, which may result in hospitalization or death, and rarely, serious GI side effects such as ulcers (sores) and bleeding. If you experience any of the following during your treatment, stop taking the medicine and seek medical help immediately: passing blood in your stool, black tarry stools, vomiting blood, or passing dark particles such as coffee grounds.

- If you have indigestion or burning sensation in the chest, abdominal pain or other abnormal abdominal symptoms, stop taking the medicine and consult your doctor.
- Inform your doctor if you gain unexplained weight or if edema (swelling) occurs in your body.
- If you experience signs and symptoms of hepatotoxicity (liver toxicity), such as nausea, weakness, fatigue, jaundice, pruritus, right upper quadrant tenderness, flu-like symptoms, discontinue treatment and seek medical treatment immediately.
- As with the use of other NSAIDs, DEKSIT can cause exfoliative dermatitis (a skin disease that causes skin peeling and flaking), Stevens-Johnson syndrome (inflammation of the skin and around the eyes with blood settling, swelling and redness) and toxic epidermal necrolysis, which can result in hospitalization or death. It may cause serious skin reactions such as (a serious disease characterized by fluid-filled blisters on the skin). These serious skin reactions can 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 formed in the body while using DEKSIT, can cause damage (abnormal chromosome number) in some cells when used in high doses. This has been shown in animal and laboratory studies. This damage, which can occur in human cells, poses a risk factor for cancer, can harm the unborn child, and cause infertility in men. Therefore, strictly comply with the dosage and treatment duration specified in the “instructions for appropriate use and dosage/frequency of application” section. Do not use the drug in higher doses and for more than 7 days. If you have any other questions, please consult your doctor.
- Liver problems may occur during treatment with DEKSIT. Tell your doctor immediately if you experience any of the following symptoms: pain or discomfort in the stomach (abdomen), loss of appetite, nausea, vomiting, yellowing of the skin or whites of the eyes (jaundice), darker urine than normal, itching, as well as fever and fatigue (especially if the symptoms listed above are present together). These could be symptoms of liver problems.
- As with other NSAIDs, Dexketoprofen may mask signs of infection (inflammatory microbial disease).
- If diarrhea occurs during treatment, discontinue treatment with DEKSIT.
- Using the lowest dose that is effective in relieving the symptoms of your disease and for the shortest duration will minimize the possibility of undesirable effects of the drug.

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

### **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 intestines. However, if you have acute pain, take the tablets on an empty stomach. Taking the medicine at least 30 minutes before meals will help the medicine take effect a little faster.

### **Pregnancy**

*Consult your doctor or pharmacist before using this medication.*

*Women of childbearing potential must use effective birth control 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 breast-feeding.

### **Driving and using machines**

DEKSIT may cause dizziness, drowsiness, or drowsiness as a side effect of the treatment, which may slightly affect your ability to drive and use machines. If you notice these effects, do not drive or use machines until the symptoms disappear. Consult your doctor for advice.

### **Important information about some excipients contained in 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.

### **Use with other drugs**

If you are using any of the following drugs along with DEKSIT, be sure to inform your doctor, dentist or pharmacist. Some medications may not be used together or their doses may need to be adjusted if used.

Not recommended combinations:

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

Combinations requiring precautions:

- ACE inhibitors, diuretics, beta-blockers and angiotensin II antagonists (medicines used for 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, or nephrotic syndrome.
- Methotrexate (a drug used to treat cancer and rheumatoid arthritis [a persistent disease that causes pain and deformities in the joints] when used in doses of 15 mg or less per week)
- Pentoxifylline and oxpentifylline (medicines used to treat ongoing venous ulcers)
- Zidovudine (medicine used to treat viral infections)
- Chlorpropamide, sulphonylurea and glibenclamide (drugs used to treat diabetes)
- Aminoglycoside antibiotics (drugs used for bacterial infections)

Combinations to pay attention to:

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

Please note that these warnings may also apply to products that have been used within a certain period of time or will be used at some time in the future.

*If you are currently using or have recently used any prescription or non-prescription medication, 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 tells you. When you are not sure, consult your doctor or pharmacist.

The recommended and maximum daily dose is one tablet, taken every 12 hours (twice a day, 12 hours apart). In other words, do not use more than 2 tablets per day (total 50/8 mg dexketoprofen/thiocolchicoside/day) of DEKSIT 25 mg/4 mg Tablets.

Normally, the treatment duration with DEKSIT 25 mg/4 mg Tablet is 5-7 days. Do not use the medicine for more than 7 consecutive days. Do not exceed the recommended dose and avoid long-term use. Do not forget to take your medicine on time.

Your doctor will inform you how long your treatment with DEKSIT will last. Do not stop treatment early because you may not get the desired result.



**Application way and method:**

DEKSIT is for oral use only.

DEKSIT tablet 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 to severe renal dysfunction and/or severe liver dysfunction.

The safety and effectiveness of DEKSIT in patients with renal/liver failure have not been examined.

If you have the 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**

In case of accidental ingestion or overuse, symptomatic treatment should be administered immediately according to the clinical condition of the patient. If more than 5 mg/kg is taken by an adult or a child within one hour, administration of activated charcoal should be considered.

Alternatively, in adults, gastric lavage (a medical procedure to empty the stomach contents) should be considered within one hour in the event of a potentially life-threatening overdose.

Good urine output should be ensured

Depending on the patient's clinical condition, other measures may need to be taken.

If you have used more DEKSIT than you should, consult 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 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 problems with the use of 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, there may be side effects in people who are sensitive to the substances contained in DEKSIT.

**If any of the following happens, stop using DEKSIT and IMMEDIATELY notify your doctor or go to the emergency department of the nearest hospital:**

- Swelling of the hands, feet, ankles, face, lips, or swelling of the mouth or throat that makes swallowing or breathing difficult,
- The body's very severe response to allergenic substances, sudden hypersensitivity (Anaphylactic reaction),
- Itching, swelling on the skin and mucosa, face or lips and throat (angioneurotic edema),
- Swelling, redness, open wounds in the skin, mouth, eyes and genital areas (Stevens Johnson syndrome),
- Faintness (vasovagal syncope), fainting,
- Seizure (seizure),
- Toxic epidermal necrolysis (a serious disease characterized by fluid-filled blisters on the skin. Lyell syndrome)
- Perforation or bleeding of peptic ulcer, manifested by vomiting blood or black stools,
- Palpitation,
- Breathlessness (bronchospasm) due to narrowing of the airways.

These are all very serious side effects.

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

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

Side effects are described as shown in the following categories:

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

Common: It may occur in less than 1 in 10 patients, but in more than 1 in 100 patients.

Uncommon: may occur in less than 1 in 100 patients, but in more than 1 in 1000 patients. Rare:

It can be seen in less than 1 in 1,000 patients, but can be seen in more than 1 in 10,000 patients.

Very rare: It may occur in less than 1 in 10,000 patients.

Unknown: Cannot be estimated from available data.

**Common:**

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

**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,
- Nausea-vomiting,
- 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 (sudden developing kidney failure),
- Prostate problems,
- Liver function test abnormality,
- Throat edema,
- Anorexia,
- Numbness - fainting,
- Hives,
- Regional (peripheral) edema,
- Low blood pressure (hypotension),

**Very rare:**

- Blurred vision,
- Ringing in the ears (tinnitus),
- Sensitivity to the skin,
- Sensitivity to light,
- Water retention and swelling of the body away from the body (e.g. 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,
- 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),
- Yellowing of the skin or whites of the eyes (jaundice), darker urine than usual, 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),
- Contraction of the smooth muscles of the trachea branches leading to the lungs

**Unknown:**

- Temporary confusion, confusion, seizures,
- Serious allergic reactions that may occur in the body to allergenic substances (anaphylactic shock),
- Severe itching, stool color almost white, urine color very dark.

If you have previously 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 (e.g. abdominal pain, burning, bleeding).

Stop using DEKSIT as soon as you notice a skin rash or any lesion in the mouth or genital area or any allergy symptoms.

Fluid retention and swelling (especially in the ankles and legs), increased blood pressure, and heart failure have been reported during treatment with nonsteroidal anti-inflammatory drugs. Medicines such as DEKSIT may be associated with a slightly increased risk of heart attack (“myocardial infarction”) or stroke. 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 experience any side effects not mentioned in this instruction manual, 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.*

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

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

### ***Registration Certificate Owner:***

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*These leaflet for use are approved on 20/03/2023.*