PACKAGE LEAFLET

DIKLORON SR 75 mg Film Coated Tablets
Taken by mouth.

Active Substance(s): Each film-coated tablet contains 75 mg diclofenac sodium.
Excipient(s): Sucrose, hydroxypropyl methylcellulose 4000 SR, colloidal silicone dioxide, polyvinylpyrrolidone K25, polyethylene glycol 6000, magnesium stearate, Opadry-OY-LS-28913 [HPMC 2910 / Hypromellose 15 cP (E 464), titanium dioxide (E171), lactose monohydrate (from bovine milk), macrogol/PEG (E1521)].

Read all of this PACKAGE LEAFLET carefully before you start taking this medicine because it contains important 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.*
- *While you are taking this medicine, tell your doctor that you use this medicine when you go to a doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher or** a **lower** dose other than recommended to you.*

In this leaflet:

1. WHAT IS DIKLORON AND WHAT IT IS USED FOR
- Each film-coated tablet contains 75 mg active substance (diclofenac sodium).
- DIKLORON SR belongs to a group of medicines called “nonsteroidal anti-inflammatory drugs” (NSAIDs) which are used for the treatment of pain and inflammation.
- DIKLORON SR contains 10 tablets, which are white colored, round and slightly convex, in a transparent PVC – PVDC Al foil blister pack in a cardboard box.

DIKLORON SR is used for the treatment of symptoms and signs of calcification (osteoarthritis), painful and deformed joints (rheumatoid arthritis), and painful progressive rheumatism characterized by stiff joints of neck, back and rib cage (ankylosing spondylitis) and treatment of joint inflammation due to acute gout (acute gouty arthritis), acute musculoskeletal pain, and pain after surgery (post-operative pain).

Please ask your doctor if you have any questions about how DIKLORON SR affects and why this medicine has been prescribed for you.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DIKLORON SR
Carefully follow all instructions given by your doctor. Those instructions may differ from the general information given in this leaflet.

DO NOT USE DIKLORON SR in the following situations:

- If you are allergic to diclofenac or any of the other ingredients of DIKLORON SR listed at the beginning of this leaflet.
- If you ever had allergic symptoms and signs after taking medicines to treat inflammation or pain (e.g. acetylsalicylic acid/aspirin, diclofenac or ibuprofen). This may include asthma (shortness of breath, cough, wheezing due to narrowing of the airways in the lungs), runny nose, skin rash, and swelling of the lips, tongue, throat, and/or hands and feet (signs of edema). Severe, rarely fatal clinical condition called anaphylaxis, accompanied with swelling of tongue, difficulty in breathing, low blood pressure and skin rash, to non-steroidal anti-inflammatory drugs (NSAIDs) has been reported in these patients. If you think you may be allergic, ask your doctor for advice.
- If you have had coronary artery surgery (such as cardiovascular operation or bypass), in treatment of pain before, during and after the surgery.
- If you have established heart disease and/or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA = transient ischemic attack) or blockages in blood vessels to the heart or brain or if you have had an operation to clear or bypass blockages.
- If you have now or have ever had a stomach or duodenal ulcer (wound).
- If you have now or have ever had bleeding or perforation in the gastrointestinal tract, (this can include blood in vomit, bleeding when emptying bowels, fresh blood in stools or black tarry stools).
- If you have a history of ulcers or bleeding in your stomach or intestines that have occurred at least twice
- If you have severe kidney or liver disease.
- If you have severe heart failure.
- If you have congestion in the heart vessels; congestion in the arteries that carry blood to the internal organs, arms, and legs other than the heart; congestion in the vessels that feed the brain; heart failure (at a level that restricts movements).
- If you are in the last 3 months of pregnancy.

Consult your doctor before using DIKLORON SR if these warnings were applicable to you even at any time in the past. Your doctor will decide whether this medicine is suitable for you. Talk to your doctor if you think you have allergy.

USE DIKLORON SR CAREFULLY in the following situations:

- Patients with significant risk factors for cardiovascular diseases (such as a heart disease, vascular occlusion, high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, smoking, etc.) should be treated with diclofenac only after a careful consideration.
- The lowest effective dose should be used for the shortest possible duration in the treatment with diclofenac. Healthcare professionals should regularly re-evaluate the necessity of continuation of diclofenac treatment.
- Use of medicines such as DIKLORON SR may be associated with an increased risk of heart attack or stroke. Any risks become more likely with high doses and long-term treatment. Do not exceed the recommended dose or duration of treatment.
- If you have a known disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure (that the heart cannot pump enough blood to meet body needs), known ischemic heart disease (narrowing of the vessels that supply oxygen and blood to the heart) or peripheral arterial disease

(narrowing of the arteries and causing blood flow to decrease to an area) as treatment with DIKLORON SR is generally not advised. (If you have a known heart disease or are at risk of heart disease and particularly you have been treated longer than 4 weeks; your doctor will decide whether you need to continue your treatment with DIKLORON SR or not).
- It is generally important to take the lowest dose of DIKLORON SR that relieves your pain and/or swelling and for the shortest time possible in order to keep your risk for cardiovascular side effects as small as possible.
- If you are taking DIKLORON SR simultaneously with other anti-inflammatory medicines (acetylsalicylic acid, corticosteroids, blood thinners and antidepressant medicines classified as SSRIs) (see "Use of DIKLORON SR with other medicines").
- If you have asthma or hay fever (seasonal allergic rhinitis) or other allergies; if you have a polyp (extra piece of soft tissue) in your nose; if you have difficulty breathing (may be caused by COPD); or if you have a long-term respiratory tract infection.
- If you have ever had gastrointestinal problems such as stomach ulcers, stomach bleeding or black stools, or if you have had stomach upset or heartburn after taking anti-inflammatory drugs in the past.
- If you have inflammation of colon (ulcerative colitis) or inflammation of bowel (Crohn's disease).
- If you have liver or kidney problems.
- If you possibly suffer from dehydrated body (e.g. by sickness, diarrhea, before or after major surgery).
- If you are elderly.
- If you have swollen feet.
- If you have a bleeding disorder or other blood-related disorder (including a rare liver problem called porphyria).
- If you have been told that you have an intolerance (sensitivity) to some sugars.
- If you have recently had or will have a stomach or bowel surgery.

Please consult your doctor if the above warnings apply to you, even at any time in the past. Please inform your doctor if you are going to have a major surgery.

- Contact your doctor immediately if you experience signs or symptoms that indicate heart or blood vessel problems, such as chest pain, shortness of breath, weakness or slurred speech at any time while using DIKLORON SR.
- DIKLORON may reduce the symptoms of an infection (e.g. headache, high temperature) and may therefore make it more difficult to detect any other infection. If you feel unwell and need to see a doctor, remember to tell your doctor that you are using DIKLORON SR.
- Serious skin reactions have been reported in association with non-steroidal anti-inflammatory drug (NSAID) therapy. The risk of this type of reaction appears to be highest at the beginning of treatment. If you experience a skin rash including fever, mucous membrane lesions, blisters or other allergy symptoms, you should discontinue DIKLORON SR and seek immediate medical treatment, as these may be the first signs of a very severe skin reaction (see section "Possible side effects").
- There may be an increased risk of aseptic meningitis (inflammation of the membranes surrounding the brain and spinal cord, often caused by viruses) if you use this medicine while you have systemic lupus erythematosus (SLE) (a chronic inflammatory disease that affects many systems of the body) or another mixed connective tissue disease.

- If you have a history of stomach problems when using medications to relieve pain and inflammation (NSAIDs); especially if you are elderly; or if you notice any unusual symptoms, tell your doctor immediately.

If you get any of the symptoms described above, please inform your doctor immediately.

Using DIKLORON SR with food and drink
- Swallow DIKLORON SR tablet with a glass of water or another drink.
- Take DIKLORON SR tablet preferably at meal times.

Pregnancy
Ask your doctor or pharmacist before using this medicine.
Tell your doctor if you are pregnant or think you may be pregnant. Do not use DIKLORON SR during pregnancy unless it is essential and prescribed by a doctor. If you are taking this medicine during the first 6 months of pregnancy, the dose should be as low as possible and treatment should be as short as possible. Taking non-steroidal anti-inflammatory drugs (NSAIDs) after the 20th week of pregnancy can harm your unborn baby. If you need to use NSAIDs for more than 2 days, your doctor may need to monitor the amount of fluid around your baby in your womb.

As with other anti-inflammatory drugs, DIKLORON SR should not be used in the last 3 months of pregnancy as it could harm the kidney functions and circulation of the unborn baby and affect the birth as well as blood clotting in both mother and baby.

DIKLORON SR can make it difficult to get pregnant. If you are planning to become pregnant or if you have problems becoming pregnant, do not use DIKLORON SR unless necessary.

If you realize that you are pregnant during your treatment, contact your doctor or pharmacist immediately.

Breast-feeding
Ask your doctor or pharmacist before using this medicine.
If you are breast-feeding, tell your doctor.
If you are using DIKLORON SR, you should discontinue breast-feeding, as it could be harmful for your baby.

Driving and using machines
Patients using DIKLORON SR may experience rarely side effects such as visual disturbances, dizziness or drowsiness. If you notice such effects, you should not drive or use machines or perform any task requiring alertness. Call your doctor within the shortest possible time when you experience these effects.

Important information about some of the ingredients of DIKLORON SR
DIKLORON SR contains lactose and sucrose. If you have been told by your doctor that you are intolerant to certain sugars, talk to your doctor prior to use of this medicine.

Use of DIKLORON SR with other medicines
It is important to inform your doctor if you are using particularly the following medicines:
- Lithium (used for some psychological problems) or selective serotonin reuptake inhibitors (SSRIs) (medicines used to treat some types of depression)
- Cardiac glycosides (a group of medicines often used in heart failure)
- Digoxin (a medicine used for heart problems)
- Mifepristone (a medicine used to terminate unwanted pregnancy)
- Diuretics (water pills)
- ACE inhibitors or beta-blockers (medicines used to treat high blood pressure and heart failure)
- Other anti-inflammatory medicines (such as acetylsalicylic acid/aspirin or ibuprofen)
- Corticosteroids (cortisone and similar medicines used to provide relief for inflamed areas of the body)
- Blood thinners (warfarin and similar medicines used to prevent blood clotting)
- Medicines used to treat diabetes (such as metformin; except insulin)
- Methotrexate (a medicine used to treat some types of cancers or joint inflammation)
- Cyclosporine, tacrolimus (medicines primarily used in patients who have received organ transplants)
- Trimethoprim (a medicine used to prevent or treat urinary tract infections)
- Quinolone antibacterials (medicines used against infections)
- Voriconazole (a medicine used against fungal infections)
- Phenytoin (a medicine used to treat epilepsy)
- Colestipol and cholestyramine (medicines used to lower cholesterol)
- Rifampicin (an antibiotic used against bacterial infections)
- Oral steroids (used against inflammation and allergies, such as prednisolone)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. HOW TO USE DIKLORON SR
Carefully follow your doctor's instructions. Do not exceed the recommended dose and treatment duration.

Instructions for proper use and dose/frequency of administration
Do not exceed recommended dose. It is important that you use the lowest dose that controls your pain and that you do not use DIKLORON SR for longer than necessary.

Your doctor will tell you how many DIKLORON SR tablets you should take. Your doctor may advise a lower or a higher dose for you depending on your response to the treatment.

In adults:
The recommended daily dose for adults is usually 75-150 mg. In milder cases and long-term treatments, 75 mg per day is usually sufficient. DIKLORON SR is taken once or twice a day. Do not exceed 150 mg per day.

Where the symptoms are most pronounced during the night or in the morning, DIKLORON SR should preferably be taken in the evening.

Route and method of administration
DIKLORON SR should be swallowed as whole with a glass of water or other liquid. It is recommended to take DIKLORON SR during meals. Do not split or chew the tablets.

Different age groups
Use in children
DIKLORON SR should not be given to children and adolescents (under 18 years of age) due to its dose.

Use in elderly
Elderly patients may be more sensitive to the effects of DIKLORON SR than other adults may. Therefore, elderly patients should carefully follow their doctor's instructions particularly and use the lowest number of tablets, which provide relieve of complaints. It is extremely important for elderly patients to report any adverse effects promptly to their doctor.

Special use conditions
Kidney impairment
DIKLORON SR should not be used in patients with kidney impairment. No specific studies have been carried out in patients with kidney impairment; therefore, no specific dose adjustment recommendations can be made. If you have mild to moderate kidney impairment, you doctor will warn you to use DIKLORON SR carefully. Please ask your doctor.

Liver impairment
DIKLORON SR should not be used in patients with liver impairment. No specific studies have been carried out in patients with liver impairment; therefore, no specific dose adjustment recommendations can be made. If you have mild to moderate liver impairment, your doctor will warn you to use DIKLORON SR carefully. Please ask your doctor.

A known cardiovascular disease or the significant cardiovascular risk factors:
Treatment with DIKLORON SR is not recommended in patients with known cardiovascular diseases that are not under control or with high blood pressure that cannot be controlled. Since the risks of DIKLORON SR for cardiovascular diseases may increase with dose and duration of exposure, the lowest effective daily dose should be used for the shortest possible duration. Therefore, in the treatment of DIKLORON SR, the shortest possible treatment duration and the lowest effective dose should be preferred. Especially in treatments exceeding 4 weeks, the doctor should regularly re-evaluate your need to continue treatment with DIKLORON SR.

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

If you use more DIKLORON SR than you should
If you have accidentally taken more tablets than you have been told by doctor, immediately contact your doctor or pharmacist or go to the nearest hospital emergency department. You may need to seek a medical attention.
If you take too much DIKLORON SR, talk to your doctor or pharmacist.

If you forget to use DIKLORON SR
Do not take a double dose to make up for a forgotten dose.
If you forget to take a dose, take it as soon as you remember. However, if it is almost time for the next dose, take the next tablet when it is due.

4. POSSIBLE SIDE EFFECTS

As with all medicines, side effects may occur in people with sensitivity to ingredients of DIKLORON SR.

If any of the following occur, stop using DIKLORON SR and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:

- Sudden and oppressive chest pain (a sign of myocardial infarction or a heart attack).
- Breathlessness, difficulty breathing when lying down, swelling of the feet and legs (signs of cardiac failure).
- Sudden weakness or numbness in the face, arms, or legs, especially on one side of the body; sudden loss or impairment of vision; sudden difficulty in speaking or in the ability to understand speech; sudden migraine-like headaches occurring for the first time, with or without visual impairment. These symptoms may be an early sign of stroke.
- Abdominal pain, indigestion, heartburn, wind, nausea, or vomiting.
- Any signs of bleeding in stomach or intestines (e.g. blood in vomit, black or dark stools).
- Allergic reactions such as skin rash, itching, bruising, painful red areas, skin peeling or blistering.
- Wheezing or shortness of breath (bronchospasm: transient narrowing of the lower airways of the lungs).
- Swelling of the face, lips, hands or fingers.
- Yellowing of the skin or the white parts of the eyes.
- Persistent sore throat or high fever.
- An unexpected change in the amount and/or appearance of urine.
- Mild cramps and tenderness in the abdomen that begin shortly after the start of treatment with DIKLORON SR and are followed by rectal bleeding or bloody diarrhea, usually within 24 hours after the onset of abdominal pain.
- Stevens-Johnson syndrome (serious diseases characterized by blisters on the skin, mouth, eyes and genitals).

These are all very serious side effects. If you experience any of these, you may need emergency medical attention or hospitalization.

Side effects are listed as shown in the following categories:

Very common	: may affect at least 1 in 10 patients.
Common	: may affect less than 1 in 10 patients but more than 1 in 100 patients.
Uncommon	: may affect less than 1 in 100 patients but more than 1 in 1,000 patients.
Rare	: may affect less than 1 in 1,000 patients but more than 1 in 10,000 patients.
Very rare	: may affect less than 1 in 10,000 patients.
Not known	: cannot be estimated from the available data.

Other side effects:

Common

- Headache
- Dizziness
- Vertigo (dizziness caused by balance disorder)
- High blood pressure (hypertension)
- Vomiting
- Nausea
- Indigestion (a sign of dyspepsia)

- Diarrhea
- Abdominal pain
- Flatulence (gas)
- Loss of appetite
- Abnormal results of liver function tests (e.g. increased transaminase levels)
- Skin rash
- Excessive fluid accumulation in tissues and intercellular spaces (fluid retention and/or edema)

Uncommon
- A disease that often occurs with sudden chest pain and shortness of breath due to blockage in the vessels feeding the heart (heart attack, myocardial infarction).
- Heart failure (the heart becomes unable to pump enough blood to other organs and tissues; main complaints include shortness of breath, swelling in the feet and legs, fatigue)
- Palpitations
- Chest pain

Rare
- Difficulty in breathing and swallowing, skin rash, itching, hives, dizziness (hypersensitivity, anaphylactic and anaphylactoid reactions)
- Drowsiness
- Tiredness
- Sudden difficulty breathing and feeling of tightness in the chest accompanied by wheezing and cough (signs of asthma or pneumonia if there is fever)
- Vomiting blood (signs of hematemesis) and/or black or bloody stools (signs of gastrointestinal bleeding)
- Bloody diarrhea (signs of hemorrhagic diarrhea)
- Black stools (signs of melena)
- Stomach pain, nausea (signs of gastrointestinal ulcers, bleeding or perforation)
- Yellowing of the skin or eyes (sign of jaundice), nausea, loss of appetite, dark urine (signs of hepatitis [inflammation of the liver] / liver failure)
- Overall swelling (signs of edema)

Very rare
- Spontaneous bleeding or bruises (signs due to thrombocytopenia, i.e. a decrease in the cells called platelets that stop bleeding)
- High fever, frequently recurring infections, constant sore throat (signs of agranulocytosis, i.e. decreased number of some cells playing role in the defense of the body against infections)
- Low levels of red blood cells (a sign of anemia)
- Low levels of white blood cells (a sign of leukopenia)
- Swelling of the face and throat (signs of angioneurotic edema)
- Impaired perception of time, place and direction (disorientation)
- Depression
- Difficulty sleeping (a sign of insomnia)
- Nightmares
- Excessive sensitivity to stimuli (irritability)
- Disturbing thoughts or moods (signs of psychotic disorders)

- Tingling or numbness of the hands or feet (signs of paresthesia)
- Memory impairment
- Anxiety
- Seizure (a sign of convulsion)
- Shivering (tremor)
- Stiff neck, fever, nausea, vomiting, headache (signs of aseptic meningitis)
- Sudden and severe headache, nausea, dizziness, numbness, inability or difficulty to speak, weakness or paralysis of the limbs or face (signs of cerebrovascular accident or stroke)
- Taste disturbance (a sign of dysgeusia)
- Difficulty hearing (a sign of hearing impairment)
- Visual disorders* (signs of impaired vision, blurred vision and double vision)
- Tinnitus
- Constipation, sores in the mouth (signs of stomatitis [inflammation in the mouth])
- Rash, purplish-red spots, fever, itching (signs of vasculitis)
- Lung inflammation (pneumonitis)
- Diarrhea, abdominal pain, fever, nausea, vomiting (signs of colitis, including hemorrhagic colitis, and exacerbation of ulcerative colitis or Crohn's disease)
- Swelling, redness and pain of the tongue (signs of glossitis [inflammation of the tongue])
- Defect in the tube that carries food from the throat to the stomach (esophagus disorder)
- Pain in the upper abdomen, especially after meals (a sing of intestinal diaphragm disease)
- Severe pain in the upper abdomen (a sign of pancreatitis)
- Flu-like symptoms, feeling tired, muscle aches, high liver enzymes in blood test results (sings of liver disorders including fulminate hepatitis, liver necrosis, liver failure)
- Blistering of the skin (a sign of bullous dermatitis)
- Itchy, red and burning skin rashes (signs of eczema)
- Skin redness (erythema)
- Red or purple skin (possible signs of blood vessel inflammation), skin rash with blisters, blistering of the lips, eyes and mouth, skin inflammation with flaking or peeling (signs of erythema multiform or Stevens Johnson syndrome if there is fever or toxic epidermal necrolysis [Lyell's syndrome])
- Rashes with flaking or peeling of the skin (signs of exfoliative dermatitis)
- Hair loss (alopecia)
- Increased skin sensitivity to the sun (a sign of photosensitivity)
- Purple spots on skin (signs of purpura if caused by allergy or purpura Henoch-Schonlein)
- Itching (pruritus)
- Detection of blood in the urine (hematuria)
- Swelling, feeling of weakness or abnormal urination (signs of acute kidney failure)
- Excessive amount of protein in the urine (a sign of proteinuria)
- Swelling of the face or stomach, high blood pressure (signs of nephrotic syndrome)
- High or low urine output, drowsiness, confusion, nausea (signs of tubulointerstitial nephritis)
- Severe decrease in urine output (a sign of renal papillary necrosis)
- Impotence

*Visual disorders: If signs of visual disorders occur during treatment with DIKLORON SR, an eye examination may be required to exclude other causes, consult your doctor.

Not known
- Confusion
- Hallucination (the situation of perceiving non-real objects, sounds or images as if they exist, which may occur due to neurological or mental diseases)
- Sensory disorders (impairment in the perception of taste, vision, hearing, touch and smell)
- Weakness
- Coincident occurrence of chest pain and allergic reactions (signs of Kounis syndrome)
- Inflammation of the optic nerve (the main symptom is blurred vision)
- Circulatory disorder in the large intestine (may cause nausea, vomiting, abdominal pain, defecation problems and bleeding; it may develop due to conditions such as aging, diabetes, heart failure, abdominal surgery or radiation therapy)
- A serious skin reaction known as DRESS syndrome (Drug Rash with Eosinophilia and Systemic Symptoms) may occur. DRESS symptoms include skin rash, fever, swollen lymph nodes, and an increase in eosinophils (a type of white blood cell).

Tell your doctor if you experience any of these side effects.

If you have been taking DIKLORON SR for more than a few weeks, you must visit your doctor for regular check-ups to ensure you are not suffering from unnoticed side effects.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE DIKLORON SR

Keep DIKLORON SR out of the reach and sight of children and in its original container.
Store at room temperature below 25°C.

Use it in line with the expiry date.
Do not use DIKLORON SR after the expiry date, which is stated on the pack.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Marketing Authorization Holder:
DEVA Holding A.Ş.
Küçükçekmece – İSTANBUL / TÜRKİYE

Manufacturing Site:
DEVA Holding A.Ş.
Kapaklı – TEKİRDAĞ / TÜRKİYE

This package leaflet was last approved on 15/03/2024.