PACKAGE LEAFLET

DIKLORON 75 mg / 3 ml Solution for IM Injection
Applied into the muscle.
Sterile

Active Substance: Each 3 ml solution for injection (total volume) contains 75 mg diclofenac sodium.
Excipients: Mannitol, sodium metabisulphite, benzyl alcohol, propylene glycol, sodium hydroxide, water for injection.

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 lower** dose other than recommended to you.*

In this leaflet:

1. WHAT IS DIKLORON AND WHAT IS IT USED FOR

- DIKLORON 75 mg/3 ml with the active ingredient diclofenac sodium is presented as an ampoule containing solution for IM injection.
- DIKLORON belongs to a group of medicines called “non-steroid anti inflammatory drugs” (NSAID) which are used for the treatment of pain and inflammation
- It is presented in packs of 4, 10 or 100 ampoules of 3 ml.

DIKLORON intramuscular injection is used to treat a number of painful conditions including:
- The treatment of symptoms and signs of calcification (osteoarthritis), painful and deformed joints (rheumatoid arthritis)
- The treatment of painful progressive rheumatism characterized by stiff joints of neck, back and rib cage (ankylosing spondylitis)
- The treatment of joint inflammation due to acute gout (acute gouty arthritis),
- The treatment of acute musculoskeletal pain, pain after surgery (post-operative pain) and painful menstruation (dysmenorrhea)

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

2. BEFORE YOU USE DIKLORON

Follow all directions given to you by your doctor or pharmacist carefully. These instructions may differ from the information contained in this leaflet.

DO NOT use DIKLORON, if:

- You are allergic to diclofenac, sodium metabisulphite (or other sulphite) or any of the other ingredients of DIKLORON (listed at beginning of this leaflet).
- You ever had allergic symptoms or signs after taking medicines to treat inflammation or pain (e.g. acetylsalicylic acid/aspirin, diclofenac or ibuprofen). These reactions may include asthma, runny nose, skin rash, and face swelling. Severe, rarely fatal clinical reactions to non-steroidal anti-inflammatory drugs (NSAIDs) have been reported in these patients. Ask your doctor if you think you may be allergic.
- You have had coronary artery surgery (cardiovascular operation, bypass etc.), for the treatment of pain before or after the surgery.
- You have stomach or duodenal ulcer (wound)
- You have bleeding or perforation in the digestive tract, the symptoms may include bloody or black stool
- You have severe kidney or liver disease
- You have severe heart failure
- You are in the last 3 months of pregnancy

Please talk to your doctor before using DIKLORON, even if these warnings apply to you 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 may be allergic.

TAKE SPECIAL CARE with DIKLORON

- Patients with significant risk factors for cardiovascular disease (such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, and smoking) should only be treated with diclofenac after careful consideration. In particular, this risk is increased at high doses (150 mg daily) and in long term treatment. The lowest effective dose should therefore be used for the shortest possible duration treatment with diclofenac. Health care personnel should regularly revaluate the necessity of continuation of diclofenac treatment.
- If you have established disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure (the heart cannot pump enough blood to meet body needs), established 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), treatment with DIKLORON is generally not recommended. If you have established 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 or not.
- It is generally important to take the lowest dose of DIKLORON 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 simultaneously with other anti-inflammatory medicines (acetylsalicylic acid/aspirin, corticosteroids (cortisone and -like medicines), “blood thinners” and depression medicines classified as selective serotonin reuptake inhibitors) (see “Using other medicines”).

- If you have asthma or hay fever (seasonal allergic rhinitis).
- If you previously have stomach problems such as stomach ulcer, stomach bleeding or black stool or you suffered from stomach problems or heartburn after you take anti-inflammatory medicines.
- If you have inflammation of colon (ulcerative colitis) or inflammation of bowel (Crohn's disease)
- If you have liver or kidney problems
- If you may be dehydrated (e.g. by sickness, diarrhea, before or after major surgery)
- If you have swollen feet
- If you have a bleeding disorder or other blood-related disorders (including a rare liver problem called porphyria)
- If you have connective tissue disorders or a similar disease

If these warnings are valid for you, even for a period in the past, please consult your doctor.

- If, at any time while taking DIKLORON you experience any signs or symptoms, which may point to heart or blood disorders such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately.
- 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.
- In very rare cases, DIKLORON, like other anti-inflammatory medicines, may cause severe allergic reactions (e.g. rash).

If any of the above applies to you, immediately tell your doctor.

Using DIKLORON with food and drink
Not applicable.

Pregnancy
Consult your doctor or pharmacist before taking this medicine.
If you are pregnant or you think you may be, tell your doctor.
You should not use DIKLORON during pregnancy unless it is essential.

As with other anti-inflammatory drugs, DIKLORON should not be used in the last three months of pregnancy as it could harm your unborn baby or cause problems at delivery.

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

Breast-feeding
Consult your doctor or pharmacist before taking this medicine.
If you are breast-feeding, tell your doctor.

If you are using DIKLORON, you should discontinue breast-feeding, as it could be harmful for your baby.

Driving and using machines
Patients using DIKLORON may experience rarely side effects such as visual disturbances, dizziness or somnolence. If you experience any of these, you should not drive or use machinery 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
DIKLORON contains sodium metabisulphite. It may rarely cause hypersensitivity reactions and bronchospasm.

DIKLORON contains benzyl alcohol. DIKLORON must not be given to premature babies or neonates. It may cause toxic reactions and allergic reactions in infants and children up to 3 years of age.

DIKLORON contains less than 1 mmol (23 mg) sodium per 1 ml of solution, i.e. sodium free.

Use of DIKLORON with other medicines
It is important to inform your doctor if you are using particularly the following medicines:
- Lithium or selective serotonin reuptake inhibitors (SSIRs); (medicines used to treat some types of depression)
- Digoxin (medicine used for heart problems)
- Mifepristone (medicine used to terminate pregnancy)
- Diuretics (water tablets)
- 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 (Medicines used for the relief of inflamed areas of the body)
- Blood thinners (warfarin and similar medicines used to prevent blood clotting)
- Medicines used to treat diabetes (except insulin)
- Methotrexate (medicine used to treat types of joint inflammation and some types of cancers)
- 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 for infections)
- Voriconazole (a medicine used for fungal infections)
- Phenytoin (a medicine used to treat seizures)
- Colestipol and cholestyramine (medicines used to lower cholesterol).

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

Follow your doctor's instructions carefully. Do not exceed 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 for longer than necessary.

Your doctor will tell you how many DIKLORON injections you will receive. Your doctor may advise a higher or dose lower dose depending on your response to your treatment.

In adults
In adults, 1 ampoule given daily for 2 days at the most, in some cases, 2 ampoules may be given a day. If necessary, treatment can be continued with DIKLORON tablet or suppositories.

Route and method of administration
The solution is drawn from the ampoule into a syringe and injected deep into buttock muscle.

Different age groups

Use in children and adolescents
DIKLORON should not be given to children and adolescents (below 18 years of age).

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

Special populations

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

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

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

If you are given more DIKLORON than you should
If you have been administered more DIKLORON than you should, immediately contact your doctor or pharmacist or go to the nearest hospital emergency department. You may need medical attention.

If you have used too much DIKLORON, talk to your doctor or pharmacist.

If you forget to use DIKLORON
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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DIKLORON can cause side effects in patients with hypersensitivity to its ingredients.

Some side effects could be serious
These common side effects may affect between 1 and 10 in every 1000 patients, particularly when high daily dose (150 mg) is used for long periods of time.
- Sudden and oppressive chest pain (sign of myocardial infarction or a heart attack)
- Breathlessness, difficulty breathing when lying down, swelling of the feet and legs (signs of cardiac failure)
- Stomach pain, indigestion, heartburn, wind, nausea, vomiting
- Any sign of bleeding in stomach or intestine (blood in vomit, black or tarry stools)
- Allergic reactions which can include skin rash, itching, bruising, painful red areas, skin peeling or blistering
- Swollen face, lips, hands or fingers
- Yellowing of skin or the whites of eyes
- Persistent sore throat or high fever
- An unexpected change in the amount of urine or its appearance

Common side effects (May affect 10 in 100 patients)
- Headache,
- Dizziness
- Vertigo (dizziness caused by balance disorder)
- Nausea
- Vomiting
- Diarrhea
- Indigestion difficulty (sign of dyspepsia)
- Abdominal pain
- Flatulence
- Loss of appetite
- Abnormal results of liver function tests (e.g. increased transaminase levels)
- Skin rash
- Injection site reaction, pain and induration
- Application site irritation
- Stomach pain

Rare side effects (May affect between 1 and 10 in every 10,000 patients)
- Spontaneous bleeding or bruising (signs of thrombocytopenia, decrease in the numbers of platelets in the blood that stop bleeding)
- High fever, frequent infections, persistent sore throat (signs of agranulocytosis, decreased number of some cells playing role in the defense of the body against infections)
- Difficulty in breathing and swallowing, skin rash, itching, hives, vertigo (hypersensitivity, anaphylactic and anaphylactoid reactions)

- Sudden difficulty of breathing and feeling of tightness in chest with wheezing or coughing (signs of asthma or a type of inflammation of lung called pneumonitis if there is fever).
- Sudden and severe headache, nausea, dizziness, numbness, inability or difficulty to speak, weakness or paralysis (stroke) on lips and face (signs of cerebral attack, convulsions)
- Stiff neck, fever, nausea, vomiting, headache (sign of aseptic meningitis, inflammation of the membranes that cover the brain)
- Vomiting blood (sign of hematemesis) and/or black or bloody stools (signs of bleeding of stomach- intestine)
- Bloody diarrhea (signs of bloody diarrhea)
- Black stools (signs of melena, bowel bleeding)
- Stomach pain, nausea (signs of stomach-bowel ulcer)
- Yellowing of the skin or the eyes (sign of jaundice), nausea, loss of appetite, dark urine (sign of hepatic (inflammation of liver)/liver failure)
- Drowsiness (sign of sleepiness)
- Stomach pain (sign of gastritis)
- Liver failure
- Itchy skin rash (signs of urticaria [hives])
- Overall swelling (signs of edema)
- Administration site necrosis
- Pain in large bowel (sometimes with bleeding and discharge)

Very rare side effects (May affect less than 1 in every 10,000 patients)

- Swelling mainly of the face and throat (signs of angioedema)
- Seizure (signs of convulsion)
- Headache, dizziness (signs of hypertension)
- Skin rash, purplish-red spots, fever, itching (signs of vasculitis [inflammation of blood vessels])
- Diarrhea, stomach pain, fever, nausea, vomiting (signs of colitis including hemorrhagic colitis [inflammation of large bowel] and exacerbation of ulcerative colitis or Crohn's disease)
- Severe upper stomach pain (signs of inflammation of the pancreas)
- Flu-like symptoms, feeling tired, muscle pain, increased level of liver enzyme in blood test results, (sings of liver disorders including fulminate hepatitis, liver necrosis, liver failure)
- Blistering of the skin (signs of bullous dermatitis)
- 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 (inflammation characterized by swelling, redness and blood accumulation in the skin and around the eyes) or toxic epidermal necrolysis (a serious illness with blistering of the skin))
- Skin rash with flaking or peeling of the skin (signs of exfoliative dermatitis)
- Increased skin sensitivity to sun (signs of photosensitivity)
- Purple spots on skin (purpura or signs of purpura Henoch-Schonlein if caused by allergy)
- Swelling, feeling of weakness or abnormal urination (signs of acute kidney failure)
- Excessive amount of protein in the urine (signs of proteinuria)
- Swelling of the face or stomach, high blood pressure (signs of nephrotic syndrome)
- Increase or decrease the amount of urine, drowsiness, confusion, nausea (signs of tubule-interstitial nephritis)

- Seriously reduce the amount of urine (sign of renal papillary necrosis)
- Decreased number of red blood cells (sign of anemia)
- Low white blood cells (sign of leucopenia)
- Impaired perception of time, place and direction (Disorientation)
- Depression
- Difficulty sleeping (sign of insomnia)
- Nightmares
- Excessive sensitivity to stimuli
- Disturbing thoughts or moods (sign of psychotic disorders)
- Tingling or numbness of the hands or feet (sign of paresthesia)
- Memory weakness (sign of memory disorder)
- Anxiety, Shaking (tremor)
- Taste disturbance (signs of dysgeusia)
- Difficulty hearing (sign of hearing impairment)
- Visual disturbance (signs of impaired vision, blurred vision, double vision)
- Tinnitus
- Constipation, mouth wounds (sign of stomatitis [inflammation of inner mouth])
- Swelling, redness and pain of the tongue (sign of glossitis [inflammation of the tongue])
- Esophageal disorder
- Pain in the upper abdomen, especially after meals (sings of intestinal diaphragm disease)
- Palpitations
- Chest pain
- Itchy, red, burning skin rash (signs of eczema)
- Skin redness (erythema)
- Hair loss (alopecia)
- Itching (pruritus)
- Blood in the urine (hematuria)
- Injection site pus (abscess)

Tell your doctor if you experience any of these side effects.
If you take DIKLORON for more than a few weeks, you should make sure to visit your doctor for regular check-ups, to ensure that you are not suffering from unnoticed undesirable 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

Keep DIKLORON out of the reach and sight of children and in its original package.
Store at room temperature below 25°C. Protect from light.

Use it in line with the expiry date.
Do not use DIKLORON 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.
Kartepe – KOCAELİ / TÜRKİYE

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