

DIFENAK 100 mg Enteric Coated Tablet
Diclofenac Sodium

1. Administrative Information

1.3 Summary of Product Characteristics, Labeling and Instructions for Medical Use
PATIENT INFORMATION LEAFLET

DIFENAK 100 mg enteric-coated tablet

For oral use.

- **Active ingredient:** Each enteric-coated tablet contains 100 mg of diclofenac sodium.
- **Excipients:** Microcrystalline cellulose, colloidal silica, magnesium stearate, polyvinylpyrrolidone, methocell (HPMC E-15 CP), instacoat enteric (titanium dioxide (E171), red iron oxide (E172)), PEG 400 and deionized water.

Read all of this 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, please ask to your doctor or pharmacist.*
- *This medicine is prescribed only for you. Do not pass it on to others.*
- *If you visit a doctor or hospital during usage of this medicine, please give information to your doctor that you are taking this medicine.*
- *Please strictly follow instructions in this prescribing leaflet. Do not take lower or higher dose than recommended dose.*

In this Instructions for Use:

- 1. What DIFENAK is and what it is used for?**
- 2. What you need to know before you take DIFENAK.**
- 3. How to use DIFENAK?**
- 4. What are possible side effects?**
- 5. How to store DIFENAK?**

Headings are included.

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

- DIFENAK is presented as a brick red, round, enteric coated tablet with both sides slightly bent outwards.
- Each tablet contains 100 mg of active substance (diclofenac sodium).

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- DIFENAK belongs to a group of drugs called “non-steroidal anti-inflammatory drugs” (NSAIDs) used in the treatment of pain and inflammation.
- Available in packages of 10 and 30 tablets.

DIFENAK can be used to treat the following conditions:

Treatment of the signs and symptoms of calcification (osteoarthritis), pain and deformity in the joints (rheumatoid arthritis) and painful progressive rheumatism (ankylosing spondylitis) with stiffness in the joints of the back, neck and rib cage, and acute gout-related joint inflammation (acute gouty arthritis), acute muscle- It is indicated for the treatment of skeletal system pain, post-operative pain (postoperative pain), and painful menstruation (dysmenorrhea).

If you have any questions about how DIFENAK works or why it is given to you, please consult your doctor.

2.2. What you need to know before you take DIFENAK.

Carefully follow all instructions given by your doctor or pharmacist. This information may differ from the general information contained in this leaflet.

DO NOT USE DIFENAK in the following situations

If,

- If you are allergic to Diclofenac or any of the other components of Diclofenac listed at the beginning of this leaflet,
- If you have experienced signs and symptoms of an allergy after taking medications previously used to treat inflammation or pain (eg acetylsalicylic acid/aspirin, Diclofenac or ibuprofen). These may include asthma (shortness of breath due to narrowing of the airways in the lungs, coughing wheezing), runny nose, skin rash, facial **swelling**. It has been reported that in these patients, severe, rarely fatal, swelling of the tongue called anaphylaxis, shortness of breath, low blood pressure and skin rashes may occur with non-steroidal anti-inflammatory drugs (NSAIDs). If you think you have allergies, consult your doctor.
- If you have had coronary artery surgery (such as cardiovascular surgery by-pass), in the treatment of pain before, during and after the operation,
- If you have stomach or intestinal ulcers,
- If you have bleeding or perforation in the gastrointestinal tract, bloody or black stools may be among the symptoms that occur in such cases,
- If you have severe kidney or liver disease,
- If you have severe heart failure,

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- If there is narrowing of the vessel that provides oxygenation and blood supply to the heart (ischemic heart disease),
- If you have narrowing of the arteries, resulting in insufficient blood supply to the area supplied by the vein (peripheral artery disease) and/or a disease that disrupts the supply of the brain (cerebrovascular disease) and/or a defined heart disease (eg if you have had a heart attack),
- If you are in the pregnancy and breastfeeding period,
- If you are likely to become pregnant and do not use an effective method of contraception,
- If you are under the age of 18
- If there is a situation where the muscle or muscles cannot function (contract).

If these warnings apply to you even at any time in the past, consult your doctor before using DIFENAK. Your doctor will decide if this medicine is right for you.

If you think you have allergies, consult your doctor.

USE DIFENAK CAREFULLY in the following situations

- Diclofenac treatment should only be started after careful evaluation in patients with important risk factors for cardiovascular system diseases (for example, high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, smoking). It has been observed that this risk increases especially in high-dose use (150 mg daily) and in long-term treatments. Therefore, in the treatment of diclofenac, the shortest possible duration of treatment and the lowest effective dose should be preferred. Healthcare professionals should regularly reassess the need for patients to continue diclofenac therapy.
- If you have a known heart or blood vessel disease [as well as uncontrolled high blood pressure, congestive heart failure (the heart cannot pump enough blood to meet the body's needs), known ischemic heart disease (narrowing of the blood vessels that supply the heart's oxygenation and blood supply), or peripheral arterial disease (narrowing of the arteries) and, as a result, insufficient blood supply to the area fed by the vein) is defined as cardiovascular system disease.] Treatment with DIFENAK is generally not recommended. (If you have known heart disease or are at risk of heart disease, and especially if you are being treated for more than 4 weeks, your doctor will reassess whether you should continue your treatment with DIFENAK.)
- In order to keep your risk of cardiovascular side effects as low as possible, it is generally important to take the lowest dose of DIFENAK separately and/or for the shortest period of time that relieves your swelling.
- If you are taking DIFENAK concomitantly with other anti-inflammatory drugs (including acetylsalicylic acid/aspirin, corticosteroids, "blood thinners" and antidepressants called SSRIs) (see "Concomitant use with other drugs").

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- If you have asthma or hay fever (seasonal allergic rhinitis).
- 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 the colon (ulcerative colitis) or inflammation of the intestinal tract (Crohn's disease).
- If you have liver or kidney problems.
- If you are likely to be dehydrated (eg illness, diarrhoea, before or after major surgery).
- If your feet are swollen
- If you have a bleeding disorder or other blood-related disorders (including a rare liver problem called porphyria).
- If you have connective tissue diseases or similar ailments.
- If the above warnings apply to you, even at any time in the past, please consult your doctor.
- Call your doctor right away if at any time you experience signs and symptoms that indicate problems with the heart or blood vessels, such as chest pain, shortness of breath, weakness or slurred speech, while taking DIFENAK.
- DIFENAK may alleviate the symptoms of an infection (eg headache, high fever) and thus make it difficult to detect and adequately treat the infection. If you feel unwell and need to see a doctor, do not forget to tell your doctor that you are using DIFENAK
- In very rare cases, DIFENAK, like other anti-inflammatory drugs, can cause severe allergic reactions (eg rash).

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

Using DIFENAK with food and drink

- DIFENAK should be swallowed with a glass of water or other liquid.
- It is recommended to use DIFENAK during meals.

Pregnancy

Consult your doctor or pharmacist before using this medication.

If you are pregnant or think you may be pregnant, tell your doctor.

Unless absolutely necessary, you should not use DIFENAK during pregnancy.

As with other anti-inflammatory drugs, DIFENAK should not be used during the last three months of pregnancy as it may harm your unborn child or cause problems during delivery.

DIFENAK may make it difficult to become pregnant. If you are planning to become pregnant or have problems conceiving, you should not use DIFENAK unless necessary.

Breast-feeding

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Consult your doctor or pharmacist before using this medication.

If you are breastfeeding your baby, tell your doctor.

If you are taking DIFENAK you should not breast-feed your baby as this may be harmful to your baby.

Vehicle and machine use

Rarely, side effects such as visual disturbances, drowsiness or drowsiness may occur in patients using DIFENAK enteric-coated tablets. If you notice such effects, you should not drive, use machines, or engage in other activities that require your attention. If you experience such an effect, inform your doctor as soon as possible.

Important information about some excipients in the content of DIFENAK

There is no adverse effect due to the excipients used in this medicine.

Concomitant use with other drugs

It is especially important to tell your doctor if you are taking any of the following medicines:

- Lithium or selective serotonin reuptake inhibitors (SSRIs); (drugs used to treat certain types of depression).
- Digoxin (a medicine used for heart problems).
- Mifepristone (a medicine used to terminate unwanted pregnancies).
- Diuretics (diuretic drugs).
- ACE inhibitors or beta-blockers (classes of drugs used to treat high blood pressure and heart failure).
- Other anti-inflammatory drugs (such as acetylsalicylic acid/aspirin or ibuprofen)
- Corticosteroids (cortisone and similar drugs used to provide relief in areas of the body affected by inflammation).
- “Blood thinners” (warfarin and similar drugs used to prevent blood clotting)
- Drugs used in the treatment of diabetes (except insulin).
- Metotrexat (bazı kanser ya da artrit türlerinin tedavisinde kullanılan bir ilaç).
- Cyclosporine, tacrolimus (drugs used especially in organ transplant patients).
- Trimethoprim (used to prevent and treat urinary tract infections).
- Quinolone derivative antibacterial drugs (Some drugs used against infection).
- Vorikanozole (a drug used in fungal infections)
- Phenytoin (a drug used to treat seizures)
- Colestipol and cholestyramine (drugs used to lower cholesterol).

Please inform your doctor or pharmacist if you are currently using or have recently used any prescription or non-prescription medicine.

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3. How to use DIFENAK?

Carefully follow the instructions given by your doctor. Do not exceed the recommended dose and duration of treatment.

Instructions for proper use and dose/frequency of administration:

Do not exceed the recommended dose. It is important that you use the lowest dose that can control your pain and that you do not take DIFENAK for longer than necessary.

Your doctor will tell you exactly how many DIFENAK to take. Depending on your response to treatment, your doctor may recommend a higher or lower dose.

In adults:

If the complaints are more intense at night or in the morning, DIFENAK should preferably be taken in the evening.

Application route and method:

DIFENAK should be swallowed whole with a glass of water or other liquid. It is recommended to take DIFENAK during meals. Do not split or chew the tablets.

Different age groups:

Use in children and adolescents:

DIFENAK should not be given to children and adolescents (under 18 years of age) due to its dosage.

Use in the elderly:

Elderly patients may be more sensitive to the effects of DIFENAK than other adults. For this reason, the elderly should pay special attention to following the doctor's instructions and use the minimum amount of tablets necessary to alleviate the complaints. It is extremely important for elderly patients to report undesirable effects to their doctor immediately.

Kidney failure:

DIFENAK should not be used in patients with renal insufficiency. No dose adjustment recommendations can be made as studies in patients with renal impairment are not available. If you have mild and moderate renal failure, your doctor will warn you about the careful application of DIFENAK. Please consult your doctor.

Liver failure:

DIFENAK should not be used in patients with hepatic impairment. Since studies in patients with hepatic impairment are not available, recommendations for dose adjustment cannot be made any suggestion. If you have mild or moderate hepatic impairment, your doctor will warn you about the careful administration of DIFENAK. Please consult your doctor.

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

If you use more DIFENAK than you should:

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If you accidentally take more tablets than your doctor has told you, contact your doctor or pharmacist immediately, or go to a hospital emergency department. You may need to seek medical care.

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

If you forget to use DIFENAK:

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

If you forget to take a dose, take it as soon as you remember. However, if this time is close to the time of your next dose, simply take the next tablet on time.

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 DIFENAK.

If you get any of the following side effects after taking DIFENAK, stop taking them and seek urgent medical advice IMMEDIATELY:

- Sudden and pressing chest pain (signs of myocardial infarction and heart attack).
- Breathlessness, difficulty breathing when lying down, swelling of the feet and legs (signs of cardiac failure).
- Abdominal pain, indigestion, heartburn, gas, nausea, vomiting.
- Any signs of bleeding in the stomach and intestines (blood in the vomit, black and dark stools)
- Allergic reactions, including skin rashes, itching, bruising, painful red areas, skin peeling or blisters
- Swelling of the face, lips, hands or fingers
- Yellowing of the skin or the whites of the eyes
- Constant sore throat or high fever
- Unexpected change in the amount or appearance of urine

All these are serious side effects. If you have any of these symptoms, you may need emergency medical attention or hospitalization.

Side effects are classified as shown in the following categories:

Very common:	May occur in at least 1 in 10 patients.
Common:	Less than 1 in 10 patients, but more than 1 in 100 patients
Uncommon:	Less than 1 in 100 patients, but more than 1 in 1,000 patients.
Rare:	Less than 1 in 1,000 patients, but more than 1 in 10,000 patients.

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Very rare: Less than 1 in 10,000 patients.

Not known: Cannot be estimated from the available data.

Common

- Headache,
- Feeling dizzy,
- Vertigo (dizziness caused by balance disorder),
- Nausea,
- Vomiting,
- Diarrhea,
- Digestive difficulty (symptom of dyspepsia (dyspepsia, digestive disorder)),
- Abdominal pain,
- Gas,
- Loss of appetite,
- Abnormal liver function test results (eg, elevated transaminase levels),
- Skin rash.

Rare

- Spontaneous bleeding or bruises (thrombocytopenia, symptoms due to a decrease in the cells called platelets that stop bleeding),
- High fever, frequent infections, constant sore throat (agranulocytosis, symptoms due to the decrease of some cells that play a role in the body's defense against infections),
- Difficulty in breathing and swallowing, skin rash, itching, hives, dizziness (hypersensitivity, anaphylactic and anaphylactoid reactions),
- Sudden difficulty in breathing and chest tightness with wheezing and coughing (signs of asthma or a type of lung inflammation called pneumonitis if fever is present),
- Sudden and severe headache, nausea, drowsiness, inability to speak or difficulty speaking, weakness or facial paralysis of the lips (symptoms of cerebrovascular accident or stroke).
- Stiff neck, fever, nausea, vomiting headache (a sign of meningitis called aseptic meningitis).
- Vomiting blood (signs of hematemesis) and/or black or bloody stools (signs of gastrointestinal bleeding),
- Bloody diarrhea (signs of bleeding diarrhea),
- Black stools (signs of intestinal bleeding called melena),
- Stomach pain, nausea (signs of gastrointestinal ulcer),
- Yellowing of the skin or eyes (signs of jaundice), nausea, loss of appetite, dark urine (hepatitis [liver inflammation] / signs of liver failure),

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- Dizziness (symptom of sleepiness),
- Stomach pain (sign of gastritis),
- Liver disorder,
- Itchy skin rash (signs of urticaria [hives]),
- General swelling (signs of edema),
- Necrosis at the application site,
- Pain in the large intestine (sometimes with bleeding and voiding/discharge).

Very rare

- Swelling, especially of the face and throat (signs of angioedema),
- Convulsion (symptoms of convulsions),
- Headache, dizziness (symptoms of hypertension or high blood pressure),
- Skin rash, purplish red patches, fever itching (signs of vasculitis [inflammation of blood vessels]),
- Diarrhea abdominal pain, fever, nausea, vomiting (signs of colitis including hemorrhagic colitis (inflammation of the large intestine) and exacerbation of ulcerative colitis or Crohn's disease),
- Severe pain on the stomach (signs of pancreatic inflammation),
- Flu-like symptoms, feeling tired, muscle aches, increased liver enzymes in blood test results (signs of liver disorder including fulminant hepatitis, liver necrosis, liver failure),
- Blistering on the skin (signs of bullous dermatitis),
- Red or purple skin color (possible signs of vascular inflammation), blistering skin rash, blistering of the lips, eyes and mouth, skin inflammation with scaling or peeling (erythema multiforme or Stevens-Johnson syndrome (blood on the skin and around the eyes if you have a fever) sitting, swelling, redness) or toxic epidermal necrolysis (a serious disease with fluid-filled blisters on the skin),
- Skin rash with flaking or peeling (signs of exfoliative dermatitis),
- Increased sensitivity of the skin to the sun (signs of a photosensitivity reaction),
- Purple skin patches (signs of Henoch-Schonlein purpura if caused by purpura or allergies),
- Bloating, feeling weak or abnormal urination (signs of acute kidney failure),
- Excessive amount of protein in the urine (signs of proteinuria),
- Swelling of the face and abdomen, high blood pressure (signs of nephrotic syndrome),
- High or low urine output, drowsiness, confusion, nausea (signs of tubulointerstitial nephritis),
- Severe decrease in urine output (signs of renal papillary necrosis),
- Low red blood cell level (sign of anemia),
- Low white blood cell level (sign of leukopenia),

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- Distortion in perception of time, place and direction (Disorientation)
- Depression,
- Difficulty sleeping (symptom of insomnia),
- Having nightmares,
- Hypersensitivity to stimuli, ability to react (irritability),
- Disturbing thoughts or mood (symptoms of psychotic disorder),
- Tingling or numbness in the hands or feet (sign of paresthesia),
- Memory impairment (signs of memory impairment),
- Anxiety,
- Tremor,
- Impairment of the sense of taste (symptoms of dysgeusia),
- Difficulty in hearing (sign of hearing impairment),
- Visual disturbances (vision disorder, blurred vision, double vision symptoms),
- Tinnitus,
- Constipation, sores in the mouth (symptoms of stomatitis [inflammation in the mouth]),
- Swelling, redness and pain in the tongue (signs of glossitis [tongue inflammation]),
- Defect in the pipe that carries the food from the throat to the stomach (esophageal disorder),
- Upper abdominal pain especially after eating (sign of intestinal diaphragm disease),
- Palpitations,
- Chest pain,
- Itchy, red and burning rash (eczema symptoms),
- Redness (erythema) on the skin,
- Hair loss (alopecia),
- Itching (pruritus)
- Detection of blood in the urine (hematuria),

If you notice any of these side effects, tell your doctor.

If you have been taking DIFENAK for more than a few weeks, you should have regular check-ups with your doctor to make sure you don't have undesirable effects.

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

Reporting of side effects

Talk to your doctor, pharmacist or nurse in case of any side effects that are included or not in the instructions for use. Also, report the side effects you encounter to the Turkish Pharmacovigilance Center (TÜFAM) by clicking on the "Drug Side Effects Reporting" icon on www.titck.gov.tr or by calling the side effect reporting line on 0 800 314 00 08. By

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reporting the side effects that occur, you will contribute to obtaining more information about the safety of the drug you are using.

5. How to store DIFENAK

Keep DIFENAK out of the sight or reach of children and in its package.

Store at room temperature below 30°C.

Keep it in its original packaging.

Use in accordance with expiration dates.

Do not use DIFENAK after the expiry date on the package.

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

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization.

License owner: Terra İlaç ve Kimya San. Tic.A.Ş.
Ümraniye/İstanbul

Production place: Myfarma İlaç San. Tic. A.Ş.
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