

Diclofenac natrium 25 mg enteric-coated tablets , 50 mg enteric-coated tablets ,75 mg sustained-release tablets , 100 mg sustained-release tablets, 25 mg suppositories , 50 mg suppositories ,100 mg suppositories

What is diclofenacnatrium and what is it used for?

Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) used to treat pain and inflammation. It relieves symptoms of inflammation such as pain, swelling, and fever. It does not treat the underlying cause of inflammation or fever. In adults, diclofenac can be used for conditions including rheumatism, joint pain, stiff shoulder, postoperative pain, and severe menstrual pain. For infectious diseases accompanied by fever, especially for short-term use as an adjunct to chemotherapy.

Diclofenacnatrium Retard 75 mg and 100 mg sustained-release tablets are not suitable for acute indications or when rapid pain relief is desired.

Diclofenac suppositories and 25 mg tablets can be used in children for the following conditions: Symptomatic, short-term treatment of: Pain caused by inflammation of the ear, nose, or throat. Pain after minor surgical procedures.

When should you not use this medicine or be extra cautious?

- If you think you are allergic to diclofenac sodium, aspirin, ibuprofen, or any other NSAID, or to any of the ingredients in this medicine. Signs of an allergic reaction may include swelling of the face and mouth (angioedema), breathing difficulties, chest pain, runny nose, skin rash, or other allergic reactions.
- If you have a stomach or gastrointestinal ulcer, or have had one in the past.
- If you have bleeding in the stomach or gastrointestinal tract, or have had it in the past. Signs of this may include blood in the stool or black, tarry stools.
- If you have liver or kidney failure (severe liver or kidney disease).
- If you have been diagnosed with a heart condition or cerebrovascular disease; for example, if you have had a heart attack, stroke, mini-stroke (TIA), or blockage of blood vessels to the heart or brain, or if you have undergone surgery for this (such as a bypass operation).
- If you have or have had problems with your circulation (peripheral arterial disease).
- If you are in the last 3 months (third trimester) of pregnancy.
- If you have ever had an asthma attack or wheezing, or an extensive itchy skin rash (urticaria) or "hay fever-like" runny nose after taking other NSAIDs, such as aspirin or ibuprofen.
- If you have bleeding or bleeding disorders. If you have blood disorders (blood dyscrasias).
- If you have abnormalities in the composition of your blood (bone marrow depression): a decreased number of white blood cells (sometimes severe with an increased risk of infection), a decreased number of platelets (with an increased risk of bleeding and bruising), or a decreased amount of red blood cells (dizziness, headache). This can occur after radiation treatment. If any of the above applies to you or if you are unsure about anything, consult your doctor or pharmacist.

When should you be extra cautious with this medicine?

Consult your doctor or pharmacist if:

- You have ever had stomach or intestinal problems, such as an ulcer, bleeding, or black stools, or if you have experienced stomach problems or heartburn after taking NSAIDs in the past. If you have had asthma, hay fever, or other chronic respiratory problems, such as nasal polyps or chronic obstructive pulmonary diseases.

- If you are prone to developing allergic skin conditions, itchy skin, or hives.
- If you have inflammation of the intestine, such as ulcerative colitis or Crohn's disease.
- If you have bleeding disorders or other blood problems, including the rare liver disease porphyria.
- If you have the inflammatory disease systemic lupus erythematosus or another connective tissue disorder.
- If you have chest tightness, angina (chest pain), blood clots, high blood pressure, diabetes mellitus (diabetes), elevated levels of cholesterol or triglycerides (certain fats) in your blood, or if you smoke, you should discuss this with your doctor or pharmacist before taking this medicine.
- If you have liver or kidney problems.
- If you think you are dehydrated, for example, due to diarrhea or illness or following surgery.
- Inform your doctor if you have recently undergone or will undergo gastrointestinal surgery before taking/using this medicine, as it may sometimes impair intestinal wound healing after surgery.

If any of the above conditions apply to you, your doctor may provide specific advice or adjust your treatment.

Elderly people may be more susceptible to the effects of diclofenac than other adults. If you are over 65 years old, it is important to follow your doctor's instructions carefully and take the lowest number of tablets that still provide sufficient relief of symptoms. It is especially important for older people to immediately report any side effects to their doctor or pharmacist.

Diclofenac can reduce or mask the symptoms of an infection, such as headache or high body temperature. This can make it more difficult to detect or treat the infection. If you feel unwell and visit a doctor, remember to mention that you are using Diclofenacnatrium.

The risk of side effects can be reduced by using the lowest effective dose for the shortest possible period.

Are you taking any other medications?

If you are taking or have recently taken any other medications, or if there is a possibility that you will be taking other medications in the near future, please inform your doctor or pharmacist. This also applies to medications that do not require a prescription. This is important because certain medications should not be used together with diclofenac sodium.

The following medications, when used concomitantly with diclofenac sodium, may increase the risk of bleeding or ulcers. If you are using any of these medications, you should inform your doctor: Systemic corticosteroids used to treat inflamed body parts. Anticoagulants or antiplatelet agents used to thin the blood. Selective serotonin reuptake inhibitors (SSRIs) used to treat certain types of depression.

Other NSAIDs, such as aspirin (also known as acetylsalicylic acid) and ibuprofen, used to relieve inflammation/pain. Bleeding from the gastrointestinal tract or the formation of ulcers can be side effects of all NSAIDs, including diclofenac. This problem, which can be more serious in older people, can occur at any time during treatment with or without warning symptoms or a history of serious gastrointestinal problems.

You should also inform your doctor if you are using any of the following medications:

- Lithium, used for the treatment of mood disorders, including mania or depression.
- Digoxin, used for the treatment of heart conditions.
- Diuretics, used to increase urine production.
- Antihypertensive medications, such as ACE inhibitors or beta-blockers, used to treat high blood pressure (or certain other heart conditions).
- Medications used for inflammation and infections (other NSAIDs and corticosteroids).
- Blood thinning medications (anticoagulants and

antiplatelet agents). • Certain antidepressants (selective serotonin reuptake inhibitors (SSRIs)). • Medications taken orally to treat diabetes (oral antidiabetic drugs). • Methotrexate, used for the treatment of severe arthritis and certain types of cancer. • Cyclosporine, used to prevent immune reactions after organ transplants. • Quinolone antibiotics, used to treat certain infections. • Phenytoin, used in epilepsy. • Colestipol and colestyramine, used for high cholesterol levels in the blood. • CYP2C9 inhibitors, such as sulfapyrazone and voriconazole.

What to consider regarding food and drink: Take the tablets before meals.

Pregnancy and breastfeeding: Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Pregnancy: Do not use this medicine in the last three months of pregnancy; it can harm your unborn child or cause problems during childbirth. Your unborn child may experience kidney and heart problems. The medicine can affect the susceptibility of you and your baby to bleeding and may lead to delayed or prolonged labor.

Do not use diclofenac during the first six months of pregnancy unless absolutely necessary and recommended by your doctor. If you need to be treated during this period or while trying to conceive, the lowest dose should be used and the treatment should be kept as short as possible. From week 20 of pregnancy, if this medicine is used for more than a few days, it may cause kidney problems in your unborn child, which can result in insufficient amniotic fluid (oligohydramnios) or constriction of a blood vessel in your baby's heart (ductus arteriosus). If you need to be treated for longer than a few days, your doctor may recommend additional monitoring.

Breastfeeding: If you are breastfeeding, you can use diclofenac. Small amounts of diclofenac may be excreted in breast milk, but it is likely not harmful to the baby.

Driving and using machinery: Diclofenac can cause side effects such as blurred vision, dizziness, or drowsiness (see section 4). If this applies to you, do not drive or operate machinery.

How to use this medicine: Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, please contact your doctor or pharmacist. Your doctor will prescribe a personalized dosage tailored to your symptoms.

The general dosage is only a guideline and is as follows: It is important to take the lowest possible dose that adequately treats inflammation or pain for the shortest possible period. Depending on your initial response to the treatment, your doctor may recommend a higher or lower dose. Never take more than the dose prescribed by your doctor.

Take the tablets whole with liquid.

Do not chew the tablets, as this may cause the extended release of the active ingredient diclofenac sodium from the tablets to be lost.

Adults (over 18 years): • Rheumatoid joint pain (arthritis): the starting dose is 150 mg per day, and the maintenance dose for long-term treatment is 75-100 mg per day.

Worn-out joints (osteoarthritis): the starting dose is 100-150 mg per day, depending on the severity of the pain. The maintenance dose for long-term treatment is 75-100 mg. • Acute gout attack: 150 mg per day for 1-3 days, then reduce the dose based on symptoms.

Painful stiffness of the shoulder and painful postoperative and post-traumatic inflammation and swelling, for example after dental or other surgery: the starting dose is 150 mg per day, the maintenance dose will be gradually reduced based on the symptoms. • Severe menstrual pain: the starting dose is 50-100 mg as soon as you notice the first symptoms, then continue with a maximum of 50 mg three times a day for a few days. If the maximum daily dose of 150 mg has insufficient effect for 2-3 menstrual periods, you may increase the dose to a maximum of 200 mg in the next menstrual period.

In diseases accompanied by fever, especially for short-term use as an adjunct to chemotherapy in an infection: a daily dose of 0.5 mg per kg body weight is recommended, divided into 2-3 doses.

Use in children Both Diclofenacnatrium tablets of 50 mg and Retard tablets of 75 mg and 100 mg, as well as suppositories of 50 mg and 100 mg, are not suitable for use in children. Diclofenacnatrium tablets of 25 mg and Diclofenacnatrium suppositories of 25 mg are suitable for children. The recommended daily dose of tablets and suppositories is 1.5-2 mg per kg body weight per 24 hours, divided into three or four separate doses of 25 mg.

Elderly (over 65 years) Older people seem to have a greater risk of possible side effects from NSAIDs such as diclofenac sodium, so it is particularly important that older people are treated with the lowest possible dose that still has an effect." To protect your stomach and intestines.

Have you used too much of this medicine? If you have accidentally taken too much diclofenac sodium, contact your doctor or pharmacist immediately or go directly to the emergency department of the nearest hospital. You may need medical attention. Symptoms of an overdose may include: vomiting, diarrhea, dizziness, ringing in the ears (tinnitus), seizures/convulsions, severe stomach pain or bloody or black stools.

Did you forget to use this medicine? If you have forgotten to take a dose, take it as soon as you remember. If it is almost time for your next dose, just take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

Possible Side Effects: Like all medicines, this medicine can also have side effects, although not everyone gets them. The following descriptions of frequencies are used for the evaluation of side effects: **Very common:** in more than 1 in 10 of the treated patients. **Common:** in less than 1 in 10 but more than 1 in 100 of the treated patients. **Rarely:** in less than 1 in 1,000 but more than 1 in 10,000 of the treated patients **Very rarely:** in less than 1 in 10,000 treated patients

Stop using Diclofenac sodium and contact your doctor immediately if you notice the following: • Unusual bleeding or bruising. • High fever or persistent sore throat. • Allergic reactions with swelling of the face, lips, mouth, tongue or throat, often combined with rash and itching, which can cause difficulty swallowing, hypotension (low blood pressure), fainting. Wheezing and tightness in the chest (symptoms of asthma). • Suddenly occurring severe headache, nausea, dizziness, numbness, inability to speak or difficulty speaking, paralysis (symptoms of a stroke). • Stiff neck (symptom of meningitis). • Seizures. • Hypertension (high blood pressure).” If you have diabetes (diabetes mellitus), an increased amount of cholesterol or triglycerides (certain fats) in your blood, or if you smoke, you should discuss this with your doctor or pharmacist before taking this medication. • If you have liver or kidney problems. • If you think you are dehydrated, for example, due to diarrhea, illness, or surgery. • Inform your doctor if you have recently undergone or are scheduled to undergo gastrointestinal surgery before taking or using this medication, as it may sometimes impair wound healing in your intestines after surgery.

If any of the above conditions apply to you, your doctor may provide specific advice or adjust your treatment. Elderly people may be more sensitive to the effects of diclofenac than other adults. If you are over 65 years old, it is important to follow your doctor's instructions carefully and take the lowest number of tablets that still provide sufficient relief of symptoms. It is especially important for older people to immediately report any side effects to your doctor or pharmacist.

Diclofenac can reduce or mask the symptoms of an infection, such as headache or high body temperature. This can make it difficult to detect or treat the infection. If you feel unwell and visit a doctor, remember to mention that you are using Diclofenac Sodium. The risk of side effects can be reduced by using the lowest effective dose for the shortest possible period.

Are you taking any other medications?

In addition to Diclofenac Sodium, are you currently taking any other medications or have you recently taken them, or is there a possibility that you will use other medications in the near future? Inform your doctor or pharmacist about that. This also applies to medications that do not require a prescription. This is important because certain medications should not be used together with diclofenac sodium.

The following medications, if used concurrently with diclofenac sodium, can increase the risk of bleeding or ulcers. If you are using any of these medications, you should inform your doctor:

- Systemic corticosteroids used to treat inflamed body parts.
- Anticoagulants or platelet aggregation inhibitors used to thin the blood.
- Selective serotonin reuptake inhibitors (SSRIs) used to treat certain types of depression.

Blood and lymphatic system disorders: Very rare: Decrease in red and white blood cells, anemia, abnormalities in platelets.

Immune system disorders: Rare: Hypersensitivity, anaphylactic reactions (including lowering of blood pressure, fainting, and shock).

Very rare: Swelling of the face, lips, mouth, tongue, or throat (angioedema).

Psychiatric disorders: Very rare: Disorientation, depression, insomnia, nightmares, irritability, severe mental reactions with impaired control over behavior and actions (psychotic reactions).

Nervous system disorders: **Frequent:** Headache, dizziness. **Rare:** Drowsiness. **Very rare:** Numbness or tingling sensation in limbs, memory disorders, seizures, anxiety, tremors, meningitis, taste disorders, stroke (especially at high doses and long-term use).

Eye disorders: Very rare: Visual disturbances, blurred vision, double vision.

Ear and labyrinth disorders: Frequent: Dizziness.

Very rare: Ringing in the ears, impaired hearing.

Cardiac disorders: Very rare: Palpitations, chest pain, heart failure, heart attack (especially at high doses and long-term use).

Vascular disorders: Very rare: High blood pressure, blood vessel inflammation. **Respiratory, thoracic, and mediastinal disorders:** Rare: Asthma (including breathing difficulties). **Very rare:** Pneumonia.

Gastrointestinal disorders: Frequent: Nausea, vomiting, diarrhea, heartburn, abdominal pain, flatulence, loss of appetite.

Rare: Intestinal inflammation, gastrointestinal bleeding, bloody vomiting, bloody diarrhea, black-colored stools, gastrointestinal ulcers (with or without bleeding or perforation). **Very rare:** Intestinal wall inflammation (possibly with bleeding and possible worsening of existing ulcerative colitis or Crohn's disease), constipation, inflammation of the oral mucosa (possibly with ulcers), inflammation of the tongue, esophageal abnormalities and problems, pancreatitis.

Liver and gallbladder disorders: Frequent: elevation of liver enzymes.

Rare: liver inflammation, jaundice, liver abnormalities. **Very rare:** acute liver inflammation, (partial) liver necrosis, liver failure.

Skin and subcutaneous tissue disorders: Frequent: skin rash. **Rare:** hives. **Very rare:** blister formation, eczema, skin redness, severe skin conditions such as erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis (Lyell's syndrome), skin peeling, hair loss, unusual sensitivity of the skin to sunlight, causing redness, swelling, and blistering, bruising, itching.

Renal and urinary disorders: Very rare: acute kidney failure, blood in urine, proteins in urine, kidney inflammation and other kidney problems.

General disorders and administration site conditions: Frequent: pain at the administration site, irritation (with suppositories).

Rare: swelling.

How to store this medicine?

Store below 25°C, in the original packaging.