

LEAFLET: INFORMATION FOR THE USER

Diclofenac sodium Aurobindo 25 mg, enteric-coated tablets
Diclofenac sodium Aurobindo 50 mg, enteric-coated tablets
Diclofenac sodium Aurobindo Retard 75 mg, prolonged-release tablets
Diclofenac sodium Aurobindo Retard 100 mg, prolonged-release tablets
Diclofenac sodium Aurobindo 25 mg, suppositories
Diclofenac sodium Aurobindo 50 mg, suppositories
Diclofenac sodiumium Aurobindo 100 mg, suppositories
diclofenac sodium

Read the entire leaflet carefully before you start using this medicine, because it contains important information for you.

Keep this leaflet. You may need to read it again.

Do you have any questions? Please contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.

Do you experience a lot of discomfort from one of the side effects listed in section 4?

Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. What is Diclofenac sodium Aurobindo and what is this medicine used for?
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1. WHAT IS DICLOFENAC SODIUM AUROBINDO AND WHAT IS THIS MEDICINE USED FOR?

Diclofenac belongs to the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs); these medicines are used to treat pain and inflammation.

Diclofenac relieves the symptoms of inflammation, such as pain and swelling, and also reduces fever. It has no effect on the cause of the inflammation or the fever. Diclofenac can be used in adults for the following conditions:

In rheumatism, including joint pain due to inflammation (arthritis) and juvenile rheumatoid arthritis, "worn" joints (osteoarthritis), and certain forms of back pain (spinal joint disorders).

In a painful, inflamed stiff shoulder.

In painful inflammation and swelling, for example after dental procedures or orthopedic surgeries.

In severe menstrual pain.

In infectious diseases accompanied by fever, especially for short-term use as an adjunct to chemotherapy.

Diclofenac sodium Aurobindo Retard 75 mg and 100 mg prolonged-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 due to inflammation of the ear, nose, or throat.

Pain after minor surgical procedures.

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR SHOULD YOU BE EXTRA CAUTIOUS WITH IT? BEING PRESENT?

You think you are allergic to

diclofenac sodium diclofenac sodium You have a stomach ulcer or an ulcer in the gastrointestinal tract or have had this in the past.

You have liver or kidney failure (severe liver or kidney disease).

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If you have or have had problems with your blood circulation (peripheral arterial disease).

You are in the last 3 months (third trimester) of pregnancy.

You have ever had an asthma attack or wheezing, or a widespread itchy skin rash (urticaria) or a "hay fever-like" runny nose after taking other

You have ever had an asthma attack or wheezing, or an extensive itchy skin rash (urticaria) or a "hay fever-like" runny nose after taking other NSAIDs, such as aspirin or ibuprofen.

You have bleeding or bleeding disorders. You have blood count abnormalities (blood dyscrasia).

You have conditions affecting the composition of your blood (bone marrow depression): reduced number of white blood cells (sometimes severe with an increased risk of infection), a reduced 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 a treatment with radiation.

If the above applies to you or you are unsure about anything, consult your doctor or pharmacist.

When should you be extra careful 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 previously experienced NSAIDs stomach problems or heartburn.

You have had asthma, hay fever, or other long-term respiratory problems, such as nasal polyps or chronic obstructive pulmonary diseases.

You have a tendency to develop allergic skin diseases, an itchy skin, or hives.

You have an inflammation of the bowel, such as ulcerative colitis or Crohn's disease.

You have bleeding disorders or other blood problems, including the rare liver disease porphyria.

You have the inflammatory disease systemic lupus erythematosus or another connective tissue disorder.

You have a tight, painful feeling in the chest (angina), blood clots, high blood pressure, 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 medicine.

You have liver or kidney problems.

You think you are dehydrated, for example due to diarrhea or illness or due to surgery. Tell your doctor if you have recently undergone or will soon undergo gastrointestinal surgery before taking/using this medicine, as this medicine can sometimes reduce wound healing in your intestines after surgery.

You have ever had severe skin rash or peeling of the skin, blistering and/or sores in the mouth after using this medicine or other painkillers.

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

Older 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 report any side effects to their doctor or pharmacist immediately.

Diclofenac can reduce or mask the symptoms of an infection, such as headache or a high body temperature. This can make the infection more difficult to detect or treat. If you feel unwell and visit a doctor, do not forget to mention that you are using Diclofenac sodium Aurobindo .

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

Are you using any other medications?

Are you using any other medications besides Diclofenac sodium Aurobindo , or have you done so recently, or is there a possibility that you will use other medications in the near future?

Then tell your doctor or pharmacist. This also applies to medications for which you do not need a prescription. This is important because certain medications should not be used together with diclofenac sodium may be used.

The following medications, when used simultaneously with diclofenac sodium, can increase the risk of bleeding or ulcer. If you are using any of these medications, you must tell 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.

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 signs 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 the amount of urine.

Antihypertensives, 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 medicines (anticoagulants and antithrombotics).
Certain antidepressants (selective serotonin reuptake inhibitors (SSRIs)).
Medicines taken orally to treat diabetes (oral antidiabetics).
Methotrexate, used for the treatment of severe arthritis and some types of cancer.
Cyclosporin, used to prevent rejection reactions after organ transplants.
Quinolone antibiotics, used to treat certain infections.
Phenytoin, used in epilepsy.
Colestipol and cholestyramine, used for high cholesterol levels in the blood.
CYP2C9 inhibitors, such as sulfinpyrazone and voriconazole.

What should you pay attention to with food and drink?

Take the tablets before meals.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you 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 delivery. Your unborn child may experience kidney and heart problems. The medicine can affect your and your baby's susceptibility to bleeding and may cause the delivery to occur later or last longer than expected.

Use diclofenac not during the first six months of pregnancy unless absolutely necessary and recommended by your doctor. If you need treatment during this period or while trying to become pregnant, the lowest dose should be used, and the treatment should be kept as short as possible.

From week 20 of pregnancy, this medicine – if used for more than a few days – can cause your unborn child to develop kidney problems, which may result in the child having too little amniotic fluid around them (oligohydramnios) or narrowing of a blood vessel in your baby's heart (ductus arteriosus). If you need to be treated for more 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 this is unlikely to harm the baby.

Driving and using machines

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

Diclofenac gastro-resistant tablets contain lactose

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Diclofenac prolonged-release tablets contain sucrose

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Diclofenac sodium Aurobindo contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet/suppository, which means it is essentially “sodium-free”.

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Your doctor will prescribe a personal dosage tailored to your complaints. The general dosage is only a guideline and is as follows:

It is important that the lowest possible dose that sufficiently treats the inflammation or pain is taken 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.

Swallow the tablets whole with liquid.

Do not chew the tablets, as this may affect the extended release of the active ingredient diclofenac sodium from the tablets.

Adults (over 18 years):

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

Worn joints (osteoarthritis): the starting dose is 100-150 mg per day, depending on the severity of the pain. The maintenance dose for a 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 shoulder stiffness and painful postoperative and post-traumatic inflammation and swelling, e.g., after dental or other surgery: the starting dose is 150 mg per day, the maintenance dose will be gradually reduced based on 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 is insufficient 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 Diclofenac sodium Aurobindo tablets of 50 mg and Retard tablets of 75 mg and 100 mg, as well as the suppositories of 50 mg and 100 mg, are not suitable for use in children.

Diclofenac sodium Aurobindo tablets of 25 mg and Diclofenac sodium Aurobindo

Suppositories of 25 mg are suitable for children. The recommended daily dose of the 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 the possible side effects of NSAIDs such as diclofenac sodium, therefore it is particularly important that the elderly are treated with the lowest possible dose that is still effective.

If you have a stomach/intestinal ulcer or bleeding

If you have had an ulcer or bleeding in your stomach or intestines in the past or if you are taking other medications that increase the risk of this (see section 2), your doctor may advise you to use diclofenac sodium in combination with a proton pump inhibitor or misoprostol 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.

Have you forgotten to use this medicine?

If you forget 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.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like any medicine, this medicine can cause side effects, although not everybody gets them.

For the evaluation of side effects, the following descriptions of frequencies are used:

Very common: in more than 1 in 10 treated patients

Common: in less than 1 in 10, but more than 1 in 100 treated patients

Uncommon: in less than 1 in 100, but more than 1 in 1,000 treated patients

Rare: in less than 1 in 1,000, but more than 1 in 10,000 treated patients

Very rare: in less than 1 in 10,000 treated patients

Unknown: cannot be estimated from the available data

Some side effects can be serious.

Stop using Diclofenac sodium Aurobindo 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 in combination with rash and itching, which may cause difficulty swallowing, hypotension (low blood pressure), fainting. Wheezing and tightness in the chest (symptoms of asthma).

Sudden severe headache, nausea, dizziness, numbness, inability to speak or difficulty speaking, paralysis (symptoms of a stroke).

Stiff neck (symptom of meningitis).

Seizures.

Hypertension (increased blood pressure).

Red or purple skin (possible sign of inflammation of a blood vessel), rash with blisters, blisters on the lips, eyes, and mouth, inflammation of the skin with peeling or shedding.

Severe stomach pain, bloody or black stools.

Vomiting blood.

Yellow discoloration of the skin or eyes (sign of liver inflammation).

Blood in the urine, excessive protein in the urine, severely reduced urine production (signs of kidney disorders).

Inflammation of the pancreas causing severe abdominal pain and back pain (pancreatitis).

Heart disorders, such as chest pain, heart attack, and heart failure.

Mild abdominal cramps and tenderness occurring shortly after starting treatment with Diclofenac sodium Aurobindo and followed by rectal bleeding or bloody diarrhea, usually within 24 hours after the onset of abdominal pain (frequency not known, cannot be determined from available data).

Chest pain, which may be a sign of a possible severe allergic reaction called Kounis syndrome is called.

A severe allergic skin reaction that may include large widespread red and/or dark spots, skin swelling, blisters, and itching (generalized bullous fixed-drug eruption).

The side effects mentioned above are all serious. You may need urgent medical attention. These serious side effects are rare.

The following side effects have been observed with short or long-term use.

Blood and lymphatic system disorders

very rarely decrease in red and white blood cells, anemia, abnormalities in blood platelets.

Immune system disorders

rarely hypersensitivity, anaphylactic reactions (including lowering of blood pressure, fainting and shock).

very rarely swelling of face, lips, mouth, tongue or throat (angioneurotic edema).

Psychiatric disorders

very rarely disorientation, depression, insomnia, nightmares, irritability, severe mental reactions where control over one's own behavior and actions is disturbed (psychotic reactions).

Nervous system disorders

often headache, dizziness.

rarely drowsiness.

very rarely numb or tingling sensation in the limbs, memory disorders, seizures, anxiety, tremors, meningitis, taste disorders, stroke (especially with high dosages and prolonged use).

Eye disorders

very rarely visual disturbances, blurred vision, double vision.

Ear and labyrinth disorders often dizziness. very rarely tinnitus, impaired hearing.

Cardiac disorders

very rarely palpitations, chest pain, heart failure, heart attack (especially with high dosages and prolonged use).

Vascular disorders

very rarely increased blood pressure, vasculitis.

Respiratory system, thoracic and mediastinal disorders

rarely asthma (including difficulty breathing).

very rarely pneumonia.

Gastrointestinal disorders

often nausea, vomiting, diarrhea, belching, abdominal pain, flatulence, loss of appetite.
rarely inflammations of the intestines, intestinal bleeding, hematemesis, bloody diarrhea, black-colored stools, gastrointestinal ulcers (with or without bleeding or perforation).

very rarely inflammation of the intestinal wall (possibly with bleeding and possible worsening of pre-existing ulcerative colitis or Crohn's disease Crohn's disease), constipation, inflammation of the oral mucosa (possibly with ulcers), inflammation of the tongue, esophageal abnormalities and problems, pancreatitis.

Liver and biliary disorders

often elevation of liver enzymes.

rarely hepatitis, jaundice, liver abnormalities.

very rarely Skin and subcutaneous disorders

often

skin rash. rarely hives. very

rarely rare formation of vesicles, eczema, redness of the skin, severe skin conditions such as erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis (Lyell's syndrome), scaling of the skin, hair loss, unusual sensitivity of the skin to sunlight, causing the skin to become red and swollen and blisters to form, bruising, itching.

Unknown An allergic skin reaction, which may include round or oval red and swollen patches on the skin, blistering, and itching (fixed-drug eruption). In the affected areas, dark discoloration of the skin may also occur, which can persist after healing. This side effect usually recurs in the same location(s) when the medication is used again.

Kidney and urinary tract disorders

severe rare acute kidney failure, blood in the urine, proteins in the urine, nephritis, and other kidney problems.

General disorders and administration site conditions

often pain at the administration sites, irritation (with suppositories).

rare swellings.

Medicines such as diclofenac sodium may be associated with a small increased risk of a heart attack (myocardial infarction) or stroke.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Store below 25°C, in the original packaging.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It is stated on the packaging after "Exp.:". It includes a month and a year. The last day of that month is the expiry date. Consult your pharmacist.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

6. CONTENTS OF THE PACKAGE AND OTHER INFORMATION

What substances are in this medicine?

The active substance in this medicine is diclofenac sodium.

Diclofenac sodium Aurobindo 25 and 50 mg, enteric-coated tablets contain per enteric-coated tablet 25 mg or 50 mg diclofenac sodium.

Diclofenac sodium Aurobindo Retard 75 and 100 mg, sustained-release tablets contain per sustained-release tablet 75 mg or 100 mg diclofenac sodium.

Diclofenac sodium Aurobindo 25, 50 and 100 mg suppositories contain per suppository 25 mg, 50 mg or 100 mg diclofenac sodium.

The other ingredients in this medicine are:

Diclofenac sodium Aurobindo 25 mg and 50 mg, enteric-coated tablets: corn starch, lactose, sodium starch glycolate, pre-gelatinized starch, cellulose (E460), magnesium stearate (E470b), talc (E553b), macrogol 6000, methacrylic acid ethyl acrylate copolymer, dimethicone, polysorbate 80, sorbic acid (E200), titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172) (only 50 mg).

Diclofenac sodium Aurobindo Retard 75 mg and 100 mg, controlled-release tablets release: sucrose, cetyl alcohol, anhydrous colloidal silicon dioxide (E551), magnesium stearate (E572), povidone, red iron oxide (E172), titanium dioxide (E171), methylhydroxypropylcellulose, polysorbate 80 (E433) and talc (E553b).

Diclofenac sodium Aurobindo 25 mg, 50 mg and 100 mg, suppositories: hard fat.

What does Diclofenac sodium Aurobindo look like and how much is in a package?

Diclofenac sodium Aurobindo 25 mg gastro-resistant tablets are yellow, film-coated and inscribed with 'D25'. The tablets are supplied in a box with 30 tablets in 3 blister packs of 10 each and a bottle with 100 tablets.

Diclofenac sodium Aurobindo 50 mg gastro-resistant tablets are brown, film-coated and inscribed with 'D50'. The tablets are supplied in a box with 30 or 90 tablets in 3 or 9 blister packs à 10 pieces and bottle with 100 tablets.

Diclofenac sodium Aurobindo Retard 75 mg and 100 mg are old pink, round, biconvex film-coated tablets without inscription. The tablets are supplied in a box with 30 tablets in 3 blister packs of 10 pieces and bottle with 100 tablets (only for the 100 mg).

Diclofenac sodium Aurobindo 25 mg, 50 mg and 100 mg suppositories are white to ivory-colored, homogeneous suppositories. The suppositories are supplied in a box with 10 suppositories in 2 blister packs of 5 pieces.

Marketing authorization holder and manufacturer

Marketing authorization holder:

Aurobindo Pharma B.V., Baarnsche Dijk 1, 3741 LN Baarn

Manufacturer:

Aurobindo Pharma B.V., Baarnsche Dijk 1, 3741 LN Baarn, Netherlands

Diclofenac sodium Aurobindo is registered under:

RVG 16273 Diclofenac sodium Aurobindo 25 mg, gastro-resistant tablets

RVG 16274 Diclofenac sodium Aurobindo 50 mg, gastro-resistant tablets

RVG 22690 Diclofenac sodium Aurobindo Retard 75 mg, prolonged-release tablets

RVG 16275 Diclofenac sodium Aurobindo Retard 100 mg, prolonged-release tablets

RVG 16276 Diclofenac sodium Aurobindo 25 mg, suppositories

RVG 16277 Diclofenac sodium Aurobindo 50 mg, suppositories

RVG 16278 Diclofenac sodium Aurobindo 100 mg, suppositories

This leaflet was approved in October 2025.