

Package leaflet: information for the user

diclofenac cinfa 50 mg gastro-resistant tablets

diclofenac sodium

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, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What diclofenac cinfa is and what it is used for
2. What you need to know before taking diclofenac cinfa
3. How to take diclofenac cinfa
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1. What diclofenac cinfa is and what it is used for

Diclofenac sodium, the active substance in diclofenac cinfa, belongs to the group of medicines called non-steroidal anti-inflammatory drugs, which are used to treat pain and inflammation.

Diclofenac cinfa is used to treat the following conditions:

- Chronic inflammatory rheumatic diseases (rheumatoid arthritis, ankylosing spondylitis, osteoarthritis),
- Extra-articular rheumatism,
- Acute attacks of gout,
- Period pains,
- Post-traumatic inflammation.

2. What you need to know before taking diclofenac cinfa

It is important that you use the lowest dose that relieves/controls the pain and you must not take this medicine for longer than required to control your symptoms.

Do not take diclofenac cinfa:

- if you are allergic to diclofenac sodium or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic or have had allergic reactions to acetylsalicylic acid (aspirin) or other similar analgesics (medicines used to treat pain). Reactions may include asthma (difficulty breathing), chest pain, urticaria (allergic skin reaction with itching), acute rhinitis (inflammation of the nasal mucosa) or swelling of the face, lips, tongue, throat and/or extremities (signs of angioedema). If you believe you may be allergic, consult your doctor.
- if you have previously experienced stomach or duodenal bleeding or have experienced, on two or more occasions, perforation of the digestive tract while taking a non-steroidal anti-

inflammatory drug.

- if you currently suffer or have suffered on more than one occasion from stomach or duodenal ulcer or bleeding.
- if you suffer from active ulcerative colitis or Crohn's disease (diseases that cause diarrhoea with or without blood and abdominal pain).
- if you suffer from severe kidney disease.
- if you have severe liver disease.
- if you have established heart disease and/or cerebrovascular disease, for example, if you have had a heart attack, stroke, mini-stroke (TIA) or blockages in the blood vessels of the heart or brain, or a coronary bypass or operation to eliminate an obstruction.
- if you have or have had blood circulation problems (peripheral arterial disease).
- if you are in the last trimester of pregnancy.
- if you suffer from a blood clotting disorder.
- if you think you may be allergic to diclofenac sodium, acetylsalicylic acid, ibuprofen or any other NSAID, or any of the other components of diclofenac. (Listed at the end of the package insert.) Signs of a hypersensitivity reaction are swelling of the face and mouth (angioedema), trouble breathing, chest pain, runny nose, rash or any other allergic reaction.

Before taking diclofenac, make sure your doctor knows:

- if you smoke.
- if you have diabetes.
- if you have angina, blood clots, high blood pressure, high cholesterol or high triglycerides.

Adverse effects can be minimised by using the lowest effective dose for the shortest possible time.

Warnings and precautions

Talk to your doctor or pharmacist before taking diclofenac cinfa.

- If you have had or develop an ulcer, bleeding or perforation in the stomach or duodenum, which can manifest as severe, persistent abdominal pain and/or black stools, or even without previous warning symptoms.
- This risk is higher when high doses and long-term treatments are used in patients with a history of peptic ulcer and in elderly patients. In these cases, your doctor will consider using a stomach protecting medicine.
- If you suffer from any of the following conditions: asthma, mild heart disease, liver or kidney disease, high blood pressure (hypertension), bleeding disorders or other blood disorders including hepatic porphyria.
- If you are taking other anti-inflammatory medicines, corticosteroids, anticoagulants or antidepressants, as they increase the risk of ulcers and/or gastrointestinal bleeding (see section "Other medicines and diclofenac cinfa").
- If you are taking blood pressure medicines or ciclosporin, as they increase the risk of kidney damage (see section "Other medicines and diclofenac cinfa").

Talk to your doctor:

- If you concomitantly take medicines that affect blood clotting or increase the risk of ulcers, such as oral anticoagulants or platelet aggregation inhibitors, such as acetylsalicylic acid. You must also report the use of other medicines that could increase the risk of bleeding, such as corticosteroids and selective serotonin reuptake inhibitor antidepressants.
- If you suffer from Crohn's disease or ulcerative colitis, as medicines like diclofenac can exacerbate these conditions.
- If you have high blood pressure, high cholesterol or triglyceride levels, diabetes or are a

smoker (cardiovascular risk factors), your doctor should periodically re-evaluate whether you should continue your treatment with diclofenac, especially if you have been taking it for more than 4 weeks.

- If you have liver failure, kidney failure or blood disorders, you will need frequent blood tests during your treatment. This will make it possible to control your liver (transaminase level), kidney (creatinine level) or blood (lymphocyte, erythrocyte and platelet levels) function. Your doctor may therefore decide to stop or change your dose of diclofenac.
- Tell your doctor if you have recently undergone or are due to undergo surgery on your stomach or intestine before taking diclofenac, as diclofenac can sometimes worsen wound healing after surgery.
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Patients with cardiovascular problems

Medicines such as diclofenac can be associated with an increased risk of heart attack (“myocardial infarction”) or stroke, especially when used in high doses and in prolonged treatments. Do not exceed the recommended dose or duration of treatment. If you have heart problems, a history of stroke or think you may be at risk (for example, if you have high blood pressure, diabetes, elevated cholesterol or triglycerides, or are a smoker) and your doctor decides to prescribe diclofenac, you should not take more than 100 mg a day if the treatment lasts more than 4 weeks.

Furthermore, this type of medicine can cause fluid retention, particularly in patients with heart disease and/or high blood pressure (hypertension).

In general, it is very important to take the lowest effective dose of diclofenac for the shortest possible time that relieves pain and/or inflammation in order to reduce the risk of adverse cardiovascular effects. If you notice chest pain, shortness of breath, weakness or difficulty speaking while you are taking diclofenac, contact your doctor immediately.

Children and adolescents

Not recommended for use in children and adolescents under 14 years of age.

Use in elderly patients

Elderly patients may be more sensitive to the effects of diclofenac than other adults, especially if they are frail or have a low body weight. For this reason, it is especially important that elderly patients inform the doctor immediately of any adverse effects.

Other medicines and diclofenac

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can interact with diclofenac; in these cases, it may be necessary to change the dose or stop treatment with some of the medicines.

It is important that you inform your doctor if you are taking, or have recently taken, any of the following medicines:

- medicines that contain lithium or serotonin reuptake inhibitors (to treat some types of depression),
- medicines that contain methotrexate (to treat rheumatoid arthritis and cancer),
- medicines that contain ciclosporin, tacrolimus (for after transplants),
- medicines that contain trimethoprim (to prevent and treat urinary tract diseases),

- medicines to treat heart problems (digoxin, calcium channel blockers such as verapamil or isradipine),
- medicines used to treat diabetes, except insulin.
- medicines to control blood pressure (diuretics, beta blockers and ACE inhibitors),
- medicines to prevent blood clots,
- medicines that contain quinolone or ceftriaxone (to treat infections),
- other medicines from the same group as diclofenac (non-steroidal anti-inflammatory drugs) such as acetylsalicylic acid or ibuprofen,
- corticosteroids (medications that reduce inflammation and the action of the immune system),
- medicines that contain voriconazole (a medicine used in the treatment of fungal infections),
- medicines that contain phenytoin (a medicine used to treat epileptic seizures),
- medicines that contain misoprostol (to treat stomach ulcers),
- medicines that contain cholestyramine and colestipol (to lower blood cholesterol),
- medicines that contain pentazocine (to relieve pain),
- an antibiotic medicine used to treat bacterial infections (rifampicin).

diclofenac cinfa with food, drink and alcohol

This medication should be taken preferably before meals or on an empty stomach as it delays the onset of the effect.

The intake of alcoholic beverages together with diclofenac may increase its toxicity.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Since the administration of medicines like diclofenac has been associated with an increased risk of suffering congenital anomalies/miscarriages, its administration is not recommended during the first and second trimester of pregnancy, unless it is considered to be completely necessary.

In these cases, the dose and duration will be kept to the minimum.

The administration of this medicine is contraindicated in the third trimester.

For women of child-bearing potential, it must be considered that medicines like diclofenac have been associated with reduced fertility.

Breast-feeding

Ask your doctor or pharmacist for advice before using any medicine.

Small amounts of diclofenac may be found in breast milk, so you should not take diclofenac if you are breast-feeding.

Driving and using machines

Diclofenac has no or negligible influence on the ability to drive and use machines, but patients who experience visual disturbances, dizziness, vertigo, drowsiness or other disorders of the central nervous system while being treated with diclofenac should avoid driving vehicles or operating machinery.

diclofenac cinfa contains lactose.

This medicine contains lactose. If you have been told by your doctor that you are intolerant to certain sugars, please talk to your doctor before taking this medicine.

diclofenac cinfa contains sodium.

This medicine contains less than 1 mmol of sodium (23 mg) per tablet; it is essentially “sodium-free”.

3. How to take diclofenac cinfa

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Remember to take your medicine.

Use in adults and children over 14 years of age

The recommended dose for milder cases is 100 mg (one tablet twice daily). Do not exceed the dose of 150 mg (3 tablets) per day. The total daily dose should be divided into 2 or 3 separate doses.

For period pains, the daily dose, which must be adjusted individually, is 50-200 mg (1 to 4 tablets). An initial dose of 50-100 mg (1 to 2 tablets) will be administered and it will be increased in the following menstrual cycles if necessary. Treatment should be initiated when the first symptoms appear. Depending on their intensity, the treatment should be taken for a few days.

Method of administration

The tablets should be swallowed whole with a glass of water or other liquid, without breaking or chewing them. Take diclofenac preferably before meals or on an empty stomach (see section “diclofenac cinfa with food, drink and alcohol”).

If you take more diclofenac cinfa than you should

In case of overdose or accidental ingestion, tell your doctor or pharmacist immediately.

If you forget to take diclofenac cinfa

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

4. Possible side effects

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

Some side effects may be serious.

Stop using this medicine and consult your doctor immediately if you notice:

Mild abdominal cramping and abdominal tenderness that begins soon after starting treatment with diclofenac followed by rectal bleeding or bloody diarrhoea, normally seen within 24 hours after the onset of abdominal pain (frequency unknown, cannot be estimated from the available data).

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

Other side effects that have been reported with the use of diclofenac are the following:

Common side effects (may affect up to 1 in 10 people):*Nervous system disorders*

- headache
- light-headedness

Ear and labyrinth disorders

- vertigo

Gastrointestinal disorders

- nausea
- vomiting
- diarrhoea
- heartburn
- abdominal pain
- flatulence
- loss of appetite

Hepatobiliary disorders

- alterations in liver function blood test results (increased serum transaminases)

Skin and subcutaneous tissue disorders

- skin rash

Uncommon side effects (may affect up to one in 100 people):

Cardiac disorders (at high doses during prolonged treatments)

- palpitations
- severe sudden chest pain (symptoms of myocardial infarction or heart attack)
- shortness of breath, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure)

If these symptoms occur, consult your doctor immediately

Rare side effects (may affect up to one in 1,000 people):

Immune system disorders

- swelling of the face, eyes or tongue, difficulty swallowing, wheezing, hives and generalised itching, skin rash, fever, abdominal cramps, chest discomfort or tightness, shortness of breath, dizziness, unconsciousness (severe allergic reaction)

If these symptoms occur, consult your doctor immediately

Nervous system disorders

- drowsiness

If these symptoms occur, consult your doctor immediately

Respiratory, thoracic and mediastinal disorders

- asthma

Gastrointestinal disorders

- stomach pain
- reflux
- bloody diarrhoea

- gastric or intestinal ulcer with or without bleeding or perforation (vomiting of blood and appearance of blood in stool).

If these symptoms occur, consult your doctor immediately

Hepatobiliary disorders

- impaired liver function
- hepatitis with or without yellowing.

If these symptoms occur, consult your doctor immediately

Skin and subcutaneous tissue disorders

- hives

General disorders and administration site conditions

- fluid retention with swelling (oedema)

Very rare side effects (may affect up to one in 10,000 people):

Blood and lymphatic system disorders

- signs of a lack of blood cells resulting in tiredness, headache, shortness of breath when exercising, dizziness, paleness (anaemia), frequent infections with fever, chills, sore throat or mouth ulcers (leukopenia), bleeding or more bruising than usual (thrombocytopenia)

If these symptoms occur, consult your doctor immediately

Immune system disorders

- swelling of the face

Psychiatric disorders

- disorientation
- depression
- insomnia
- nightmares
- irritability
- psychotic reactions

Nervous system disorders

- tingling sensation
- memory disorders
- seizures
- anxiety
- tremors
- meningitis (inflammation of the membranes that surround the brain) with symptoms such as fever, nausea, vomiting, headache, stiff neck or extreme sensitivity to bright light.

If these symptoms occur, consult your doctor immediately

- taste disorders
- cerebral infarction

Eye disorders

- blurred vision
- double vision

Ear and labyrinth disorders

- ringing in the ears

Vascular disorders

- hypertension (high blood pressure)
- vasculitis (vessel wall inflammation)

Respiratory, thoracic and mediastinal disorders

- shortness of breath, wheezing (pneumonitis)

If these symptoms occur, consult your doctor immediately

Gastrointestinal disorders

- exacerbation of Crohn's disease and ulcerative colitis
- constipation
- swelling of the tongue (glossitis)
- inflammation of the mucosa of the mouth (stomatitis)
- problems swallowing (oesophagus disorders)
- severe pain in the upper abdomen, nausea, vomiting and loss of appetite (signs of pancreatitis).

If these symptoms occur, consult your doctor immediately

Skin and subcutaneous tissue disorders

- severe skin reactions with rash, redness, blisters on the lips, mouth or eyes, peeling skin, accompanied by fatigue, nausea, loss of appetite, fever, chills, headache, cough or body aches (Stevens-Johnson syndrome or toxic epidermal necrolysis).

If these symptoms occur, consult your doctor immediately

- generalised rash (eczema)
- redness (erythema and erythema multiforme)
- peeling skin (exfoliative dermatitis)
- hair loss
- sun allergy (photosensitivity reaction)
- bruising
- itching

Renal and urinary disorders

- impaired kidney function, which causes swelling in feet or legs and sudden decrease in urine quantity (acute renal failure, interstitial nephritis, renal papillary necrosis)
- blood in urine (haematuria)
- foamy urine (nephrotic syndrome)

If these symptoms occur, consult your doctor immediately

Isolated cases

Hepatobiliary disorders

- abnormalities in the functioning of the liver that cause yellowing of the skin and eyes, fever, pain in the upper part of the gut, and bruising (liver failure, fulminant hepatitis, hepatic necrosis)

If these symptoms occur, consult your doctor immediately

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store diclofenac cinfa

Keep this medicine out of the sight and reach of children.

Do not store at temperatures above 25°C.

Do not use this medicine after the expiry date which is stated on the container after “EXP”. The expiry date refers to the last day of that month.

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.

6. Contents of the pack and other information

What diclofenac cinfa contains

- The active substance is diclofenac sodium. Each gastro-resistant tablet contains 50 mg of diclofenac sodium.

- The other ingredients (excipients) are:

Core: lactose monohydrate, microcrystalline cellulose (E-460), maize starch, croscarmellose sodium, colloidal anhydrous silica, sodium lauryl sulphate, povidone (E-1201), talc (E-553b), magnesium stearate (E-470B).

Coating: hydroxypropyl methylcellulose (E-464), methacrylic acid copolymer and ethyl acrylate (1: 1) 30% dispersion, triethyl citrate (E-1505), talc (E-553b), titanium dioxide (E-171), yellow iron oxide (E-172), brown iron oxide (E-172).

What diclofenac cinfa looks like and contents of the pack

Light brown biconvex cylindrical tablets, coated and marked with the code “D50C”.

They are supplied in PVC-PVDC/Aluminium blisters. Each pack contains 40 gastro-resistant tablets.

Marketing authorisation holder and manufacturer

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10. Polígono Industrial Areta,
31620, Huarte (Navarra) - Spain

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