

Package leaflet: Information for the patient

Diclofenac T ratiopharm 50 mg film-coated tablets

diclofenac potassium

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 T ratiopharm* is and what it is used for
2. What you need to know before you take *Diclofenac T ratiopharm*
3. How to take *Diclofenac T ratiopharm*
4. Possible side effects
5. How to store *Diclofenac T ratiopharm*
6. Contents of the pack and other information

1. What *Diclofenac T ratiopharm* is and what it is used for

Diclofenac T ratiopharm contains diclofenac potassium.

Diclofenac T ratiopharm acts against **pain** (is an analgesic) and **inflammation** (an anti-inflammatory). Medicinal products with this or similar properties are also called “non-steroidal anti-inflammatory drugs”, or **NSAIDs**.

***Diclofenac T ratiopharm* is used for:**

Short-term treatment of following conditions

- rheumatic diseases of the soft tissues (e.g. bursitis or tendonitis)
- pain or inflammation following injury and surgery (including dental surgery)
- period pain (primary dysmenorrhoea)

Acute treatment of migraine with or without aura.

Diclofenac T ratiopharm 50 mg shall not be used in children under 16 years of age.

2. What you need to know before you take *Diclofenac T ratiopharm*

Do not take *Diclofenac T ratiopharm*

- if you think you may be allergic to diclofenac, acetylsalicylic acid, ibuprofen or any other NSAIDs (non-steroidal anti-inflammatory drugs), or to any of the other ingredients of this medicine (listed in section 6 at the end of the leaflet). Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic type reaction.
- if you previously have had an allergic reaction such as asthma, sneezing or a rash on taking painkillers containing acetylsalicylic acid or other drugs for pain/inflammation within the group of NSAIDs
- if you have stomach ulcer or intestinal ulcer, bleeding or perforation
- if you have a history of gastrointestinal bleeding/perforation related to previous use of painkillers (NSAIDs)

- if you have had two or more episodes of a stomach ulcer, or bleeding
- during the final 3 months of a pregnancy
- if you have severe liver and kidney function disorders
- if you have established heart disease and/or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages
- if you have or have had problems with your blood circulation (peripheral arterial disease)
- if you have hepatic porphyria (a particular haemoglobin formation disorder)
- if you have conditions with increased bleeding propensity including bleeding diathesis

Warnings and precautions

Talk to your doctor or pharmacist before taking *Diclofenac T ratiopharm*

- if you recently had or you are going to have a surgery of the stomach or intestinal tract as diclofenac can sometimes worsen wound healing in your gut after surgery.
- if you suffer from bronchial asthma (respiratory tract disease with respiratory distress), seasonal allergic rhinitis, swelling of the nasal mucosa, chronic pulmonary diseases or infections of the respiratory tract
- if you have a blood coagulation disorder
- if you have a kidney function disorder
- if you have substantial fluid loss (e.g. due to illness, diarrhoea or before or after major surgery)
- if you have a liver function disorder
- if you have a condition called porphyria
- if you have any disease of the gastrointestinal tract, such as ulcerative colitis or Crohn's disease (a particular bowel disease)
- if you are at risk of infection (*Diclofenac T ratiopharm* may mask the symptoms of an infectious disease, e.g. headache or high fever and therefore make it difficult to detect the infection and treat it properly. If you feel unwell and need to see a doctor, remember to mention that you are taking *Diclofenac T ratiopharm*).
- if you smoke
- if you have diabetes
- if you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- if you have or have had heart disease
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking *Diclofenac T ratiopharm* or other pain medications.

When taking *Diclofenac T ratiopharm*, talk to your doctor immediately, if you notice chest pain. Chest pain can be a sign of a potentially serious allergic reaction called Kounis syndrome.

Side effects may be minimised by using the **lowest effective dose** for the shortest time necessary to control the symptoms.

Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained and treatment should be discontinued.

Laboratory tests

When taking *Diclofenac T ratiopharm* for a long period of time your doctor will regularly check your liver values, your kidney function and your blood count.

Bleeding of the gastrointestinal tract, ulcers and perforation

Treatment with any non-steroidal anti-inflammatory drug (NSAID) can cause bleeding of the gastrointestinal tract, ulcers and perforation, possibly with a fatal outcome. The risk of becoming ill is higher

- the higher the dose of NSAID
- in patients who have already had ulcers, particularly if they have involved bleeding or perforation
- in elderly patients

If you have one of these risk factors and/or if you are additionally being treated with

- low-dose acetylsalicylic acid (ASA) as an anticoagulant
- other drugs that raise the risk of gastrointestinal disease

your doctor may possibly prescribe a gastroprotective drug in addition.

If you have **previously had gastrointestinal side effects** you should report any unusual abdominal symptoms to your doctor. This particularly applies to bleeding from the stomach or bowels. Such bleeding is recognisable by the vomit or stool being coloured black. The elderly are particularly at risk.

If you have gastrointestinal bleeding or ulcers while taking *Diclofenac T ratiopharm* the treatment must be discontinued.

Effects on the cardiovascular and cerebrovascular system

Medicinal products like *Diclofenac T ratiopharm* are possibly related to a slightly increased risk of heart attack (cardiac infarct) or stroke. The risk is greater with high doses and longer periods of treatment. Do not exceed the recommended dose or period of treatment.

If at any time while taking *Diclofenac T ratiopharm* you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately.

Skin reactions

There have very rarely been reports of serious skin reactions, when taking an NSAID, involving erythema and blistering, sometimes with a fatal outcome. At the first signs of a disorder affecting the skin or mucous membranes you should **discontinue** taking *Diclofenac T ratiopharm* and inform your doctor without delay. This also applies to other signs of a sensitivity reaction (see also section 4.).

Elderly patients

Side effects appear more frequently in elderly or frail elderly patients taking NSAIDs. Bleeding and perforation of the gastric and intestinal regions are the effects particularly concerned, which in some circumstances can be life-threatening.

Children and adolescents

Diclofenac T ratiopharm 50 mg shall not be used in children under 16 years of age.

Other medicines and *Diclofenac T ratiopharm*

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

You should avoid taking *Diclofenac T ratiopharm* at the same time as:

- **other** anti-inflammatory and analgesic medicines from the non-steroidal anti-inflammatory drug group (NSAIDs)
- **COX-2 inhibitors** such as celecoxib (also anti-inflammatory substances)
- **glucocorticosteroids** (anti-inflammatory drugs).

Your doctor will decide this on a case to case basis.

Particular caution is required when taking *Diclofenac T ratiopharm* with:

- **digoxin** (a medicine for increasing the strength and vigour of the heart)
- **lithium** (a medicine for treating mental/emotional disorders)
- medicines **acting against water retention** (diuretics)
- **antihypertensives including beta-blockers, ACE inhibitors and angiotensin-II receptor antagonists** (likewise medicines for treating cardiac insufficiency and lowering blood pressure)
- certain **medicines for depression** (selective serotonin reuptake inhibitors/SSRI)
- **methotrexate** (another rheumatism medicine)
- **anticoagulant** medicines such as warfarin (to prevent blood clots)

- **antiplatelet agents** such as acetylsalicylic acid (ASA)
- **ciclosporin** and **tacrolimus** (medicines used to treat some inflammatory diseases and after transplants)
- medicines **lowering blood sugar levels** such as metformin (antidiabetic drugs).
- **quinolone antibiotics** (a medicine to treat bacterial infections)
- **colestipol/cholestyramine** (lipid-lowering drug)
- **phenytoin** (a medicine used to treat seizures)
- **voriconazole** (a medicine used to treat fungal infection)
- **rifampicin** and **trimethoprim** (medicines used to treat bacterial infections)
- **carbamazepine** (a medicine used to treat epilepsy)
- **barbiturates** (e.g. phenobarbital, a medicine used to treat epilepsy)
- **sulfinpyrazone** (a medicine used to treat gout).

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

Do not take *Diclofenac T ratiopharm* if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

You should not take *Diclofenac T ratiopharm* during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, *Diclofenac T ratiopharm* can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breast-feeding

The active substance, diclofenac, passes in small quantities into the maternal milk. Therefore *Diclofenac T ratiopharm* should not be administered during breast-feeding.

Female fertility

Like other medicinal products that inhibit prostaglandin synthesis (the formation of certain tissue hormones) *Diclofenac T ratiopharm* may make it more difficult to become pregnant. You should inform your doctor if you plan to become pregnant or have had problems becoming pregnant.

Driving and using machines

Diclofenac T ratiopharm can induce side effects such as visual disturbances, vertigo, dizziness and drowsiness. As a result your capacity to react may be altered and your ability to drive and use machines can be impaired.

***Diclofenac T ratiopharm* contains lactose**

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

***Diclofenac T ratiopharm* contains sodium**

This medicine contains less than 1 mmol (23 mg) sodium per film-coated tablet that is to say essentially 'sodium-free'.

3. How to take *Diclofenac T ratiopharm*

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

Method of administration

Take *Diclofenac T ratiopharm* **without chewing and with a small amount of fluid preferably before a meal.**

Duration of use and how much *Diclofenac T ratiopharm* to take

The doctor treating you will decide the duration of use.

Do not exceed the recommended dose. It is important that you use the lowest dose that keeps the pain under control and that you do not use this medicine for longer than necessary. Your doctor will prescribe the appropriate dosages for you. Your doctor may prescribe a higher or lower dose depending on how the medicine affects you.

The recommended dose for adults and adolescents over 16 years is

The starting dose is generally 2-3 tablets of *Diclofenac T ratiopharm* 50 mg per day. In milder cases a dose of 1-2 tablets of *Diclofenac T ratiopharm* 50 mg per day is usually sufficient.

The daily dose should be taken in two or three separate doses.

Period pain:

1-3 tablets of *Diclofenac T ratiopharm* 50 mg per day taken in one to three doses.

The dose should be adapted to the individual case. A lower dose (1-2 tablets per day) should be taken at the start which may be increased in stages from period to period.

The treatment begins when the first symptoms of pain occur and continues for a few days depending on the intensity of the pain.

Migraine:

Take 1 tablet *Diclofenac T ratiopharm* 50 mg at the first signs of an attack.

In cases where pain relief in the 2 hours after the first tablet is not sufficient a further tablet can be taken. If necessary additional *Diclofenac T ratiopharm* 50 mg tablets can be taken at 4 to 6 hour intervals. **Do not take more than 4 tablets *Diclofenac T ratiopharm* 50 mg per day!**

Elderly patients:

The lowest effective dose should be used particularly in treating frail or low weight elderly patients.

Patients with renal or hepatic impairment:

Diclofenac must not be used in patients with severe renal or hepatic impairment (see section 2 “Do not take...”). Caution is advised if you have a mild to moderate kidney or liver function disorder (see section 2 “Talk to your doctor...”). Your doctor may want to adjust your dose or perform regular checks.

Use in children and adolescents:

Diclofenac T ratiopharm 50 mg shall not be used in children younger than 16 years of age.

If you take more *Diclofenac T ratiopharm* than you should

If you have accidentally taken too much *Diclofenac T ratiopharm* tell your doctor or pharmacist or go straight to the nearest hospital Accident and Emergency unit. You may require medical attention.

Take your medicine pack with you so that people can see what you have taken. The following effects may happen: vomiting, bleeding in your stomach, diarrhoea, feeling dizzy, hearing problems or fits. In severe overdose kidney or liver problems can happen.

If you forget to take *Diclofenac T ratiopharm*

Do not take a double dose to make up for a forgotten dose but continue the treatment with the next dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Side effects of medicines are as a rule dose-dependent and differ from patient to patient. The risk particularly of gastrointestinal bleeding (ulcers, damage to the mucosa, inflammation of the gastric mucosa) and the increased risk of arterial thrombotic events (for example heart attack or stroke) depends on the dose range and period of use.

Serious side effects and countermeasures

Stop taking *Diclofenac T ratiopharm* and tell your doctor straight away if you notice:

- Increased heart rate, a fall in blood pressure leading to shock (signs of severe hypersensitivity reactions.) This can occur when taking for the first time, but it is rare.
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema). This is very rare.
- Severe skin reactions, including blistering, red or purple marks or peeling of the skin. It can also affect the mouth, eyes and other mucous membranes. (Stevens-Johnson syndrome, toxic epidermal necrolysis or Erythema multiforme). This is very rare.
- A serious allergic skin reaction which may include large widespread red and/or dark patches, swelling of the skin, blisters, and itching (Generalised bullous fixed drug eruption).
- Severe **pain in the upper abdomen**, vomiting, vomiting of blood, diarrhoea with blood in it and faeces coloured black (signs of gastric/intestinal bleeding or ulcers). This is rare.
- **Mild cramping and tenderness of the abdomen**, starting shortly after the start of the treatment with *Diclofenac T ratiopharm* and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain. This occurs very rarely.
- **Superficial lesions** in the mouth, fever, sore throat, nose bleed and bruising, influenza-like symptoms, severe exhaustion (signs of disturbance to blood formation, reduction in the number of different types of some blood cells). This is very rare. Do not take any analgesics or medicines to lower the fever.
- Severe **headache**, nausea, vomiting, **fever**, stiffness of the neck or clouding of consciousness (signs of meningitis). This is very rare.
- **Reduced urinary excretion**, retention of water in the body and general malaise (signs of kidney disease or kidney failure). This is very rare.
- **Chest pain**, which can be a sign of a potentially serious allergic reaction called Kounis syndrome. Talk to your doctor immediately, if you notice chest pain. The frequency is not known, this means that the frequency cannot be estimated from the available data.
- **Sudden and crushing chest pain** (signs of myocardial infarction). This occurs uncommonly.
- **Breathlessness, difficulty breathing** when lying down, **swelling** of the feet or legs (signs of heart failure). This occurs uncommonly.

If the following side effects appear you must **inform a doctor** as soon as possible:

- **Urticaria** (a kind of skin rash with pale red, raised, itchy bumps). This is rare.

Other side effects

The following side effects may occur during treatment with *Diclofenac T ratiopharm*:

Common (may affect up to 1 in 10 people):

- Headache, dizziness
- Sensation of spinning or whirling motion (vertigo)
- Pain in the upper abdomen, nausea, vomiting, diarrhoea, indigestion, flatulence, loss of appetite
- Raised liver enzyme levels in the blood
- Skin rash and irritation

Uncommon (may affect up to 1 in 100 people):

- Fast or irregular heart beat (palpitations), pain in the chest

Rare (may affect up to 1 in 1 000 people):

- Drowsiness
- Wheezing and shortness of breath (Asthma)
- Liver function disorders including hepatitis with or without jaundice
- Inflammation of the gastric mucosa, gastric and duodenal ulcers (possibly with bleeding, obstruction and perforation that may lead to inflammation of the peritoneum with signs as belly pain and/or bloating and fever)
- Fluid retention, symptoms of which include swollen ankles (oedema)

Very rare (may affect up to 1 in 10 000 people):

- Mental/emotional disorders, depression, feelings of anxiety, nightmares
- Disorders of perception and memory, disturbance to normal perception of space and time, sleeplessness, irritability, convulsions, trembling
- Disorders of the sense of taste
- Tingling or numbness in the hands, fingers and feet
- Vision disorders, (blurred or double vision)
- Stroke
- Buzzing in the ears and impaired hearing
- High blood pressure
- Inflammation of blood vessels (vasculitis)
- Inflammation of the lung (pneumonitis)
- Lower abdominal symptoms and lower gut disorders, such as intestinal bleeding and inflammation, exacerbation of Crohn's disease/ulcerative colitis
- Inflammation of the mouth or tongue, damage to the oesophagus, constipation, cramps in the upper abdomen especially after meals (signs of intestinal strictures)
- Inflammation of the pancreas
- Flu-like symptoms, tiredness, muscle aches, elevated liver enzyme levels in the blood (signs of liver dysfunction, such as fulminant hepatitis, liver necrosis, liver failure)
- Small patches of bleeding under the skin (purpura, also caused by allergies), skin eruptions, eczema, sensitivity to light, redness of the skin, itching, blistered inflammation of the skin
- Skin rash with scaly or flaky skin (signs of so-called exfoliative dermatitis)
- Loss of hair
- Acute kidney function disorders, protein in the urine, blood in the urine, nephrotic syndrome (retention of water in the body and major urinary excretion of protein), damage to kidney tissue
- Decreased volume of urine or blood in the urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness (so-called tubulointerstitial nephritis symptoms)
- Significantly reduced amount of excreted urine (renal necrosis characters)

Not known (Frequency cannot be estimated from the available data)

- Medicinal products like Diclofenac T ratiopharm are possibly related to a slightly increased risk of heart attack (cardiac infarct) or stroke.
- An allergic skin reaction, that may include round or oval patches of redness and swelling of the skin, blistering, and itching (Fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur. Fixed drug eruption usually reoccurs at the same site(s) if the medication is taken again.

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. You can also report side effects directly via the national reporting system listed in [Appendix V*](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Diclofenac T ratiopharm

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

Do not use this medicine after the expiry date which is stated on the outer carton and the blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.

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 T ratiopharm* contains

- The active substance is diclofenac potassium.
Each film-coated tablet contains 50 mg of diclofenac potassium.
- The other ingredients are:
Microcrystalline cellulose, lactose monohydrate, maize starch, croscarmellose sodium, magnesium stearate, anhydrous colloidal silica, hypromellose, glycerol 85 %, talc, titanium dioxide (E171), red and yellow iron oxide (E172).

What *Diclofenac T ratiopharm* looks like and contents the pack

Diclofenac T ratiopharm 50 mg is a red-brown, round, biconvex film-coated tablet with a diameter of 11.1 mm.

Diclofenac T ratiopharm 50 mg is available in packs with 10, 20, 20x1, 30, 50, 50x1, 100, 100x1 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This leaflet was last revised in {month YYYY}.

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