

Package Informations Leaflet: Informations for the user
Diclofenac 100 mg - Suppositories
(diclofenac sodium)

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

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

1. What Diclofenac is and what it is used for

Diclofenac contains diclofenac sodium as the active ingredient, which is a non-steroidal anti-inflammatory drug (NSAID).

This means that it is a painkilling medicine which reduces inflammation and swelling, but it does not contain any steroid medicine.

Diclofenac suppositories are used rectally in the symptomatic management of rheumatoid arthritis including juvenile chronic arthritis, osteoarthritis, ankylosing spondylitis, psoriatic arthropathy, low back pain and acute musculoskeletal disorders including peri-arthritis, tendonitis, tenosynovitis, bursitis, sprains, strains, dislocations and in acute gout. It can also be used to treat pain and inflammation after orthopaedic, dental or other minor surgery.

2. What you need to know before you take Diclofenac Suppositories

Do not take Diclofenac if you:

- are allergic (hypersensitive) to diclofenac or any components of the preparation. Please refer to section 6 of this leaflet for a list of ingredients of Diclofenac.
- have ever had an allergic reaction (difficulty in breathing, skin rash and runny nose) to aspirin (acetylsalicylic acid) or any other NSAID such as ibuprofen.
- have had any gastrointestinal problems after taking any other NSAID, e.g. vomiting blood or passing black, tarry stools.
- have or have ever suffered from a stomach ulcer or bleeding from the stomach.
- have an inflammation of your anus, rectum or colon.
- have severe heart failure.
- are in the last three months of pregnancy - please see section on „Pregnancy and breastfeeding“.

If any of these apply to you, tell your doctor or pharmacist. Your doctor will decide whether this medicine is suitable for you.

Warnings and Precautions

Speak to your doctor before using Diclofenac if you:

- have high blood pressure
- have heart problems
- have mild to moderate heart failure
- have severe liver or kidney disease
- suffer from a disorder of your metabolism such as porphyria
- suffer from any bowel problems such as ulcerative colitis or Crohn's disease
- suffer from an upset stomach or irritation of the gut
- have suffered from any blood or bleeding disorder such as haemophilia
- are taking Diclofenac long-term or if you have severe liver impairment as you will undergo monitoring while taking Diclofenac suppositories
- have heart problems, previous stroke or mini stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes, or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.
- have recently had major surgery

If any of these apply to you, tell your doctor or pharmacist. Your doctor will decide whether this medicine is suitable for you.

Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

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

If you are not sure about using Diclofenac suppositories then talk to your doctor or pharmacist.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you are taking other medicines, make sure your doctor is aware of them, particularly if they are any of the following:

- other anti-inflammatory or “painkilling” medicines (NSAIDs)
- water tablets (diuretics)
- steroids which are used as the main treatment for certain inflammatory conditions (corticosteroids)
- aspirin (anti-platelet agents)
- medicines used to thin the blood such as warfarin (anticoagulants)
- mood stabilizing drugs such as lithium
- immunosuppressive agents which are drugs that inhibit or prevent activity of the immune system (ciclosporine)
- medicines that may be used to treat cancer (methotrexate)
- medicines for heart conditions or high blood pressure (beta blockers, ACE inhibitors, digoxin)
- quinolone antibiotics (ciprofloxacin, ofloxacin)
- aminoglycosides antibiotics used in serious infections (streptomycin)
- tablets to treat diabetes
- medicines for the treatment of depression (selective serotonin re-uptake inhibitors)

- an anticoagulant such as heparin
- treatment of hypertension and congestive heart failure (angiotensin-receptor blockers)
- if taking tablets to relieve the symptoms of inflammation and pain (COX inhibitors)
- antifungal medication (voriconazole)

If you are presently taking any of these medicines and are unsure talk to your doctor or pharmacist.

Pregnancy, breastfeeding and fertility

Do not use Diclofenac if you are pregnant or breast-feeding unless it is considered essential by your physician. Diclofenac may make it more difficult to get pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

This medicine must not be used by women who are in the last three months of pregnancy. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Diclofenac should not affect your ability to drive or operate machinery. If in the unlikely event you have dizziness or blurred vision, do not drive or operate machinery.

3. How to use Diclofenac Suppositories

Always use Diclofenac exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. It is important that you use the lowest dose that controls your pain and you should not use Diclofenac for longer than necessary. Voltaren suppositories are usually used at bedtime to relieve pain during the night and early morning stiffness.

Diclofenac suppositories are for rectal use only.

Adults:

Your doctor may start your treatment with anywhere from 75mg to 150mg per day, depending on your situation. After the early stages of treatment it is usually possible to reduce the daily dose to 75mg to 100mg per day.

Children:

12.5mg and 25mg suppositories are for use in children over 5 years of age and weighing 18kg or more with chronic juvenile rheumatoid arthritis

If you use more Diclofenac than you should

If you use too many suppositories, tell your doctor or hospital emergency department at once. Take your medicine with you.

If you forget to use Diclofenac

If you forget to use Diclofenac, use one as soon as you remember, and then go on as before. Do not insert two suppositories at the same time. No more than one suppository should be used daily. Do not take more than 150 mg in 24 hours.

If you stop using Diclofenac

Your doctor will decide how long you will take this medicine. Your doctor has carefully chosen the correct dosage for you taking into account the severity of your condition, your age and any other reasons special to you. Therefore, you should always take the dose prescribed.

4. Possible side effects

Like all medicines, Diclofenac can cause side effects, although not everybody gets them. These may occur in the initial stages of treatment and may be more serious if they occur in the elderly.

If the following happens at any time during your treatment, tell your doctor immediately:

an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing, skin rash or hives), passing blood in your faeces (stools/motions), passing black tarry stools, vomiting any blood or dark particles that look like coffee grounds, a serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome), indigestion or heartburn, abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Very common (≥1/10); Common (≥1/100 to <1/10)

Uncommon (≥1/1,000 to <1/100) Rare (≥1/10,000 to <1/1,000) Very Rare

(<1/10,000)

Not Known (cannot be estimated from available data).

Common:

Headache, dizziness, Vertigo, Nausea, vomiting, diarrhoea, indigestion, flatulence, abdominal pain, loss of appetite, Skin rash, Irritation at area of insertion

Rare:

Allergic action (e.g difficulties in breathing, wheezing or low blood pressure), Drowsiness, tiredness, Asthma, shortness of breath, Inflammation of the lining of the stomach, Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, Gastro-intestinal ulcers with or without bleeding, Fluid Retention

Very Rare:

Decrease of platelets in the blood, signs of this can be bleeding inside the body or bleeding from the skin, Decrease of white blood cells in the blood, Anaemia, abnormal bleeding, Rapid swelling, including swelling of the face, Disorientation, depression, insomnia, nightmares, irritability, psychotic disorder, Sensation of tingling, pricking, or numbness of skin, Impaired memory, Convulsions, tremors, Anxiety

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

Reporting of side effects

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

5. How to store Diclofenac Suppositories

Keep out of the reach and sight of children.

Do not store above 30° C. Do not use Diclofenac suppository after the expiry date as stated on the label and carton. The expiry date refers to the last day of the month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Diclofenac contains

The active substance is diclofenac sodium 100 mg. The other ingredient is hard fats.

What Diclofenac looks like and contents of the pack

Diclofenac suppositories are white torpedo-shaped rectal suppositories.

Diclofenac suppositories are available in packs of 10 suppositories.

Manufacturer

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