

## **Package leaflet: Information for the patient**

### **Diclofenac Sodium 100mg Suppositories**

**Read all of this 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.
- 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.

The name of your medicine is Diclofenac Sodium 100mg Suppositories. It will be referred to as Diclofenac Sodium Suppositories for ease here after.

#### **What is in this leaflet:**

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

#### **1. What are Diclofenac Sodium Suppositories and what are they used for**

Diclofenac Sodium Suppositories contain diclofenac and belong to a group of medicines called non-steroid anti-inflammatory drugs (NSAIDs).

These medicines reduce pain, swelling and ease inflammation, in conditions affecting the joints, muscles and tendons including:

- Rheumatoid arthritis, osteoarthritis, acute gout, ankylosing spondylitis
- Backache, sprains and strains, soft tissue sports injuries, frozen shoulder, dislocations and fractures
- Tendonitis, tenosynovitis, bursitis.

They are also used to treat pain and inflammation associated with dental and minor surgery.

#### **2. What you need to know before you use Diclofenac Sodium Suppositories**

##### **Do not use Diclofenac Sodium Suppositories:**

- if you are allergic to Diclofenac Sodium, aspirin, ibuprofen or any other NSAIDs or any of the other ingredients of this medicine (listed in section 6). 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 have now, or have ever had a stomach (gastric) or duodenal (peptic) ulcer or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces)
- if you have had stomach or bowel problems after you have taken other NSAIDs
- if you have severe heart, kidney or liver failure
- if you have established heart disease and/or cerebrovascular disease e.g. if you have had a heart attack, stroke, ministroke (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 are more than six months pregnant
- if you suffer from ineffectual straining to empty the bowels, diarrhoea or rectal bleeding.

#### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Diclofenac Sodium Suppositories if:

- you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease
- you suffer from any disorder of the liver or kidneys
- you have a condition called porphyria
- you suffer from haemophilia (a disorder of blood clotting) or any other bleeding disorder
- you suffer from bronchial asthma or any allergic disease
- you are breast feeding
- you have angina, blood clots, high blood pressure or raised cholesterol or raised triglycerides
- you have heart problems, or have you had a stroke, or do you think 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 smoke
- you have diabetes
- you have Lupus (systemic lupus erythematosus) or any similar condition.

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary. If you are having a medical examination, tell the doctor that you are using Diclofenac Sodium Suppositories as they reduce the signs of fever and inflammation which would otherwise be noticed.

#### **Other medicines and Diclofenac Sodium suppositories:**

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

Diclofenac Sodium Suppositories may affect or be affected by the following medicines:

- medicines for the treatment of diabetes
- anticoagulant tablets (blood thinning tablets like warfarin)
- diuretics (water tablets)
- lithium (used to treat some mental problems)
- methotrexate (for some inflammatory diseases and some cancers)
- ciclosporin or Tacrolimus (used to treat some inflammatory diseases and after transplants)
- trimethoprim (a medicine used to prevent or treat urinary tract infections)
- quinolone antibiotics (for infections)
- any other NSAID or COX-2 (cyclo-oxygenase-2) inhibitor, for example aspirin or ibuprofen
- mifepristone (a medicine used to terminate pregnancy)
- cardiac glycosides (for example digoxin), used to treat heart problems
- medicines known as SSRIs used to treat depression
- oral steroids (an anti-inflammatory drug)
- medicines used to treat heart conditions or high blood pressure, for example betablockers or ACE inhibitors
- voriconazole (a medicine used to treat fungal infections)
- phenytoin (a medicine used to treat seizures)
- colestipol/cholestyramine (used to lower cholesterol).

#### **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

Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. Do not use Diclofenac Sodium Suppositories 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 use Diclofenac Sodium suppositories 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 Sodium suppositories 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

Diclofenac Sodium Suppositories should be avoided if you are breast-feeding, as small amounts of the medicine may pass into breast milk which can cause undesirable effects in the infant.

#### Fertility

Diclofenac Sodium Suppositories may make it more difficult to conceive

#### **Driving and using machines:**

Very occasionally people have reported that Diclofenac Sodium Suppositories have made them feel dizzy, tired or sleepy. Problems with eyesight have also been reported. If you are affected in this way, you should not drive or operate machinery.

#### **Other special warnings**

- you should take the lowest dose of Diclofenac Sodium Suppositories for the shortest possible time, particularly if you are underweight or elderly
  - there is a small increased risk of heart attack or stroke when you are taking any medicine like Diclofenac Sodium Suppositories. The risk is higher if you are taking high doses for a long time.
- Always follow the doctor's instructions on how much to take and how long to take it for
- whilst you are taking these medicines your doctor may want to give you a check-up from time to time
  - if you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms
  - because it is an anti-inflammatory medicine, Diclofenac Sodium Suppositories may reduce the symptoms of infection, for example, headache and high temperature. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking Diclofenac Sodium Suppositories.

Diclofenac Sodium suppositories are not recommended for use in children.

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before using Diclofenac Sodium Suppositories, as Diclofenac Sodium Suppositories can sometimes worsen wound healing in your gut after surgery.

### **3. How to use Diclofenac Sodium suppositories**

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

The dose will be on the pharmacist's label. Check the label carefully. If you are not sure, ask your doctor or pharmacist.

Keep using the suppositories for as long as you have been told, unless you have any problems. In that case, check with your doctor.

Suppositories are designed for insertion into the back passage (rectum).

#### **Never take them by mouth.**

The doctor may also prescribe another drug to protect the stomach to be taken at the same time, particularly if you have had stomach problems before, or if you are elderly, or taking certain other drugs as well.

The recommended dose is:

**Adults:** One Diclofenac Sodium Suppository may be inserted as a once daily treatment, usually at night.

As a general principle, the smallest effective dose should be used, and for the shortest time. Side effects can worsen with increased use.

**Elderly:** If you are elderly, your doctor may want to reduce the usual adult dosage and to check that the medicine is suiting you, especially during the first four weeks of treatment. Make sure to follow your doctor's instructions carefully and to keep your appointments.

**Use in children and adolescents:** Diclofenac Sodium Suppositories are not recommended for use in children. Where necessary, you can use other medicines (tablets taken by mouth) with your suppository. Diclofenac Sodium Suppositories may be combined with oral (to be taken by mouth) tablets.

Your doctor may want to monitor you.

### **Inserting your medicine:**

Empty your bowels before inserting a suppository

Wash your hands.

Tear the foil wrapping apart at notch and take out the suppository.

Lie on one side with your knees pulled up towards your chest.

Gently push the suppository pointed end first into your back passage (rectum) with your finger. Push the suppository up as far as possible.

Lower your legs, and if possible, remain still for a few minutes.

If you feel your body wanting to expel the suppository, try to resist this. Lie still and press your buttocks together. It is important to keep the suppository in the rectum to allow it to melt and the medicine to be absorbed. Pushing the suppository high into the rectum with your finger will help to reduce this feeling.

Wash your hands.

### **If you use more Diclofenac Sodium Suppositories than you should:**

If you (or someone else) use too many Diclofenac Sodium Suppositories, you may experience headache, feeling sick, vomiting, stomach pain, black colored stools, diarrhea, fainting, seizures or even kidney or liver damage in severe cases. In such situations contact your doctor, or nearest hospital, immediately for advice. Bring the remaining suppositories with you.

### **If you forget to use Diclofenac Sodium Suppositories:**

If you miss a dose, leave it out and use the next dose whenever it is due. After that, just carry on as before. Do not take a double dose to make up for a forgotten 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.

**Some side effects can be serious.**

**Stop using the suppositories and tell your doctor straight away if you notice:**

- mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Diclofenac Sodium Suppositories and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain (frequency not known, cannot be estimated from the available data)
- stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick)
- any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry faeces
- allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering
- wheezing or shortness of breath (bronchospasm)
- swollen face, lips, hands or fingers
- yellowing of your skin or the whites of your eyes
- persistent sore throat or high temperature

- skin rashes including Stevens-Johnson syndrome, Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight. Hair loss
- Palpitations (fast or irregular heartbeat)
- headaches together with a dislike of bright lights, fever and a stiff neck; inflammation of the lining of the brain (meningitis)
- drooping in your mouth or eye, unable to lift your arms, blurred speech or unable to speak as these are symptoms of a stroke
- heart cannot pump or fill adequately (congestive heart failure)
- Kidney or severe liver disorders including liver failure, presence of blood or protein in the urine, an unexpected change in the amount of urine produced
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor.

Diclofenac Sodium Suppositories may also occasionally cause itching or burning in your back passage or make any haemorrhoids (piles) worse.

**The side effects listed below have also been reported.**

**Common: may affect up to 1 in 10 people**

- diarrhoea, loss of appetite
- headache, dizziness, a sensation of whirling and loss of balance
- raised levels of liver enzymes in the blood.

**Rare: may affect up to 1 in 1,000 people**

- gastritis (inflammation, irritation or swelling of the stomach lining)
- drowsiness, tiredness
- fluid retention, symptoms of which include swollen ankles
- liver function disorders, including liver inflammation
- irritation where the suppository is inserted.
- asthma (including Shortness of breath).

**Very rare: may affect up to 1 in 10,000 people**

**Effects on the nervous system:**

Tingling or numbness in the fingers, tremor, blurred or double vision, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, mental disorders, disorientation and loss of memory, fits

**Effects on the stomach and digestive system:**

Constipation, inflammation of the tongue, mouth ulcers, taste changes, lower gut disorders (including inflammation of the colon, or worsening of ulcerative colitis or Crohn's disease), Inflammation of the pancreas

**Effects on the heart, chest or blood:**

Chest pain, hypertension (high blood pressure), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), blood disorders (including anaemia).

Hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light

headedness).

**Effects on the liver or kidneys:**

Kidney or severe liver disorders, presence of blood or protein in the urine.

**Effects on reproductive system:**

Impotence.

**Effects on immune system**

facial swelling

**Not known: frequency cannot be estimated from the available data**

confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye, disturbances of sensation.

Do not be alarmed by this list - most people use Diclofenac Sodium Suppositories without any problems.

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. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE DICLOFENA SODIUM SUPPOSITORIES**

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 Carton after 'Expiry date'. The Expiry date refers to last day of that month. Do not store above 25°C. Store in the original package in order to protect from light.

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 Sodium Suppositories contains:**

The active substance is diclofenac sodium. The other ingredient is hard fat.

**What Diclofenac Sodium Suppositories looks like and contents of the pack:**

Diclofenac Sodium Suppositories are white, torpedo shaped with a uniform white surface. One suppository contains 100mg diclofenac sodium.

One package contains 10 suppositories for rectal use only.

**Marketing Authorization Holder:**

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This leaflet was last revised in May 2024