



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

## **DICLOFENAC INJECTION**

Diclofenac 75mg/3ml

**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 before, during or after use of this medicine.
- 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 or nurse. This includes any possible
- side effects not listed in this leaflet. See section 4.

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

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

### **1. WHAT DICLOFENAC INJECTION IS AND WHAT IT IS USED FOR**

Diclofenac Injection is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation. Diclofenac Injection can either be given as an injection into the muscle, or as a slow infusion into a vein. The intramuscular injection is used to treat a number of painful conditions including:

- acute back pain
- attacks of gout
- pain caused by gallstones or kidney stones.
- pain due to osteo- and rheumatoid arthritis
- pain caused by injuries, acute trauma, and fractures.
- pain following surgery.

The intravenous infusion is used in hospital to prevent or treat pain following an operation.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DICLOFENAC INJECTION**

**Some people must not use Diclofenac injection. Talk to your doctor if:**

- you think you may be allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAIDs, or to any of the other ingredients of Diclofenac Injection. 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 of reaction.
- you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the gut (digestive tract). This can include blood in vomit, bleeding when emptying bowels, fresh blood in stools or black, tarry stools. This may have been when you used an NSAID before.
- you have heart disease and/or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages in blood vessels to the heart or brain or an operation to clear or bypass blockages
- you have or have had problems with your blood circulation (peripheral arterial disease)



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- you have severe heart failure, kidney or liver problems.
- you are in the last three months of pregnancy
- you are a child under 14 years of age.

Do not take Diclofenac Injection if any of these applies to you. If you are not sure, talk to your doctor or pharmacist before taking Diclofenac Injection.

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

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Diclofenac Injection if:

- you are taking Diclofenac Injection simultaneously with other anti-inflammatory medicines including acetylsalicylic acid/aspirin, anti-coagulants or SSRIs.
- you have ever had gastro-intestinal problems such as stomach ulcer, bleeding or black stools or have experienced stomach discomfort or heartburn after taking anti-inflammatory medicines in the past
- you suffer from asthma, hay fever, nasal polyps, chronic obstructive pulmonary diseases (COPD) or often get chest infections
- you have any allergies
- you are elderly
- you have Lupus (SLE) or any similar condition
- you have an inflammatory bowel disease, such as ulcerative colitis (colon inflammation) or Crohn's (Intestinal tract inflammation)
- you have a bleeding disorder, or any other blood problems, including the rare liver condition called porphyria
- you have, or have ever had a heart problem or high blood pressure
- you have swollen feet
- you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").
- you think you are dehydrated, perhaps due to diarrhoea or sickness, or in association with surgery.

If any of these applies to you, tell your doctor before taking Diclofenac Injection. Diclofenac, like other anti-inflammatory medicines, may cause severe allergic skin reactions (e.g. rash). Therefore, inform your doctor immediately if you experience such reactions.

Make sure your doctor knows, before you are given Diclofenac Injection

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

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.



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Diclofenac Injection may reduce the symptoms of an infection (e.g. headache, high temperature) and may therefore make the infection more difficult to detect and to treat adequately. If you feel unwell and need to see a doctor, remember to mention that you are taking Diclofenac Injection.

Medicines, such as Diclofenac Injection, may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke, particularly at high dose and in long term treatment.

Any risk is more likely with high doses and prolonged treatment.

If you have any liver impairment, kidney impairment or blood impairment, you will have blood tests during treatment. These will monitor the function of your liver, kidney or your blood count. Your doctor will take these blood tests into consideration to decide if Diclofenac Injection needs to be discontinued or if the dose needs to be changed.

### **Elderly or underweight Patients**

Elderly patients may be more sensitive to the effects of Diclofenac Injection than other adults. Follow your doctor's instructions carefully and take the lowest dose that provides relief of symptoms. It is especially important for elderly patients to report undesirable effects to their doctor especially stomach problems.

### **Children and adolescents**

This medicine is not recommended for use in children and adolescents. It must not be given to children under 14 years of age.

### **Other medicines and Diclofenac Injection**

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

Some medicines can interfere with your treatment. Tell your doctor if you are taking, have recently taken or might take any of the following medicines:

- lithium or selective serotonin-reuptake inhibitors (SSRIs), (medicines used to treat some types of depression)
- cardiac glycosides (e.g. digoxin) (used to treat heart problems)
- diuretics (medicines used to increase the amount of urine)
- ACE inhibitors or beta-blockers (classes of medicines used to treat high blood pressure or heart failure)
- any other NSAID or COX-2 (cyclooxygenase-2), inhibitor such as acetylsalicylic acid/aspirin or ibuprofen
- mifepristone (a medicine used to terminate pregnancy)
- corticosteroids (medicines used to provide relief for inflamed areas of the body)
- anti-coagulants (medicines used to prevent blood-clotting)
- medicines used to treat diabetes, except insulin.
- methotrexate (a medicine used to treat some kinds of cancer or arthritis)
- ciclosporin, tacrolimus (a medicine primarily used in patients who have received organ transplants)
- trimethoprim (a medicine used to prevent or treat urinary tract infections)
- quinolone antibiotics (for infections)
- potent CYP2C9 inhibitors such as voriconazole (a medicine used to treat serious fungal infections)



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- phenytoin, a medicine to treat epilepsy.
- colestipol/cholestyramine (used to lower cholesterol).

### **Pregnancy and breast-feeding**

Please tell your doctor or pharmacist if you are pregnant or think you might be pregnant

- Diclofenac Injection may make it more difficult to become pregnant. You should not take Diclofenac Injection unless necessary if you are planning to become pregnant or if you have difficulty in becoming pregnant.
- Do not take Diclofenac Injection in the last three months of pregnancy as it could harm your unborn child or cause problems during delivery. You should not take Diclofenac Injection during the first 6 months of pregnancy unless necessary.
- Do not breast-feed if you are taking Diclofenac Injection, because small amounts can pass into breast milk and may harm your baby.

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 any medicine.

### **Driving and using machines**

Usually Diclofenac Injection does not affect your ability to drive or use machines. However, it may make you feel dizzy, tired or sleepy or have problems with eyesight. If you are affected in this way, you should not drive or operate machinery.

### **3. HOW TO TAKE DICLOFENAC INJECTION**

Your doctor will decide when and how to treat you with Diclofenac Injection. You will be given an intramuscular injection (an injection into the muscle) or an intravenous infusion (a drip into the vein).

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.

If necessary, treatment can be continued with Diclofenac tablets or suppositories.

#### **Adults:**

The recommended dose is one or two ampoules (75 or 150mg) each day for one or two days.

#### **Older patients**

Your doctor may give you a dose that is lower than the usual adult dose if you are elderly.

#### **Children and adolescents**

This medicine is not recommended for children and adolescents. It must not be given to children under 14 years of age.

#### **If you take more Diclofenac Injection than you should**

If you think you have been given too much Diclofenac Injection, tell your doctor or nurse straightaway. The following effects such as vomiting, bleeding in your stomach, diarrhoea, feeling dizzy, hearing problems or fits may happen.



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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 Diclofenac Injection and tell your doctor straightaway if you notice:**

- mild cramping and tenderness of the abdomen, shortly after the start of the treatment with Diclofenac Injection 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).
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

### **Some side effects can be serious**

*These uncommon side effects may affect between 1 and 10 in every 1000 patients, especially when taking a high daily dose (150mg) for a long period of time.*

- sudden and oppressive chest pain (signs of myocardial infarction or heart attack)
- breathlessness, difficulty in breathing when lying down, swelling of the feet or legs (signs of cardiac failure).

*These rare or very rare side effects may affect from less than 1 to 10 in every 10,000 patients.*

- stomach pain, indigestion, heartburn, feeling sick (nausea), or being sick (vomiting)
- chest pain, or tightness with shortness of breath
- vomiting of blood, bleeding from the bowel
- persistent sore throat or high temperature
- an unexpected change in the amount of urine produced and/or its appearance.
- sudden slurred speech, facial drooping, weakness, disorientation, or speech problems
- allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling
- blistering, wheezing or shortness of breath ('bronchospasm'), swollen face, lips, hands or fingers, hypotension (low blood pressure) and fainting

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

### **Other side effects include:**

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

- headache, dizziness, vertigo
- nausea, vomiting, diarrhoea, indigestion, abdominal pain, wind, loss of appetite
- change in liver function (e.g. raised levels of transaminases)
- skin rash
- pain, swelling or reactions at the injection site



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**Uncommon:** may affect up to 1 in 100 people

- palpitations

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

- stomach ulcers or bleeding (there have been very rare, reported cases resulting in death, particularly in the elderly)
- gastritis (inflammation, irritation, or swelling of the stomach lining)
- vomiting blood
- diarrhoea with blood in it or bleeding from the back passage
- black tarry faeces or stools
- hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness)
- drowsiness, tiredness
- skin rash and itching
- swelling of arms, hands, legs and feet (oedema)
- death of skin tissue at the injection site (necrosis)
- liver function disorders including hepatitis and jaundice.

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

- tingling or numbness in the fingers, tremor, vision disorders (signs of visual impairment, blurred or double vision), hearing loss or impairment, ringing in the ears, sleeplessness, nightmares, mood changes, depression, anxiety, mental health disorders, disorientation and memory loss, fits, headaches together with a dislike of bright lights, fever and a stiff neck, disturbances in sensation, hair loss, abscess at the site of the injection, constipation, taste changes,
- vision disorders: If symptoms of vision disorders occur during treatment with Diclofenac Injection, contact your doctor as an eye examination may be considered to exclude other causes.

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

- tissue damage at the injection site

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 healthcare provider. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

### **5. HOW TO STORE DICLOFENAC INJECTION**

- Keep this medicine out of the reach of children.
- Do not take this medicine after the expiry date which is stated on the label and carton after 'Exp. Date'. The expiry date refers to the last day of that month.
- Store below 30°C.



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Do not throw away 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. FURTHER INFORMATION

#### What Diclofenac Injection contains


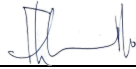

The active substance is Diclofenac. Each ml of the solution contains 25 mg diclofenac equivalent to a total of 75 mg in each 3 ml ampoule.

#### What Diclofenac Injection looks like and contents of the pack

Diclofenac Injection is a solution for injection packed as 10x3ml ampoules, placed in a carton with patient information leaflet.

#### MANUFACTURER

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