

**Package leaflet: Information for the user**

**DICLOTON 75 mg/3ml  
solution for injection/infusion  
(Diclofenac sodium)**

**Read this entire leaflet carefully because it contains important information for you.**

- Keep this leaflet. You may need it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after several days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What DICLOTON is and what it is used for
2. Before you take DICLOTON
3. How to take DICLOTON
4. Possible side effects
5. How to store DICLOTON
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**1. WHAT DICLOTON IS AND WHAT IT IS USED FOR**

Diclofenac sodium, the active ingredient in DICLOTON, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

The intramuscular injection is used to treat a number of painful conditions including:

- 'Flare-ups' of joint or back pain
- Attacks of gout
- Pain caused by kidney stones
- Pain caused by injuries.

DICLOTON can either be given as an injection into the muscle, or as a slow infusion into a vein. The intravenous infusion is used in hospitals to prevent or treat pain following an operation.

DICLOTON are not suitable for children.

**2. BEFORE YOU TAKE DICLOTON**

**Do not take DICLOTON if:**

- You think you may be allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of this medicinal product. (These are listed 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.

- 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).
- You have had stomach or bowel problems after you have taken other NSAIDs.
- You have heart, kidney or liver failure.
- 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 bypass blockages.
- You have or have had problems with your blood circulation (peripheral arterial disease).
- You are more than six months pregnant.

**Take special care with DICLOTON if:**

- You suffer from any bowel disorders including ulcerative colitis or Crohn's disease.
- You have kidney or liver problems, or are you elderly.
- You suffer from any blood or bleeding disorder.
- You have a condition called porphyria.
- You ever had asthma.
- You breastfeeding.
- You have angina, blood clots, high blood pressure, abnormally high levels of fat in your blood (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 have diabetes.
- You smoke.
- You have Lupus (SLE) or any similar condition.
- You be suffering from dehydration.
- You suffered any heavy loss of blood recently.

**Taking other medicines:**

Some medicines can interfere with your treatment. Tell your doctor or pharmacist if you are taking any of the following:

- Medicines to treat diabetes
- Anticoagulants (blood thinning tablets like warfarin)
- Diuretics (water tablets)
- Lithium (used to treat some mental problems)

- Methotrexate (for some inflammatory diseases and some cancers)
- Ciclosporin and 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 beta-blockers or ACE inhibitors.
- Voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures)
- Colestipol/cholestyramine (used to lower cholesterol)

Always tell your doctor or pharmacist about all the medicines you are taking. This means medicines you have bought yourself as well as medicines on prescription from your doctor.

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

Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not have a diclofenac during the last 3 months of pregnancy as it may affect the baby's circulation.

Having diclofenac may make it more difficult to conceive.

You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

### **Driving or using machines**

Very occasionally people have reported that diclofenac 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 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. 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.

- If at any time while taking diclofenac 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.
- 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 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.
- DICLOTON should not be used in children.

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

**DICLOTON contains sodium.**

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially ‘sodium-free’.

**DICLOTON contains benzyl alcohol.**

It must not be given to premature babies or neonates. It may cause toxic reactions and anaphylactoid reactions in infants and children up to 3 years old.

**DICLOTON contains propylene glycol.**

May cause alcohol-like symptoms.

**DICLOTON contains sodium metabisulphite.**

Sodium metabisulphite may rarely cause severe hypersensitivity reactions and bronchospasm.

**3. HOW TO TAKE YOUR MEDICINE**

Your doctor will decide when and how to treat you with DICLOTON. You will either be given an intravenous infusion (a drip into a vein) or an intramuscular injection (an injection into a muscle). The intramuscular injection is usually injected into the buttocks.

The usual dose is:

**Adults**

One or two ampoules (75 to 150 mg) each day for one or two days.

**Elderly**

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

**Children**

Not suitable for children.

A doctor, nurse or pharmacist will prepare the injection for you.

If you have had an operation and are in hospital, the ampoule contents may be diluted and put into a drip bag before being given to you. A nurse or doctor will usually then give you the injection or infusion. You would not usually have to give the injection to yourself.

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 you take more DICLOTON than you should**

If you think you have been given too much diclofenac tell your doctor or nurse straight away.

### **If you missed a dose of DICLOTON**

Your doctor or nurse will have instructions about when to give you your medicine. It is unlikely that you will not be given the medicine as it has been prescribed. If you think that you may have missed a dose, then talk to your doctor or nurse. If a dose of DICLOTON has been forgotten, it can be administered later. If it is already time for the next application, the usual dose of DICLOTON should be used.

## **4. POSSIBLE SIDE EFFECTS**

Diclofenac is suitable for most people, but, like all medicines, they can sometimes cause side effects. Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

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

Tell the doctor straight away if you notice:

- Sudden and crushing chest pain (signs of myocardial infarction or heart attack)
- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure)
- Sudden weakness or numbness in the face, arm or leg especially on one side of the body; sudden loss or disturbance of vision; sudden difficulty in speaking or ability to understand speech; sudden migraine-like headaches which happen for the first time, with or without disturbed vision. These symptoms can be an early sign of a stroke.
- 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
- An unexpected change in the amount of urine produced and/or its appearance.
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with diclofenac and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain.
- 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.

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

**Common** side effects (These may affect between 1 and 10 in every 100 patients):

- Stomach pain, heartburn, nausea, vomiting, diarrhoea, indigestion, wind, loss of appetite
- Headache, dizziness, vertigo
- Skin rash or spots
- Raised levels of liver enzymes in the blood
- Injection site reactions, symptoms include redness, swelling, change in the skin colour, inflammation, pain, and hypersensitivity.

**Uncommon** side effects (These may affect between 1 and 10 in every 1000 patients):

- Fast or irregular heart beat (palpitations), chest pain, heart disorders, including heart attack or breathlessness, difficulty breathing when lying down, or swelling of the feet or legs (signs of heart failure), especially if you have been taking a higher dose (150 mg per day) for a long period of time.

**Rare** side effects (These may affect between 1 in every 1000 to 1 in every 10,000 patients):

- 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
- Drowsiness, tiredness
- Skin rash and itching
- Fluid retention, symptoms of which include swollen ankles
- Liver function disorders, including hepatitis and jaundice
- Asthma (symptoms may include wheezing, breathlessness, coughing and a tightness across the chest)
- Injection site necrosis (dead skin and tissue around the injection site).

**Very rare** side effects (These may affect less than 1 in every 10,000 patients):

- Inflammation of the lining of the brain (meningitis), tingling or numbness in the fingers, tremor, visual disturbances such as blurred or double vision, taste changes, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, irritability, mental disorders, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck.
- Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, lower gut disorders (including inflammation of the colon, or worsening of colitis or Crohn's disease), inflammation of the pancreas.
- Hypertension (high blood pressure), hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), blood disorders (including anaemia).
- Kidney or severe liver disorders including liver failure, presence of blood or protein in the urine.
- Facial swelling, serious skin rashes including Stevens-Johnson syndrome Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight.
- Hair loss.
- Impotence.

Other side effects that have also been reported with **unknown** frequency include:

- Injection site abscess, throat disorders, confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye, disturbances of sensation, tissue damage at the injection site.

Do not be alarmed by this list - most people have an injection of DICLOTON without any problems.

### **Reporting of side effects**

If you get any side effects, talk 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. By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE YOUR MEDICINE**

Store below 25°C in the original package.

Do not refrigerate or freeze.

Keep out of the sight and reach of children.

Do not use DICLOTON after the expiry date which is stated on the carton. This is on the carton. It is also on the label of each ampoule. Do not try to open the ampoules. The expiry date refers to the last day of that month.

If you are told to stop taking DICLOTON by your doctor, or you have some left over, take it to your pharmacist for disposal.

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. FURTHER INFORMATION**

### **What DICLOTON contains:**

The active substance is diclofenac sodium. Each amber glass ampoule has 3 ml of liquid containing 75 mg of diclofenac sodium.

The other ingredients are: benzyl alcohol, sodium formaldehyde sulfoxylate, propylene glycol, sodium metabisulphite, sodium hydroxide, water for injection.

### **What DICLOTON looks like and contents of the pack**

DICLOTON injection is a clear colourless to faintly yellow solution in Type I 3.0 mL amber glass ampoules.

DICLOTON Injection is supplied in single use amber glass ampoules containing 3 ml of diclofenac sodium 25 mg/ml, in packs of one, five or ten ampoules.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Medochemie Ltd, 1 - 10 Constantinoupoleos, 3011 Limassol, Cyprus

### **Manufacturer**

Medochemie Ltd, 48 Iapetou Street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol, Cyprus

**This leaflet was last revised on July 2020.**

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## **For the Medical and Pharmaceutical Professions**

### **Dosage and Administration**

DICLOTON (given im or iv) should not be given for more than two days; if necessary, treatment can be continued with DICLOTON Tablets or Suppositories.

### Intramuscular injection:

The following directions for intramuscular injection must be adhered to in order to avoid damage to a nerve or other tissue at the injection site.



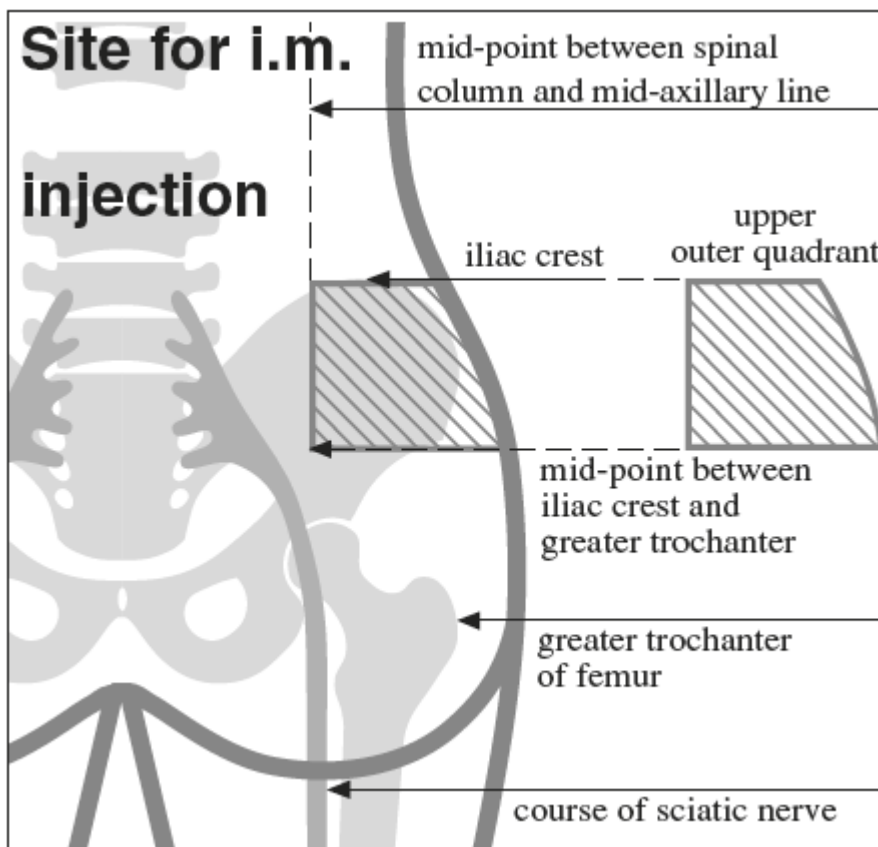
One ampoule once (or in severe cases twice) daily intramuscularly by deep intragluteal injection into the upper outer quadrant. If two injections daily are required it is advised that the alternative buttock be used for the second injection. Alternatively, one ampoule of 75 mg can be combined with other dosage forms of DICLOTON (tablets or suppositories) up to the maximum daily dosage of 150 mg.

#### Renal colic:

One 75 mg ampoule intramuscularly. A further ampoule may be administered after 30 minutes if necessary. The recommended maximum daily dose of DICLOTON is 150 mg.

#### Recommended injection procedure

1. The patient may lie down or stand (holding a stable piece of furniture for support) whichever is most comfortable.
2. The buttocks should be exposed and inspected to find the most suitable injection site. Avoid scars and lumps and choose the buttock which is free from any problems. If more than one injection needs to be given the other buttock should be used.
3. The injection site should be thoroughly disinfected e.g. with isopropyl alcohol and allowed to dry before injecting the solution.
4. Give the deep intramuscular injection high into upper outer quadrant (for boundary definitions see diagram) of the buttock taking particular care to avoid the sciatic nerve (see diagram) and blood vessels (see point 5 below). Avoid injecting into an area where resistance is felt.



N.B. In obese patients avoid deposition of the drug into the subcutaneous fatty tissue.

In small thin patients with little muscle bulk, be especially aware of the sciatic nerve which may be quite superficial.

5. Before injection and after needle insertion, pull back the syringe plunger to check the needle has not entered a vessel. If blood is drawn, withdraw the needle to another site and check again.
6. The injection should be given slowly to minimise local tissue damage.
7. If the patient complains of severe pain or pronounced discomfort stop the injection immediately. Retry at another site. A dull aching pain may be experienced after normal injection.
8. Advise the patient to remain reasonably mobile for one to two hours after the injection, whenever possible.

#### Intravenous Infusion:

Immediately before initiating an intravenous infusion, DICLOTON must be diluted with 100-500ml of either sodium chloride solution (0.9%) or glucose solution (5%). Both solutions should be buffered with sodium bicarbonate solution (0.5ml 8.4% or 1ml 4.2%). Only clear solutions should be used.

DICLOTON must not be given as an intravenous bolus injection.

Intravenous infusions should be freshly made up and used immediately. Once prepared, the infusion should not be stored.

Two alternative regimens are recommended:

- For the treatment of moderate to severe post-operative pain, 75 mg should be infused continuously over a period of 30 minutes to 2 hours. If necessary, treatment may be repeated after 4–6 hours, not exceeding 150 mg within any period of 24 hours.
- For the prevention of post-operative pain, a loading dose of 25 mg–50 mg should be infused after surgery over 15 minutes to 1 hour, followed by a continuous infusion of approx. 5mg per hour up to a maximum daily dosage of 150 mg.

#### Incompatibilities

The ampoules used im or iv as an infusion should not be mixed with other injection solutions.

#### Shelf life

3 years.