

Diclofenac Sodium Injection 75mg/1ml, 75mg/3ml

Patient Information Leaflet

What you need to know about Diclofenac sodium injection

Your doctor has decided that you need this medicine to help treat your condition.

In this leaflet:

1. What Diclofenac sodium injection are, and what they are used for
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1. What Diclofenac sodium injection are, and what they are used for

Diclofenac sodium, the active ingredient in Diclofenac sodium injection, 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.

Diclofenac sodium injection 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.

Diclofenac sodium injection are not suitable for children.

2. Things to consider before you start to take Diclofenac sodium injection Some people **MUST NOT** have this injection. **Talk to your doctor if:**

- you think you may be allergic to diclofenac sodium, sodium metabisulphite, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Diclofenac sodium injection. (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
- 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 bypass blockages
- if you have or have had problems with your blood circulation (peripheral arterial disease)
- you are more than six months pregnant

You should also ask yourself these questions before having a Voltarol Injection or Infusion:

- Do you suffer from any bowel disorders including ulcerative colitis or Crohn's disease?
- Do you have kidney or liver problems, or are you elderly?
- Do you suffer from any blood or bleeding disorder?
- Do you have a condition called porphyria?
- Have you ever had asthma?
- Are you breastfeeding?
- Do you have angina, blood clots, high blood pressure, abnormally high levels of fat in your blood (raised cholesterol or raised triglycerides)?
- Do 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)?

- Do you have diabetes?
- Do you smoke?
- Do you have Lupus (SLE) or any similar condition?
- Could you be suffering from dehydration?
- Have you suffered any heavy loss of blood recently?

If the answer to any of these questions is YES, discuss your treatment with your doctor or pharmacist because Diclofenac sodium injection might not be the right medicine for you.

Are you 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

- Are you pregnant or planning to become pregnant? Although not common,

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

- Are you trying for a baby? Having Voltarol Injections 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.

Will there be any problems with driving or using machinery?

Very occasionally people have reported that Diclofenac sodium injection 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 injection 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 injection. 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 sodium injection 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 sodium injection 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 injection.
- Diclofenac sodium injection contain the preservative, sodium metabisulphite. This can sometimes cause allergic reactions and breathing difficulties.
- Diclofenac sodium injection 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 sodium injection, as Diclofenac sodium injection can

sometimes worsen wound healing in your gut after surgery.

3. How to take Diclofenac sodium injection

Your doctor will decide when and how to treat you with Diclofenac sodium injection. 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.

What if you have had too much Diclofenac sodium injection? (Overdose)

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

4. Possible side effects

Diclofenac sodium injection are 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 sodium injection 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*):

Effects on the nervous system:

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.

Effects on the stomach and digestive system:

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.

Effects on the chest or blood:

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).

Effects on the liver or kidneys:

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

Effects on skin or hair:

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.

Effects on the reproductive system:

Impotence.

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

Injection site abscess, hroat 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 Diclofenac sodium injection 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.

5. How to store Diclofenac sodium injection

Store below 30°C. Protect from light and heat. Keep out of the reach and sight of children.

Do not use Diclofenac sodium injection after the expiry date which is printed on the outside of the pack.



6. Further information

The glass ampoules contain 75 mg of the active ingredient, diclofenac sodium, in solution.

The ampoules also contain mannitol, sodium metabisulphite, benzyl alcohol, propylene glycol, sodium hydroxide, water.

7. Manufactured in India by:

TAJ PHARMACEUTICALS LTD.

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