

Diclofenac sodium injection 25mg/ml

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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- In this leaflet DICLOFENAC SODIUM 75 mg/ml solution for injection will be referred to as DICLOFENAC SODIUM.

In this leaflet:

1. What DICLOFENAC SODIUM is and what it is used for
2. Before you use DICLOFENAC SODIUM
3. How to use DICLOFENAC SODIUM
4. Possible side effects
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1 What DICLOFENAC SODIUM is and what it is used for

DICLOFENAC SODIUM contains the active substance diclofenac sodium. DICLOFENAC SODIUM belongs to a type of medicine called a non-steroidal anti-inflammatory drug (NSAID).

Other NSAIDs include aspirin and ibuprofen. These drugs reduce pain and inflammation.

DICLOFENAC SODIUM given by intramuscular or subcutaneous 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, fractures or trauma
- It is also used to prevent or treat pain following an operation.

DICLOFENAC SODIUM given by intravenous injection is used in hospital settings to prevent or treat pain following an operation.

2 Before you use DICLOFENAC SODIUM

Do not use DICLOFENAC SODIUM:

- If you are allergic to diclofenac, aspirin, ibuprofen or other NSAIDs.
- If you are allergic to any of the other ingredients of DICLOFENAC SODIUM (they are listed in section 6 at the end of this leaflet)
- If you have a history of bleeding in your stomach or bowels after you have taken NSAIDs
- If you have had two or more episodes of stomach (gastric) or duodenal (peptic) ulcers or bleeding in the digestive tract. (This may include blood in vomit, bleeding when emptying the bowels, or black, tarry stools)
- If you have, or have had liver failure
- If you have, or have had severe heart 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 or bypass blockages
- If you have or have had problems with your blood circulation (peripheral arterial disease)
- If you have, or have had severe kidney failure
- If you have asthma, hives or acute rhinitis (allergy) which are caused by use of NSAIDs or aspirin
- If you have a blood clotting disorder or are currently taking anticoagulants (such as warfarin)
- If you are more than 6 months pregnant
- If you are under 18 years of age.

Additionally, do not use DICLOFENAC SODIUM by intravenous injection:

- If you are using other NSAID or anticoagulant (including low dose of heparin)
- If you have an history of bleeding diathesis, specifically cerebrovascular bleeding
- If you have had operation with high risk of haemorrhage
- If you have a history of asthma
- If you have a moderate or severe renal impairment
- If you are dehydrated
- If you have suffered from heavy loss of blood

Take special care with DICLOFENAC SODIUM

Make sure your doctor knows, before you are given diclofenac

- 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.

Tell your doctor before you are given DICLOFENAC SODIUM:

- If you think you may be allergic to diclofenac, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of DICLOFENAC SODIUM. (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.
- If you have ever had an ulcer in the gullet, stomach or upper bowel, or gastrointestinal bleeding.
- Symptoms of which may include blood in vomit or when emptying bowels or black, tarry stools
- If you suffer from any bowel disorders including ulcerative colitis or Crohn's disease
- If you have, or have ever had, kidney or liver problems
- If you have had a history of or suffer from any blood or bleeding disorders
- If you have, or have ever had asthma, chronic obstructive pulmonary disease (COPD), nasal polyps or hayfever
- If you have lupus (systemic lupus erythematosus or SLE) or any similar problem
- If you are planning to become pregnant, as DICLOFENAC SODIUM may interfere with your ability to become pregnant.
- If you recently had or you are going to have a surgery of the stomach or intestinal tract before receiving/taking/using DICLOFENAC SODIUM, as DICLOFENAC SODIUM can sometimes worsen wound healing in your gut after surgery.

Other special warnings

- Medicines such as DICLOFENAC SODIUM may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment
- DICLOFENAC SODIUM is an anti-inflammatory medicine, therefore it may reduce the symptoms of infection, such as headache or high temperature. If you feel unwell and need to see a doctor, remember to tell him or her you are taking DICLOFENAC SODIUM
- Elderly patients are more prone to the side effects associated with DICLOFENAC SODIUM so tell your doctor about any unusual symptoms.

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 (e.g. over-the-counter medicines or those for recreational use). Some medicines may interfere with your treatment.

Tell your doctor if you are taking any of the following medicines:

- Any other NSAID or COX-2 (cyclooxygenase-2) inhibitor, for example aspirin or ibuprofen (medicines for inflammation or pain)
- Medicines to treat diabetes
- Anticoagulants (blood thinning tablets like warfarin or heparin)
- Antiplatelet medicines (to prevent blood clots)
- Diuretics (water tablets)
- Lithium (a medicine to treat some types of depression)
- Phenytoin (a medicine to treat epilepsy)
- Cardiac glycosides (e.g. Digoxin; medicines for heart problems)
- Methotrexate (a medicine for some types of inflammation and cancers)
- Ciclosporin and tacrolimus (medicines for some types of inflammation and after organ transplants)
- Quinolone antibiotics (medicines used to treat some infections)
- Steroids (medicines for inflammation and for treating immune system problems)
- Colestipol (a medicine used to reduce cholesterol)
- Cholestyramine (a medicine used to treat liver problems and Crohn's disease)
- Sulfapyrazole (a medicine used to treat gout)
- Voriconazole (a medicine used to treat fungal infections)
- Pemetrexed (a chemotherapy drug used to treat some forms of cancer)
- Deferasirox (a medicine used in patients having long term blood transfusions)
- Mifepristone (a medicine used during termination of pregnancy)
- Medicines for heart problems or high blood pressure, for example beta blockers or ACE inhibitors
- Tacrolimus (a medicine which decreases the action of the immune system, used to prevent organ rejection in certain patients)
- Medicines used to treat anxiety and depression known as serotonin re-uptake inhibitors (SSRIs)
- Zidovudine (a medicine for human immunodeficiency virus (HIV) infection).

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

- DICLOFENAC SODIUM may make it more difficult to become pregnant. You should talk to your doctor if you are having problems getting pregnant
- You must tell your doctor if you are pregnant or planning to become pregnant as they will consider if DICLOFENAC SODIUM should be used
- DICLOFENAC SODIUM must not be used if you are more than 6 months pregnant as it may affect the baby's circulation or damage your baby's kidneys, and delay or prolong your labour
- You must tell your doctor if you are breast-feeding. If you are breast-feeding your doctor will consider if DICLOFENAC SODIUM should be used.

Driving and using machines

DICLOFENAC SODIUM may make some people feel dizzy, tired, sleepy or have blurred vision. Do not drive or use any tools or operate

machines if you are affected in this way.

3 How to use DICLOFENAC SODIUM

Your doctor will decide when and how to treat you with DICLOFENAC SODIUM solution for injection. You will either be given an intramuscular injection (an injection into a muscle usually into the buttocks) or a subcutaneous injection (an injection into the skin usually into the buttocks or thigh) or an intravenous injection (an injection into a vein, generally of an arm).

DICLOFENAC SODIUM must not be given by intravenous (i.v.) infusion.

Adults: The usual starting dose is 25 to 75 mg depending on the severity of your pain. If you are still in severe pain, your doctor may decide to give you a second injection after 6 hours. The maximum daily dose is 150 mg. You will only be given DICLOFENAC SODIUM 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 (under 18 years).

A doctor, nurse or pharmacist will prepare the injection for you. A nurse or doctor will usually then give you the injection. Your doctor or nurse will not inject you in the same place twice.

If you use more DICLOFENAC SODIUM than you should

If you have been given too much DICLOFENAC SODIUM you may experience the following symptoms: feeling and being sick, stomach pain, stomach and or bowel bleeding, rarely diarrhoea, dizziness, tinnitus (buzzing, hissing, ringing, whistling or other persistent noises in the ear and occasionally convulsions (fits or seizures)). In severe cases, your kidneys or liver may be damaged (symptoms include having difficulty passing water or passing more water than usual, muscle cramps, tiredness, swelling in your hands, feet or face, feeling or being sick, yellowing of your skin).

If you think you have been given too much DICLOFENAC SODIUM immediately tell your doctor or nurse.

4 Possible side effects

Like all medicines, DICLOFENAC SODIUM can cause side effects, although not everybody gets them.

Some side effects can be serious

Stop using DICLOFENAC SODIUM 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 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).

Tell your doctor immediately if you get any of the following:

- Severe allergic reactions which may include: swelling of face, throat or tongue, breathing difficulties, wheezing, runny nose and skin rashes
- Stomach pain, indigestion, heartburn, wind, feeling sick or being sick
- Any sign of bleeding in the stomach or intestine, for example, blood when emptying your bowels, black, tarry stools or blood in vomit
- Serious skin rashes, itching, hives, bruising, painful red areas, peeling or blistering of skin, giant wheals (burning itchy swollen skin). These conditions may also affect mouth, lips, eyes nose and genitals
- 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.
- Bruising more easily than usual or having frequent sore throats or infections.
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

Very common side effects

(likely to affect up to 1 in 10 patients)

- Pain, redness or lumps at the injection site

Common side effects

(likely to affect between 1 in 100 and 1 in 10 patients)

- Feeling sick, discomfort sensation at the injection site

Uncommon side effects

(reported 1 in 1000 to 1 in 100)

- Dizziness and headache
- Diarrhoea, being sick and constipation
- Inflammation of stomach lining causing stomach pain, sickness and loss of appetite
- Liver problems
- Skin rash, itching.

Not known

(frequency cannot be estimated from the available data)

- Tissue damage at the injection site.

Other side effects

The following list of side effects have been reported in patients treated with NSAIDs.

Effects on the heart chest or blood

- Medicines such as DICLOFENAC SODIUM may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke
- High blood pressure, heart attack, fast or irregular heart beat, chest pain and swelling of body, hands or feet
- Asthma, breathlessness
- Blood disorders such as anaemia (decreased number of red blood cells). Symptoms include tiredness, headache, dizziness, looking pale.

Effects on stomach and digestive system

- Peptic (stomach) ulcers, mouth ulcers, tongue infections, lower gut disorders (including inflammation of gut and worsening of Crohn's disease)
- Inflammation of pancreas or stomach lining (symptoms of which include severe stomach pain which may extend to your back or shoulder).

Effects on nervous system

- Tingling or numbness, pins and needles of the hands or feet or limbs, tremors, blurred or double vision, hearing loss or impairment, tinnitus (ringing in the ears), drowsiness, tiredness
- Hallucinations (seeing or hearing things that are not there), depression, disorientation, sleep problems, irritability, anxiety, memory problems and convulsions (fits or seizures).
- Inflammation of the layers lining the brain. Symptoms of which include stiff neck, headache, nausea, vomiting, fever or disorientation and extreme sensitivity to bright light.

Effects on liver and kidney

- Liver disorders. Symptoms may include sickness, loss of appetite, generally feeling unwell, sometimes with jaundice
- Kidney disorders or kidney failure. Symptoms include blood in urine, frothy urine, swelling of feet and hands or body.

Effects on skin and hair

- Serious skin rashes such as Stevens-Johnson syndrome and other skin conditions which may be made worse by exposure to sunlight
- Hair loss.

Immune system disorder

- Hypersensitivity reaction

If any of the symptoms get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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.

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

5 How to store DICLOFENAC SODIUM

- Keep this medicine out of the sight and reach of children
 - Do not use DICLOFENAC SODIUM after the expiry date which is stated on the ampoule as 'EXP' (the expiry date refers to the last day of that month)
 - Store below 25°C. Do not refrigerate or freeze. Store in the original package in order to protect from light
 - Use immediately after opening. Discard any unused product
 - Do not use the medicine if it is cloudy or if any small bits can be seen.
- After injection of the correct dose your doctor or nurse will dispose of any solution that remains, along with the syringe, needles and containers.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use.
- These measures will help protect the environment.

6 Further information

What DICLOFENAC SODIUM contains

The active substance is: diclofenac sodium. Each 1 ml ampoule contains:

75 mg of diclofenac sodium.

The other ingredients are hydroxypropylbetadex, polysorbate 20, water for injections.

What DICLOFENAC SODIUM looks like and contents of pack

This medicinal product is a clear to slightly amber coloured transparent solution for injection contained in a clear glass container (ampoule).

Pack size of 1, 3 and 5 ampoules.

This medicinal product is also supplied as a prefilled syringe. Not all pack sizes may be marketed.

Manufactured by:

Ray Life Sciences Pvt. Ltd.

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