

PACKAGE INSERT: INFORMATION FOR THE USER

Diclofenac Sodium Injection IP 25 mg



3 ML

Composition :
Each ml contains:
Diclofenac Sodium IP 25 mg.
Benzyl Alcohol 4% v/v
(as Preservative)
Water for injection IP q.s.

What you need to know about DICLOFENAC S-AQ
Your doctor has decided that you need this medicine to help treat your condition.
Please read this leaflet carefully before you start to take your medicine. It contains important information. Keep the leaflet in a safe place, because you may want to read it again. If you have any other questions, or if there is something you don't understand, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be the same as yours. Many 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 DICLOFENAC S-AQ are, and what they are used for
 2. What you need to know before you take DICLOFENAC S-AQ
 3. How to take DICLOFENAC S-AQ
 4. Possible side effects
 5. How to store DICLOFENAC S-AQ
 6. Contents of the pack and other information
- 1. What DICLOFENAC S-AQ are, and what they are used for**
Diclofenac sodium, the active ingredient in DICLOFENAC S-AQ ampoules, 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:
- (1) Rheumatoid joint or back pain
 - (2) Attacks of gout
 - (3) Pain caused by kidney stones
 - (4) Pain caused by injuries

DICLOFENAC S-AQ 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 S-AQ are not suitable for children.

2. What you need to know before you take DICLOFENAC S-AQ
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 S-AQ. These are listed in 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 ulcer or duodenal (peptic) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, heart burn in females or faeces, 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 cardiovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or clots/poison to blood vessels to the heart or brain or an operation to clear blocked blood vessels.
• you are more than six months pregnant.

• if you have or have had problems with your blood clotting (prophylactic arterial disease).
• if you are more than six months pregnant.

You should also ask yourself these questions before having a DICLOFENAC S-AQ intrusion:
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 clot, 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 use of alcohol recently?

If the answer to any of these questions is YES, discuss your treatment with your doctor or pharmacist because DICLOFENAC S-AQ 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)
- Cyclosporin and tacrolimus (used to treat some inflammatory diseases and after transplants)

Time-dependent (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
Misoprostol (a medicine used to decrease pregnancy)
Cardiac glycosides (for example digoxin), used to treat heart problems
Medicines known as SSRIs used to treat depression
Anti steroids (an anti-inflammatory drug)
Medicines used to treat heart conditions or high blood pressure, for example beta-blockers or ACE inhibitors
Vasopressors (a medicine used to treat lung infections)
Phenytoin (a medicine used to treat seizures)
Colestipol/cholestyramine (used to lower cholesterol)
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Colestipol/cholestyramine (used to lower cholesterol)

Pregnancy, breast-feeding and fertility
Do not take DICLOFENAC S-AQ injections 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 you and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take DICLOFENAC S-AQ injections during the last 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 used for more than a few days from 20 weeks of pregnancy onward, DICLOFENAC S-AQ injections 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.

Are you trying for a baby? Having DICLOFENAC S-AQ 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 S-AQ ampoules have made them feel dizzy, tired or sleepy. Problems with vision 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 S-AQ for the shortest possible time, particularly if you are underweight or elderly.
There is a small risk of a heart attack or stroke when you are taking any medicine like DICLOFENAC S-AQ. 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 S-AQ you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or swelling of the legs, contact your doctor immediately.
What if 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 S-AQ 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 S-AQ.

DICLOFENAC S-AQ Ampoules should not be used in children.
Tell your doctor if you recently had or are now going to have a surgery of the stomach or intestinal tract before giving DICLOFENAC S-AQ Ampoules, as DICLOFENAC S-AQ Ampoules can sometimes worsen recent healing in your gut after surgery.

DICLOFENAC S-AQ Ampoules contain propylene glycol, benzyl alcohol and sodium metabisulphite
This medicine contains 400mg propylene glycol per 3ml ampoule which is equivalent to 200mg/ml. This medicine contains 100mg benzyl alcohol per 3ml ampoule which is equivalent to 40mg/ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have liver or kidney disease. This is because large amounts of benzyl alcohol can build up in your body and may cause some effects (marked metabolic acidosis).

DICLOFENAC S-AQ Ampoules contain the preservative, sodium metabisulphite.
This can sometimes cause allergic reactions and breathing difficulties.
Information about sodium content
This medicine contains less than 1mmol sodium (23mg) per 3ml ampoule, that is to say essentially sodium-free.

3. How to take DICLOFENAC S-AQ Ampoules
Your doctor will decide when and how to treat you with DICLOFENAC S-AQ Ampoules. You will either be given an intravenous infusion to play 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) twice daily for three or four days.

Children
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, before being given to you. A nurse or doctor will usually then give you the injection or infusion. You should not usually have to give the injection to yourself.
The doctor may also prescribe another drug to prevent the stomach to be upset at the same time, particularly if you have had stomach problems before, or if you are elderly, or taking certain other drugs at all.

What if you have had more than 600 mg of Diclofenac S-AQ (7 ampoules)?
What if you have been given too much Diclofenac S-AQ for your doctor or nurse straight away.
4. Possible side effects
DICLOFENAC S-AQ Ampoules 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 face 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 problems with the head/face 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)
• blood in vomit or black, tarry bowel
• Allergic reactions which can include skin rash, itching, swelling, painful red areas, peeling or blistering (itching or shortness of breath (bronchospasm))
• Swollen, fever, flu, 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 S-AQ are followed by initial 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 allergy reaction called anaphylaxis.
• Injection site reactions including injection site pain, redness, swelling, heat, pain, some bruising.
• This can progress to blackening and death of the skin and underlying tissues surrounding the injection site, that may be painful, also known as Necrosis syndrome.
• If you notice that you are bruising more easily than usual or have frequent nose bleeds 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, vomit, drowsiness or tiredness.
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 bradycardia, 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 (these have been very rare reported cases resulting in death, particularly in the elderly). Seek immediate information, redness 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, dizziness.
Stomach and bloating.
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).

Very rare side effects (These may affect less than 1 in every 10,000 patients):
Effects on the nervous system:
Information of the living of the brain (myelopathy), tingling or numbness in the fingers, hands, numbness, double vision such as blurred or double vision, balance changes, hearing loss or impairment, tremor (trembling in the arms), weakness, numbness, mood changes, decreased energy, irritability, mental disorders, disorientation and loss of memory, flu, headache together with a double of light, light and a soft neck.

Effects on the stomach and digestive system:
Concomitant inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, lower gut disorders (including inflammation of the colon, or narrowing of colitis or Crohn's disease), effects on the stomach.
Hypertension (high blood pressure), hypertension (low blood pressure), symptoms of which may include dizziness, feeling dizzy or lightheaded, information of soft vessels (vasculitis), inflammation of the lung (pneumonitis), blood disorders (leukopenia).
Kidney or severe liver disorders (including liver failure, presence of blood or protein in the urine).

Effects on the liver or kidneys:
Facial swelling, various skin rashes including Stevens-Johnson syndrome (red, itchy skin) and other skin rashes which may be too severe to describe to surgically. Injection site abscesses. Hair loss.
Effects on the reproductive system:
Other side effects that have been reported with unusual frequency include:
• 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 DICLOFENAC S-AQ 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 the leaflet.

5. How to store DICLOFENAC S-AQ Ampoules
Storage: Store below 25°C. Protected from light. Do not allow to freeze. Store in the original package in order to protect from light. Keep this medicine out of the sight and reach of children. Do not use DICLOFENAC S-AQ Ampoules after the expiry date which is printed on the outside of the pack.

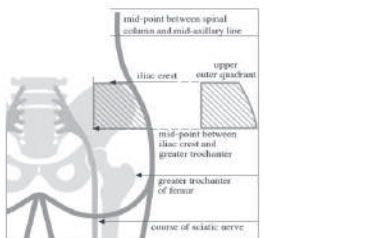
6. Contents of the pack and other information
What DICLOFENAC S-AQ Ampoules contain
Each ampoule contains 75 mg of the active ingredient, diclofenac sodium, in solution. The other ingredients are propylene glycol (E 152), sodium hydroxide (E 232), benzyl alcohol, propylene glycol (E 152), sodium hydroxide, water.
What DICLOFENAC S-AQ Ampoules look like and the contents of the pack
The glass ampoules contain colourless to faintly yellow liquid. DICLOFENAC S-AQ ampoules come in packs of 10.

For the Medical and Pharmaceutical Professionals
Dosage and Administration
Adults
DICLOFENAC S-AQ ampoules (given IM or IV) should not be given for more than two days. If necessary, treatment can be continued with diclofenac tablets or suppositories. Intravenous injections, injection site reactions have been reported after the administration of diclofenac intramuscularly, including injection site reactions and anaphylaxis (anaphylaxis), also known as Necrosis syndrome (particularly after intravenous intramuscular administration). Appropriate needle selection and technique must be followed during intramuscular administration of diclofenac.

The following directions for intramuscular injection must be followed in order to avoid damage to the nerve or other tissue at the injection site.
One ampoule (one) or in severe cases (two) daily intramuscularly by deep intragluteal injection into the upper outer quadrant. (If no ampoules 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 diclofenac (tablets or suppositories) up to the maximum daily dosage of 150 mg.

Renal effects: One 75 mg ampoule intramuscularly. A further ampoule may be administered after 20 minutes if necessary. The recommended maximum daily dose of DICLOFENAC S-AQ is 150 mg.
Recommended injection procedures

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 your upper outer quadrant (or boundary) and/or down the length of the buttock being particular care to avoid the sciatic nerve (see diagram) and about 2-3 cm (2-3 inches) below the iliac crest. Avoid injecting into an area where resistance is felt.



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

In small thin patients with little muscle bulk, especially those of the female sex, 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 so, do not draw, withdraw the needle to another site and check again.
6. The injection should be given slowly in a minimum of 10 seconds.
7. If the patient complains of severe pain or pronounced discomfort during the injection immediately, retry at another site. A dull aching pain may be experienced after normal injection.

Intravenous infusion: Immediately before infusing an intravenous infusion, DICLOFENAC S-AQ must be diluted with 100-500 ml of either sodium chloride solution (0.9%) or glucose solution (5%). Both solutions should be buffered with sodium bicarbonate solution (0.5 ml 8.4% or 1 ml 4.2%). Only clear solutions should be used.
Concomitant intravenous infusions should be freshly made up and used immediately. Once prepared, the infusion should not be stored.

DICLOFENAC S-AQ must not be given as an intravenous bolus injection. 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.

Children:
DICLOFENAC S-AQ ampoules are not recommended for use in children.
Elderly: Although the pharmacokinetics of DICLOFENAC S-AQ are not impaired to any clinically relevant extent in elderly patients, non-steroidal anti-inflammatory drugs should be used with particular caution in such patients who generally are more prone to adverse reactions. In particular it is recommended that the lowest effective dosage be used in frail elderly patients or those with a low body weight (see also Precautions) and the patient should be monitored for GI bleeding for 4 weeks following initiation of NSAID therapy.

The recommended maximum daily dose of DICLOFENAC S-AQ is 150 mg.

Incompatibilities
The ampoules used IM or IV as an infusion should not be mixed with other injection solutions.

Shelf life
Two years.

Special precautions for storage
Store below 25°C. Protected from light. Do not allow to freeze. Store in the original package in order to protect from light.
Medicine should be kept out of the sight and reach of children.
The injection solution should not be used if crystals or precipitates are observed.

Nature and contents of container
The glass ampoules contain colourless to faintly yellow liquid and come in packs of 10.

Marketed by:
AMERICAN REMEDIES
CARE & CONCERN WITH RESEARCH
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