PYRAL

Diclofenac Sodium Injection 75mg

Composition : Each 3ml contains :

Diclofenac Sodium B.P. 75mg
Water for Injection B.P. q.s.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

- 1. What Diclofenac Injection is and what it is used for
- 2. What you need to know before you are given Diclofenac Injection
- 3. How you are given Diclofenac Injection
- 4. Possible side effects
- 5. How to store Diclofenac Injection
- 1. What Diclofenac Injection is and what it is used for

Diclofenac Injection is provided as a solution for injection, containing Diclofenac sodium, to be given by intramuscularly (into a muscle) or intravenously (into a vein) as an infusion.

Diclofenac Injection is indicated for the treatment of painful conditions, such as kidney stone pain, osteoarthritis (degeneration of joints) and rheumatoid arthritis (inflammation of joints), back pain, gout (formation of crystals in joints), injuries and fractures in children aged over 12 years, adults and older patients.

2. What you need to know before you are given Diclofenac Injection (Warnings and precautions):

You should not be given Diclofenac Injection

if you are allergic to Diclofenac Injection

if you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the dioestive tract.

if you have had any allergic reaction to ibuprofen, aspirin, or other NSAIDs (including difficulty in breathing, runny nose, swelling of the face or throat, or rash)

if you have asthma, kidney or liver problems, severe heart failure

if you are dehydrated or have recently lost a lot of blood

if you are taking other non steroidal anti-inflammatory drugs, anticoagulant drugs

if you are more than 6 months pregnant or breast-feeding

Children

Diclofenac Injection is not recommended for use in children.

Other medicines and Diclofenac Injection

Tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines. This includes any herbal products or medicines bought without a prescription.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Do not take Diclofenac Injection during the last 3 months of pregnancy as it may affect your baby's circulation and kidneys.

Fertility

Taking Diclofenac Injection 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 and using machines:

Diclofenac Injection may make you feel drowsy or dizzy, or cause headaches or problems with vision. If you are affected, do not drive or operate machinery.

Diclofenac Injection contains sodium sulphite which can cause severe allergic reactions, especially in patients with a history of asthma or other allergies.

3. How you are given Diclofenac Injection

Diclofenac Injection can be given by deep injection into the large muscle of the buttock. The usual dose is one ampoule once daily. One ampoule twice daily may be required in severe cases, the second dose being injected into the buttock muscle on the other side.

The total dose in one day should not exceed 150mg (two ampoules).

4. Possible side effects

Like all medicines, this medicine can cause side-effects although not everybody gets them.

Some side effects can be serious and you should tell your doctor immediately if you notice any side effects.

Some side-effects are mentioned below:

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

Stomach pain, Heartburn, nausea (feeling sick), Vomiting (being sick), Diarrhoea, Indigestion

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist, This includes any possible side effects not listed in the leaflet.

- 5. How to store Diclofenac Injection
- · Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Keep the container in the outer carton in order to protect from light.
- · Once opened, any unused liquid should be discarded

Neutral Code: UK/Drugs/138/UA/SC/P-2007

Marketed by:



PYXUS PHARMACEUTICALS PVT. LTD.

A/707, Mondeal Heights, Beside Novotel Hotel, Nr. Iscon Square, S.G. Highway, Ahmedabad, Guiarat- 380015 (India).