Diclofenac Sodium 25 mg and 50 mg
Gastro-resistant tablets

Read all of this leaflet carefully before you start taking this medicine. Keep this leaflet. You may need to read it again.

1. What Diclofenac Sodium is and what it is used for

Diclofenac Sodium, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs work by blocking the production of prostaglandins. Prostaglandins are substances that cause the pain and swelling associated with many conditions affecting the joints and muscles:

- Arthritis
- Rheumatoid arthritis
- Osteoarthritis
- Acute gout
- Backache
- Bursitis
- Joint pain
- Rheumatoid arthritis
- Pain associated with minor surgery
- Muscle pain
- Sports injuries
- Frozen shoulder
- Dislocations and fractures

Conditions affecting the tendons for example, tendinitis, tendosynovitis, bursitis.

They are also effective for the short-term relief of the pain and inflammation of the condition:

- Soft tissue swelling (tendonitis, tenosynovitis, bursitis)
- Painful joints (arthritis)
- Painful muscles
- Joint pain
- Rheumatoid arthritis
- Pain associated with minor surgery
- Muscle pain
- Sports injuries
- Frozen shoulder
- Dislocations and fractures

For children aged 9 years and above Diclofenac Sodium 25 mg tablets are used for short-term treatment of these normal conditions due to the ear, nose or throat, and for relief of acute post-operative pain.

In children aged 1-12 years Diclofenac Sodium tablets are used to treat juvenile chronic arthritis.

Diclofenac Sodium tablets relieve pain, reduce swelling and improve movement in a number of conditions affecting the joints and muscles:

- Rheumatic pain
- Arthritis
- Rheumatoid arthritis
- Muscle pain
- Soft tissue swelling (tendonitis, tenosynovitis, bursitis)

If you have any further questions, ask your doctor or pharmacist.

5. How to store Diclofenac Sodium

Diclofenac Sodium tablets should be stored in the original packaging. Keep the container tightly closed. Store in a cool dry place. Do not refrigerate or freeze.

6. Further information

This medicinal product is subject to Directive 2001/83/EC. The pack and labels mention the European Union trademark (E110), which may cause allergic reactions.

3. When to take Diclofenac Sodium tablets

Swallow the tablets whole with a glass of water, unless you have any problems. In that case, tell your doctor or pharmacist if you are not sure. Keep taking Diclofenac Sodium exactly as your doctor has told you. You should check with your doctor or pharmacist if you think you might be pregnant or are up to 6 months pregnant.

- Talking Diclofenac Sodium tablets may make it more difficult to become pregnant. You should talk to your doctor if you are planning to become pregnant and you have problems getting pregnant.

- You should avoid taking Diclofenac Sodium until breast feeding.

Driving and using machines

Very occasionally people have reported that diclofenac sodium tablets have made them feel drowsy, dizziness, or difficulty falling asleep. It is advisable not to drive or use machinery if you feel this way.

3. How to take Diclofenac Sodium

Diclofenac Sodium tablets should be taken and when to take them. Some conditions that may affect the dose of Diclofenac Sodium tablets include:

- Weight
- Your age
- Fractures
- Gender
- Kidney or liver problems
- Problems with the blood
- Swelling of the nose and throat, face and mouth,
- Severe allergic (hypersensitive) to diclofenac
- Children under 12 years of age
- You should avoid taking Diclofenac Sodium with food and drinks.

Diclofenac Sodium 25 mg and 50 mg contain a colouring agent, sunset yellow (E110), which may cause allergic reactions or photosensitivity.

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Important information about some of the ingredients of Diclofenac Sodium tablets

Phenylalanine (a medicine used to treat some mental disorders, for example, low dose aspirin) used to prevent blood clots forming in process called thrombosis

Dapsone (a medicine used to treat leprosy infections, and to treat the primary or secondary prophylaxis have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not take Diclofenac Sodium tablets during the last 3 months of pregnancy if it may affect the baby's cardiovascular system.

- You should avoid taking Diclofenac Sodium if you are taking or have recently taken any other treatment. Please tell your doctor or pharmacist if you are taking or have recently taken any other medication.

- You should avoid taking Diclofenac Sodium tablets if you are underweight or elderly.

- You should avoid taking Diclofenac Sodium tablets if you have renal or liver problems, for example, liver disease, or if you have problems getting

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- You should avoid taking Diclofenac Sodium tablets if you have renal or liver problems, for example, liver disease, or if you have problems getting
disorientation, excitement, coma, depression, dizziness, ringing in the ears, fainting, or occasionally convulsions (uncontrolled fits).

If you forget to take Diclofenac Sodium:

If it is important that you do not miss a dose. If you forget to take a dose, skip the missed dose. Do NOT take a double dose to make up for the one you missed. Do NOT take Diclofenac Sodium to make up for the missed dose. If you have any further questions on the use of this product, ask your pharmacist.

4. POSSIBLE SIDE EFFECTS

Like many medicines, Diclofenac Sodium can cause side effects, although not everybody gets them. Some side effects can be serious. If you have any of the following at any time during your treatment STOP TAKING Diclofenac Sodium and tell your doctor as soon as possible:

• dizziness, feeling short of breath or breathlessness.

Common side effects (may affect up to 1 in 10 people):

• drowsiness, tiredness.

Effects on the nervous system:

• elevated liver enzymes in the blood

• headache (including migraine), feeling unwell, dizziness, ringing in the ears, fainting, disorientation, excitation, coma, depression, dizziness, ringing in the ears, fainting, or occasionally convulsions (uncontrolled fits).

• an abnormal change in the amount of urine produced and/or its retention.

• high blood pressure, inflammation of the pancreas (causes symptoms such as abdominal pain, nausea, vomiting).

• high blood pressure, inflammation of the nerves of the eyes.

• impotence, throat disorders, hallucinations, confusion, general feeling of discomfort, mouth ulcerations, confusions, increased sleep, drowsiness, unusual or have frequent sore throats or infections.

Very rare side effects (may affect up to 1 in 10,000 people): angioedema (serious allergic reaction which causes swelling mainly of the face, lips, hands, or feet), asthma, difficulty and/or shortness of breathing (including when using medicines to prevent or relieve asthma attacks), breathing.

Very rare side effects (may affect up to 1 in 10,000 people): development of the absence of menstruation, loss of blood, blood disorders (including anaemia), severe depression, difficulty sleeping, nightmare, disorientation, mood changes, delirium, hallucinations, delusions, depression, confusion, general feeling of discomfort, mouth ulcerations, confusions, increased sleep, drowsiness, unusual or have frequent sore throats or infections.

Effects on the gastrointestinal system:

• abdominal pain (including peptic ulceration), diarrhea, constipation, nausea, vomiting.

• epidermal necrolysis (serious illnesses with skin peeling off). Please tell your doctor. He/she may want to give you a different medicine.

• blood disorders (including anaemia), severe depression, difficulty sleeping, nightmare, disorientation, mood changes, delirium, hallucinations, delusions, depression, confusion, general feeling of discomfort, mouth ulcerations, confusions, increased sleep, drowsiness, unusual or have frequent sore throats or infections.

• bladder infections, inflammation of the pancreas (causes symptoms such as abdominal pain, nausea, vomiting).

• jaundice (inflammation of the liver).

• vomiting.

• disorientation, mood changes, delirium, hallucinations, delusions, depression, confusion, general feeling of discomfort, mouth ulcerations, confusions, increased sleep, drowsiness, unusual or have frequent sore throats or infections.

• swallowing and chest or back pains

• severe blood disorders (including anaemia), severe depression, difficulty sleeping, nightmare, disorientation, mood changes, delirium, hallucinations, delusions, depression, confusion, general feeling of discomfort, mouth ulcerations, confusions, increased sleep, drowsiness, unusual or have frequent sore throats or infections.

• purplish spots or patches and itching.

• blood disorders (including anaemia), severe depression, difficulty sleeping, nightmare, disorientation, mood changes, delirium, hallucinations, delusions, depression, confusion, general feeling of discomfort, mouth ulcerations, confusions, increased sleep, drowsiness, unusual or have frequent sore throats or infections.

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• abnormal change in the amount of urine produced and/or its retention leading to difficulty sleeping, nightmare, disorientation, mood changes, delirium, hallucinations, delusions, depression, confusion, general feeling of discomfort, mouth ulcerations, confusions, increased sleep, drowsiness, unusual or have frequent sore throats or infections.