Read all of this leaflet carefully before you start taking this medicine. 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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to other people even if you think they have the same symptoms.
- If you get any side effects, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. WHAT DICLOFENAC SODIUM IS AND WHAT IT IS USED FOR

Diclofenac sodium, the active ingredient in DICLOFENAC SODIUM 25 MG, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain, swelling and ease inflammation.

DICLOFENAC SODIUM 25 MG tablets relieve pain, reduce swelling and ease inflammation in conditions affecting the joints, muscles and connective tissue:

- Rhematoid arthritis, osteoarthritis, acute gout (painful inflammation of the joints especially in the feet and hands), and ankylosing spondylitis. (form of spinal arthritis).
- Bursitis, synovitis and strains, soft tissue sprains, injuries, frozen shoulder, dislocations and fractures.
- Conditions affecting the joints for example, tendonitis, tendinopathy, bursa.
- They are also used for mild to moderate pain and inflammation associated with dental and minor surgery.

In children aged 9 years and above DICLOFENAC SODIUM 25 mg tablets are used to treat juvenile chronic arthritis.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DICLOFENAC SODIUM 25 MG

Tell your doctor if you:

- have a history of stomach problems when taking aspirin or other NSAIDs.
- have kidney or liver problems.
- have had an asthma attack, or "strike", or "asthma attack" (an attack of asthma) and/or 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.
- have, or have had, a blood clot in your blood circulation, peripheral arterial disease.
- are more than six months pregnant.

Warnings and precautions

Talk to your doctor or pharmacist before taking Diclofenac if:

- you are allergic to diclofenac sodium, aspirin, ibuprofen, or to any of the other ingredients of DICLOFENAC SODIUM 25 MG. Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, rash, hives or skin or any other allergic type reaction.
- you have, or ever have had, a stomach (peptic) ulcer, or trouble swallowing or, in the digestive tract (this can include blood in vomit, bleeding when emptying bowels (faeces or black, tarry faeces).
- you have had difficult or painful periods after you have taken other NSAIDs.
- you have severe hea ultrasound abnormality.
- you have ever had disease or condition also affected by the other ingredients of DICLOFENAC SODIUM 25 MG tablets. (These are listed under "CONTENTS OF THE PACK AND OTHER INFORMATION" of the leaflet). Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, rash, hives or skin or any other allergic type reaction.

Driving and using machines

Very occasionally people have reported that Diclofenac Sodium tablets have made them feel dizzy, tired or sleepy. Problems with vision have also been reported. If these effects affect your ability to drive or use machines, you should not drive or operate machinery.

Other special warnings

You should take Diclofenac Sodium tablets with food.

- If you get any side effects, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You may need to read it again.

3. HOW TO TAKE DICLOFENAC SODIUM 25 MG

Take the tablets with or after food. You can take this medicine exactly as described in this leaflet. Your doctor or pharmacist will have advised you on the number of Diclofenac Sodium tablets to take and when to take them. Always follow the instructions on the label. Always follow the instructions on the label. Always follow the instructions on the label.

4. POSSIBLE SIDE EFFECTS

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Children aged 12 to 1 years

Doses vary with the weight of the child. These tablets may be given to children but not to infants, where applicable, within the daily dose range of 1.3 mg per kilogram of body weight in two or three separate doses.

The doctor may also prescribe another drug to protect the stomach to be taken at the same time, particularly, if you have stomach problems before. If you are elderly, or taking certain other drugs as well.

If you take more Diclofenac Sodium than you should

It is important that you do not miss a dose. If you forget to take a dose, as soon as you remember it; if it is nearly 4 hours your next dose, just take the next dose as usual and continue with your normal dose schedule. Do NOT take a double dose to make up for the one you missed. Do NOT take a double dose to make up for a forgotten tablet. Do not exceed 110 mg in 24 hours. If you have trouble remembering to take the tablets, tell your doctor or nurse.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Listed are Diclofenac Sodium effects that cause side effects, although not everybody gets them.

1. STOP TAKING Diclofenac Sodium tablets and tell your doctor straight away if you notice:

- Stomach pain, indigestion, heartburn, nausea, vomiting, bloating (feeling bloated)
- Any sign of bleeding in the stomach or intestines, for example, when emptying your bowels, bleeding in loose stool, blood on toilet tissue or urine, blood in the vomit, blood in the urine
- Allergic reactions which can include skin rash, itching, swelling, painful nail areas, peeling or blisters

If you notice any of the following:

- Changes in vision (notably a ring or flashes around lights (bloomorphism))
- Dizziness
- Itch, pain, lips, hands or fingers
- Itching of your skin without a rash
- Persistent sore throat or high temperature

- An unusual growth in the amount of urine produced and/or its appearance
- Mild swelling and alteration of the abdomen, abruptly after the start of the treatment with Diclofenac Sodium and sometimes bloody diarrrhea usually within 24 hours of the onset of abdominal pain
- Stevens-Johnson syndrome (serious illness with blisters of the skin and inside the mouth)
- Kidney problems

If you notice that you are breathing more easily than usual or have frequent sore throats or infections, tell your doctor.

Tell your doctor if you immediately notice the following:

- Chest pain, which can be a sign of a potentially serious allergic reaction called anaphylactic shock

The side effects listed below have also been reported.

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

- Stomach pain, heartburn, diarrhea, indigestion, wind or upset of appetite
- Headache, dizziness, vertigo

Rare (may affect up to 1 in 10,000 people):

Effects on the stomach and digestive system:

- Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, taste buds, lower gut disorders (including of the colon or worsening of ulcerative colitis or Crohn’s disease)

Effects on the heart, chest or blood:

- Palpitations, palpitations of the heart (beat), chest pain, hyperthermia (high blood pressure), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), heart disorders, constrictive pericarditis or heart failure, blood disorders (including anaemia)

Effects on the liver or kidneys:

- Kidney or liver failure, including liver failure, presence of blood or protein in the urine

Effects on skin or hair:

- Serious skin rashes including Stevanus-Johnson syndrome, Lyell’s syndrome and other skin rashes which may be made worse by exposure to sunlight

Hair loss

Other side effects that have also been reported include:

- Inflammation of the pancreas, impotence. Facial swelling, inflammation of the lining of the bronchus (mucous membrane), vertigo, dizziness

If you get any side effects, tell your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. Please tell your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also call the national reporting scheme for side effects to medicines, the MHRA Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or call the NHS Yellow Card Scheme on 0800 224 686 or talk to your pharmacist or your doctor.

If you forget to take Diclofenac Sodium Tablets

The doctor may also prescribe another drug to protect the stomach to be taken at the same time, particularly, if you have stomach problems before. If you are elderly, or taking certain other drugs as well.

If you forget to take Diclofenac Sodium Tablets

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If you have any further questions on the use of this product, ask your doctor or pharmacist.

5. HOW TO STORE Diclofenac Sodium Tablets

The name of your medicine is:

Diclofenac Sodium Tablets 25 mg gastro-resistant tablets

Doses vary with the age and weight of the child.

Doses vary with the age and weight of the child.

The doctor may also want to check closely that the treatment is suitable for you and that the doses are appropriate for you. The doctor may advise you to take a dose that is lower than the usual adult dose. For any problems.

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