

FENACTOL 75MG SR[®] and FENACTOL[®] RETARD 100MG Prolonged-release tablets (diclofenac sodium)

Read all of this leaflet carefully before you start taking 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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1. WHAT FENACTOL 75MG SR and FENACTOL RETARD 100MG ARE AND WHAT THEY ARE USED FOR

Diclofenac sodium, the active ingredient in FENACTOL 75MG SR and FENACTOL RETARD 100MG tablets, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation. FENACTOL 75MG SR and FENACTOL RETARD 100MG tablets are especially formulated to release the diclofenac sodium slowly.

FENACTOL 75MG SR and FENACTOL RETARD 100MG tablets relieve pain, reduce swelling and ease inflammation in conditions affecting the joints, muscles and tendons including:

- Rheumatoid arthritis, osteoarthritis, acute gout (painful inflammation of the joints especially in the feet and hands), ankylosing spondylitis (form of spinal arthritis).
- Backache, sprains and strains, soft tissue sports injuries, frozen shoulder, dislocations and fractures
- Conditions affecting the tendons for example, tendonitis, tenosynovitis, bursitis.

They are also used to treat pain and inflammation associated with dental and minor surgery.

FENACTOL 75MG SR and FENACTOL RETARD 100MG tablets are not suitable for children.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FENACTOL 75MG SR OR FENACTOL RETARD 100MG

Do not take FENACTOL 75MG SR or FENACTOL RETARD 100MG if

- you are allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of FENACTOL 75MG SR and FENACTOL RETARD 100MG tablets (these are listed under section 6 "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, chest pain, runny nose, skin rash or any other allergic type reaction.
- you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces)
- you have had stomach or bowel problems after you have taken other NSAIDs
- you have severe heart, kidney or liver failure
- 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.
- you have or have had problems with your blood circulation (peripheral arterial disease).
- you are more than six months pregnant

Warnings and precautions

Talk to your doctor or pharmacist before taking Diclofenac if:

- you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease
- you have kidney or liver problems, or you are elderly
- you have a condition called porphyria
- you suffer from any blood or bleeding disorder. If you do, your doctor may ask you to go for regular check-ups while you are taking these tablets.
- you ever had asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (nasal polyps), chronic pulmonary diseases or infections of the respiratory tract.
- you are breast feeding
- you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- you have heart problems or if you had a stroke or 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)
- you have diabetes
- you smoke
- you have Systemic Lupus Erythematosus SLE (inflammatory, auto-immune disorder which causes symptoms such as joint pain, joint inflammation, skin rashes, fever) or any similar condition
- you have an intolerance to some sugars such as sucrose (these tablets contain sucrose)

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking FENACTOL 75MG SR or FENACTOL RETARD 100MG as FENACTOL can sometimes worsen wound healing in your gut after surgery.

Tell your doctor or pharmacist if you have any of these conditions because FENACTOL 75MG SR or FENACTOL RETARD 100MG might not be the right medicine for you.

Children

FENACTOL 75MG SR and FENACTOL RETARD 100MG tablets are not suitable for children.

Other medicines and Fenactol 75mg SR and Fenactol Retard 100mg

Some medicines can interfere with your treatment. Please 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 treatment of some inflammatory diseases and some cancers)
- Ciclosporin and tacrolimus (used to treat some inflammatory diseases and after transplants)
- Trimethoprim (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
- Mifepristone (a medicine used to terminate pregnancy)
- Cardiac glycosides (for example digoxin), used to treat heart problems
- Medicines known as SSRIs (used to treat depression)
- Oral steroids (an anti-inflammatory drug)
- Medicines used to treat heart conditions or high blood pressure, for example beta blockers or ACE inhibitors
- Voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures)
- Colestipol/cholestyramine (used to lower cholesterol)

Always tell your doctor or pharmacist about all the medicines you are taking. This means medicines you have bought yourself as well as medicines on prescription from your doctor.

FENACTOL 75MG SR or FENACTOL RETARD 100MG with food and drink

Take this medicine with or after food

Pregnancy and breast-feeding

- Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not take FENACTOL 75MG SR or FENACTOL RETARD 100MG tablets during the last 3 months of pregnancy as it may affect the baby's circulation.
- You should advise your doctor or pharmacist if you think you might be pregnant or are up to 6 months pregnant.
- Taking FENACTOL 75MG SR or FENACTOL RETARD 100MG tablets may make it more difficult to become pregnant. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.
- You should avoid taking FENACTOL 75MG SR or FENACTOL RETARD 100MG whilst breast feeding.

Driving and using machines

Very occasionally people have reported that diclofenac sodium tablets have made them feel dizzy, tired or sleepy. Problems with eyesight 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 effective dose of Diclofenac Sodium for the shortest possible time particularly if you are underweight or elderly.
- There is a small increased risk of heart attack or stroke when you are taking any medicine like Diclofenac Sodium. 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 FENACTOL 75 MG SR or FENACTOL RETARD 100MG you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness or slurring of speech, contact your doctor immediately.
- Whilst 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 Sodium tablets 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 Sodium tablets.

FENACTOL 75MG SR and FENACTOL RETARD 100MG contains

FENACTOL 75MG SR and FENACTOL RETARD 100MG contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE FENACTOL 75MG SR or FENACTOL RETARD 100MG

The doctor will tell you how many FENACTOL 75MG SR or FENACTOL RETARD 100MG to take and when to take them. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Take the tablets with or after food. Swallow the tablets whole with a glass of water. DO NOT crush or chew the tablets as this will affect the special "slow release" system.

The recommended dose is:

Adults: 100-150mg daily divided into two or three doses. The number of tablets which you take will depend on the strength the doctor has given you.



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Your doctor may wish to increase your daily dose if required to 150mg.

Elderly: The lowest effective dose should be used. Your doctor may advise you to take a dose that is lower than the usual adult dose if you are elderly. Close surveillance is advisable.

Children: These tablets are not suitable for children.

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

If you take more FENACTOL 75MG SR or FENACTOL RETARD 100MG than you should

If you, or anyone else, accidentally takes too much FENACTOL 75MG SR or FENACTOL RETARD 100MG, tell your doctor or go to your nearest hospital casualty department immediately. Take your medicine pack with you so that people can see what you have taken.

Symptoms of an overdose can include: headache, nausea (feeling sick), vomiting, abdominal pain, stomach or intestinal bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, ringing in the ears, fainting, or occasionally convulsions (seizures, uncontrolled fits).

If you forget to take FENACTOL 75MG SR or FENACTOL RETARD 100MG

It is important that you do not miss a dose. If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, just take the next dose and forget about the one you missed. Do NOT take a double dose to make up for a forgotten tablet. Do not take more than 150 mg in 24 hours. If you have trouble remembering to take the tablets, tell your doctor or pharmacist.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, FENACTOL 75MG SR or FENACTOL RETARD 100MG can cause side effects, although not everybody gets them.

Some side effects can be serious
STOP TAKING FENACTOL 75MG SR or FENACTOL RETARD 100MG and tell your 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 feet 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 migraine-like headaches 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)
- 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
- 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 FENACTOL 75MG SR or FENACTOL RETARD 100MG and followed by rectal bleeding or bloody diarrhea usually within 24 hours of the onset of abdominal pain
- Stevens-Johnson syndrome (serious illnesses with blistering of the skin, mouth, eyes and genitals)

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

Tell your doctor immediately if you notice the following:

- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

The side effects listed below have also been reported.

Common side effects (These may affect between 1 and 1 in 10 in every 100 patients):

- Stomach pain, heartburn, nausea, vomiting, diarrhea, indigestion, wind, loss of appetite
- Headache, dizziness, vertigo
- Skin rash or spots
- Raised levels of liver enzymes in the blood

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 breathlessness, 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 1,000 to 1 in every 10,000 patients):

- Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly)
- Gastritis (inflammation, irritation 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, tiredness
- Skin rash and itching
- 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:

Inflammation of the lining of the brain (meningitis), tingling or numbness in the fingers, tremor, visual disturbances such as blurred or double vision, taste changes, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, irritability, mental disorders, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck.

Effects on the stomach and digestive system:

Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease), inflammation of the pancreas.

Effects on the chest or blood:

Hypertension (high blood pressure), hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), blood disorders (including anaemia).

Effects on the liver or kidneys:

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

Effects on skin or hair:

Facial swelling, serious skin rashes including Stevens-Johnson syndrome, Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight.

Hair loss

Effects on the reproductive system:

Impotence.

Other side effects that have also been reported with unknown frequency include:

Throat disorders, confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye, disturbances of sensation.

Medicines such as diclofenac may be associated with a small increased risk of heart attack or stroke.

Do not be alarmed by this list - most people take Diclofenac Sodium Tablets without any problems.

If any of the side effects becomes serious, or if you notice side effects not listed in this leaflet, please tell your doctor. He/she may want to give you a different medicine.

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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE FENACTOL 75MG SR and FENACTOL RETARD 100MG

Keep out of the sight and reach of children.

Do not use FENACTOL 75MG SR or FENACTOL RETARD 100MG tablets after the expiry date which is printed after 'Exp' on the carton.

Do not store above 25°C. Keep the tablets in their original pack.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What FENACTOL 75MG SR and FENACTOL RETARD 100MG contain

The name of your medicine is FENACTOL 75MG SR or FENACTOL RETARD 100MG.

FENACTOL 75MG SR: Each prolonged-release tablet contains 75mg of the active ingredient diclofenac sodium, and also contains the following inactive ingredients: tablet core: cetostearyl alcohol, colloidal anhydrous silica, compressible sugar, talc, povidone and magnesium stearate. Subcoat: copovidone and sucrose. Tablet film coat: hydroxypropylmethylcellulose, polyethylene glycol, iron oxide red (E172), titanium dioxide (E171) and gum acacia. Polish: carnauba wax.

FENACTOL RETARD 100MG: Each prolonged-release tablet contains 100mg of the active ingredient diclofenac sodium, and also contains the following inactive ingredients: tablet core: cetostearyl alcohol, colloidal anhydrous silica, compressible sugar, talc, povidone, magnesium stearate. Subcoat: copovidone and sucrose. Tablet film coat: hydroxypropylmethylcellulose, polyethylene glycol, iron oxide red (E172), titanium dioxide (E171) and gum acacia. Polish: carnauba wax.

What FENACTOL 75MG SR and FENACTOL RETARD 100MG look like and contents of the pack

FENACTOL 75MG SR prolonged-release tablets are marked D1CL75 on one side and are pink in colour. FENACTOL 75MG SR prolonged-release tablets are packed in cartons containing 28 tablets or 56 tablets in foil blister strips.

FENACTOL RETARD 100MG prolonged-release tablets are marked D1CL100 on one side and are pink in colour. FENACTOL RETARD 100MG prolonged-release tablets are packed in cartons containing 28 tablets in foil blister strips.

Not all pack sizes may be marketed.

Marketing Authorisation Holder / Manufacturer: Dexcel®-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire NN11 8PB, UK.

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