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 it later.

1. WHAT DICLOFENAC SODIUM 50MG IS AND WHAT IT IS USED FOR

DICLOFENAC sodium is an active ingredient in DICLOFENAC SODIUM 50MG tablets, which you may have bought yourself as well as medicines on prescription. This means medicines you are taking. This means medicines you are taking from your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet

• you may have bought yourself as well as medicines on prescription.
• You should avoid taking Diclofenac Sodium 50 mg tablets during the last 3 months of pregnancy as it may affect the baby’s circulation. You should avoid taking Diclofenac Sodium tablets if you think you might be pregnant or are up to 6 months pregnant.
• If you have had a condition called porphyrinuria. Taking Diclofenac Sodium tablets may make you more difficult to become pregnant. You should talk to your doctor if you are planning to become pregnant or are up to 6 months pregnant.
• If you have had problems with your blood circulation (peripheral vascular disease).
• If you have rheumatoid arthritis, osteoarthritis, osteoporosis, diabetic neuropathy, chronic pulmonary diseases or infections of the respiratory tract.
• If you have diabetics.
• If you have a history of allergic reactions.
• If you have a history of bleeding disorders.
• If you have alcoholism.
• If you have a history of peptic ulcer disease.
• If you have a history of severe heart, kidney or liver failure.
• If you have a history of angina, blood clots or cardiac problems after taking Diclofenac Sodium tablets.
• If you have had a head injury, stroke or have had, or have ever had, a stomach ulcer.
• If you have a history of abnormal bleeding.
• If you have a history of infections.
• If you have a history of bleeding.
• If you have a history of peptic ulcer disease.
• If you have a history of heart, kidney or liver problems.
• If you have a history of high blood pressure.
• If you have a history of smoking.
• If you have a history of peptic ulcer disease.
• If you have a history of gastrointestinal bleeding.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DICLOFENAC SODIUM 50MG

Do not take Diclofenac Sodium 50 mg tablets if:

• you are allergic to any of the ingredients (such as aspirin, duropin or any other NSAID, or to any of the other ingredients in DICLOFENAC SODIUM 50MG tablets (these are listed under section 6 “CONTENTS OF EACH PACK AND OTHER INFORMATION” of this leaflet). Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, rashes not related to any other allergic type reaction.
• you have ever had a serious allergic reaction (e.g. anaphylaxis, urticaria or angioedema) caused by the aspirin or any other ingredient in DICLOFENAC SODIUM 50MG tablets.
• you have severe heart, kidney or liver failure.
• you have established blood vessel disease and/or cerebrovascular disease, e.g. if you have had a head injury, stroke or have had, or have ever had, a stomach ulcer or if you have a history of blood vessel disease to the heart or brain or an operation to clear or bypass the heart’s blood vessels.
• you have or have had problems with your blood circulation (peripheral vascular 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 undergone any kind of surgery.
• you have kidney problems or you think you might be taking high doses for a long time. Always follow the instruction on the label and check with 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, fever, 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. These tablets are not suitable for children aged under 12.

Other medicines and Diclofenac Sodium 50 mg

Some medicines can change the way your treatment works. 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).
• Oral steroids (an anti-inflammatory drug)
• Cardiac glycosides (for example digoxin), used to treat heart problems.
• Steroids (to reduce the swelling associated with dental and minor surgery)
• If you have a condition called porphyrinuria. Taking Diclofenac Sodium tablets may make you more difficult to become pregnant. You should talk to your doctor if you are planning to become pregnant or are up to 6 months pregnant.
• If you have bought yourself as well as medicines on prescription from your doctor.

Diclofenac Sodium 50 mg tablets contain lactose. If you have diabetes or high cholesterol or are a smoker (including amongst other things, insulin-dependent diabetes or take medicines to treat diabetes), you may be more at risk of heart attack or stroke when you are taking any medicine like Diclofenac Sodium 50 mg tablets. This is higher if you are taking high doses for a long time. Always follow the instruction on the label and check with your doctor straight away if you notice any unusual symptoms.

3. HOW TO TAKE DICLOFENAC SODIUM 50MG

The doctor will tell you how many Diclofenac 50 mg tablets to take. Take all tablets as described in this booklet. Do not take Diclofenac Sodium 50 mg tablets if you are allergic to any of the ingredients. Check with the label or tablet blister pack. Do not swallow the tablets. Take the tablets with or after food.

Please take the tablets whole. Do not crush or chew the tablets. The recommended dose is:

Adults: 75 to 150 mg daily in two or three divided doses. Take the number of tablets which you take at regular check-ups when you are taking these tablets. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking Diclofenac Sodium tablets.

Taking Diclofenac Sodium tablets may make you more difficult to become pregnant. You should talk to your doctor if you are planning to become pregnant or are up to 6 months pregnant.

Pregnancy and breast-feeding

You should avoid taking Diclofenac Sodium whilst breastfeeding.

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 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 overweight or elderly.

There is a small increased risk of heart attack or stroke when you are taking any medicine like Diclofenac Sodium 50 mg tablets. This is higher if you are taking high doses for a long time. Always follow the instruction on the label and check with your doctor straight away if you notice any unusual symptoms.

Doxylamine sodium tablets contain lactose. You may have been told by your doctor that you have an intolerance to some sugars such as lactose (these tablets contain lactose). You may have an intolerance to some sugars such as lactose (these tablets contain lactose). You may need to read this leaflet again.

Diclofenac Sodium 50 mg tablets contain lactose. If you have diabetes or high cholesterol or are a smoker (including amongst other things, insulin-dependent diabetes or take medicines to treat diabetes), you may be more at risk of heart attack or stroke when you are taking any medicine like Diclofenac Sodium 50 mg tablets. This is higher if you are taking high doses for a long time. Always follow the instruction on the label and check with your doctor straight away if you notice any unusual symptoms.

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Effects on skin or hair:
(including anaemia).
(pneumonitis), heart disorders, including congestive blood vessels (vasculitis), inflammation of the lung hypertension (high blood pressure), inflammation of the colon or worsening of ulcerative colitis or lips, taste changes, lower gut disorders (including ulcers, inflammation of the inside of the mouth or Constipation, inflammation of the tongue, mouth fever and a stiff neck, disturbances in sensation.

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

Effects on the nervous system:
Tingling or numbness in the fingers, hands, blurred or double visions, hearing loss or a change in taste, tinnitus (ringing in the ear), sleeplessness, nightmares, mood changes, depression, anxiety, mental disorders, disorientation and loss of memory. If you notice that you are bruising more easily than usual or have frequent nosebleeds or infections, tell your doctor.

The side effects listed below have also been reported.

Contraindicated with some blood thinning treatments:

You may also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. If you notice side effects not listed in this leaflet, you can help provide more information on the safety of this medicine.

STOP TAKING Diclofenac Sodium tablets and tell your doctor straight away if you:
• Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick)
• Any sign of bleeding in the stomach or intestines; 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 blisters
• Wheezing or shortness of breath (bronchospasm)
• Swollen lips, face, hands or fingers
• Nodding of your arm or the rest of your body
• Persistent thirst or high temperature
• An unexpected change in the amount of urine produced and/or its appearance
• Kidney swelling and tenderness of the abdomen, starting shortly after the start of the treatment with Diclofenac Sodium and followed by renal bleeding or bloody diarrhea usually within 24 hours of the start of the treatment

Stevens-Johnson syndrome (serious illness with blistering of the skin and mucus membranes) if you are using the tablets, tell your doctor.

1. WHAT DICLOFENAC SODIUM 50 mg tablets contain

The name of your medicine is Diclofenac Sodium 50 mg.

2. WHAT DICLOFENAC SODIUM 50 mg tablets look like and contents of the pack

These tablets are not suitable for children aged 16 years and under. 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, or if you are elderly, or taking certain other drugs as well.

If you take more Diclofenac Sodium 50 mg than you should
If you, or anyone else, accidently take too much Diclofenac Sodium, tell your doctor or go to your nearest hospital casualty department immediately.

Take your medicine 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, narrowing of your bowels, blood in vomit or black, tarry faeces.*

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

Effects on the skin:

Blistering of the skin, mouth, eyes and genitals)

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

Other side effects that have also been reported include:

Inflammation of the pancreas, iron deficiency, cataract formation, cataract formation with or without the whites of your eyes yellowing, or jaundice.

If you forget to take Diclofenac Sodium It is important that you do not miss a dose. If you forget to take a dose, take it 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.

It is important to remember to take the tablets, tell your doctor or pharmacist.

These tablets are not suitable for children aged 16 years and under.

If you, or anyone else, accidently take too much Diclofenac Sodium, tell your doctor or go to your nearest emergency hospital casualty immediately.

Take your medicine with you so that people can see what you have taken.

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