

PACKAGE LEAFLET: INFORMATION FOR THE USER

Diclomax SR 75mg Capsules and Diclomax Retard 100mg Capsules (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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Diclomax is and what it is used for
2. What you need to know before you take Diclomax
3. How to take Diclomax
4. Possible side effects
5. How to store Diclomax
6. Contents of the pack and other information

1. WHAT DICLOMAX IS AND WHAT IT IS USED FOR

The name of this medicine is Diclomax SR 75mg Capsules or Diclomax Retard 100mg Capsules. The active substance in them is diclofenac sodium which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

They are used to relieve pain and inflammation or swelling and can be used in the treatment of painful conditions affecting the joints and muscles, e.g. rheumatoid arthritis, osteoarthritis, low back pain and sprains or broken bones, or to control pain and inflammation following orthopaedic, dental and other minor surgery.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DICLOMAX

Do not take Diclomax if

- you are allergic (hypersensitive) to diclofenac sodium, aspirin, ibuprofen or any other anti-inflammatory medicines used to treat painful conditions or to any of the other ingredients of Diclomax (listed in section 6 of this 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 ulcers in the stomach or small intestine (gastric or duodenal ulcers) or bleeding in your stomach or intestines (this can include blood in vomit, bleeding when emptying bowels, fresh blood in stools or black, tarry stools)
- you have a history of ulcers or bleeding in your stomach or intestines that has occurred at least twice

- you have any history of bleeding or perforation in your stomach or intestines related to the use of any anti-inflammatory medicines
- your doctor has told you that you have acute porphyria
- you are in your last three months of pregnancy
- 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)
- your doctor has told you that you have an intolerance to sugars called lactose or sucrose
- you have severe liver, kidney or heart failure

Diclomax Capsules are not recommended for children.

Talk to your doctor before taking this product if any of the above apply to you.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Diclomax

- if you are elderly
- if you are taking any other NSAIDs (non-steroidal anti-inflammatory drugs)
- if you smoke
- if you have diabetes
- if you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides

or if you suffer from any of the following conditions:

- stomach or bowel disorders including Crohn's disease or ulcerative colitis
- heart problems
- liver or kidney disease
- if you have ever had asthma, hayfever or other allergies, polyps in your nose, difficulty breathing (COPD) or long-term respiratory infections
- systemic lupus erythematosus (SLE) (a chronic inflammatory disease affecting many systems of the body) or other mixed connective tissue disorders (if so you may have an increased risk of aseptic meningitis if you take this medicine)
- any blood disorders where you bleed or bruise easily

If any of the above apply to you, it is important that you tell your doctor or pharmacist before taking this medicine and they will decide what to do. It may still be safe for you to take Diclomax.

Tell your doctor if you are about to have major surgery.

Tell your doctor if you recently had or you are going to have surgery of the stomach or intestinal tract before taking Diclomax, as Diclomax can sometimes worsen wound healing in your gut after surgery.

If you go into hospital or visit a dentist or any other doctor, tell them that you are taking this medicine.

Other special warnings

- If you have a history of stomach problems when you take NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms.
- Medicines such as Diclomax may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.
- Because it is an anti-inflammatory medicine, Diclomax can make the symptoms of an infection (such as fever or pain) less noticeable.

Other medicines and Diclomax

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those medicines obtained without a prescription.

This is especially important if you are taking any of the following:

- quinolone antibiotics (such as ciprofloxacin) used to treat certain bacterial infections
- warfarin (to thin the blood) or any other anticoagulant or anti-platelet medicine (e.g. low dose aspirin) used to prevent blood clots forming
- methotrexate – used in cancer and certain inflammatory diseases like rheumatoid arthritis
- lithium – a medicine used to treat mental health problems
- zidovudine – a medicine used to treat HIV
- a group of medicines called selective serotonin reuptake inhibitors that are commonly referred to as SSRIs and used to treat depression
- oral steroids (e.g. prednisolone)
- other non-steroidal anti-inflammatory drugs (NSAIDs) (e.g. aspirin and ibuprofen)
- water tablets (diuretics)
- medicines that affect your immune system (e.g. ciclosporin or tacrolimus)
- oral medicines for diabetes (e.g. hypoglycaemic agents)
- cardiac glycosides (e.g. digoxin) - medicines used to treat heart problems
- medicines to treat high blood pressure
- a medicine called mifepristone used for the termination of pregnancy. It is important to tell your doctor if you have taken mifepristone within the last 12 days.
- phenytoin – a medicine used to treat seizures
- colestipol and colestyramine – medicines used to lower cholesterol
- voriconazole – a medicine used to treat fungal infections.

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 or pharmacist for advice before taking this medicine.

Abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not take diclofenac during the last three months of pregnancy as it may affect the baby’s kidney function and circulation, blood clotting in both the mother and baby, and labour.

Diclofenac should be avoided if you are breast-feeding, as small amounts of the medicine may pass into breast milk.

Diclofenac may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

It is usually safe to drive while taking Diclomax, however, you may experience dizziness, tiredness or problems with your sight. If you are affected by any of these, do not drive or operate machinery.

Important information about some of the ingredients of Diclomax

This medicine contains lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. HOW TO TAKE DICLOMAX

Always take Diclomax exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The label on the carton will tell you how many capsules you should take and when.

Diclomax SR 75mg Capsules:

The normal dose of Diclomax SR for adults is one or two 75mg capsules daily, swallowed whole with or after food. Do not chew the capsule(s) or remove the contents.

Diclomax Retard 100mg Capsules:

The normal dose of Diclomax Retard for adults is one 100mg capsule daily, swallowed whole with or after food. Do not chew the capsule or remove the contents.

If you take more Diclomax than you should

If you take too many capsules contact your nearest hospital casualty department or tell your doctor or pharmacist immediately. Take this leaflet and any remaining capsules with you.

If you forget to take Diclomax

If you forget to take a dose, take it as soon as you remember unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Diclomax can cause side effects, although not everybody gets them. Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

If you get any of the following side effects after taking Diclomax, STOP taking them and seek urgent medical advice immediately:

- Allergic reactions which can include difficulty in breathing or starting to wheeze, swelling of the face, lips, tongue or throat. Symptoms can also include chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

- Stomach or intestinal ulcers, or intestinal bleeding (there have been very rare reported cases resulting in death particularly in the elderly) causing severe stomach pain, vomiting blood or dark coffee ground-like material, passing bloody or black tar-like stools, diarrhoea with blood in it
- Severe skin rash, itching, bruising, painful red areas, peeling or blistering
- Yellowing of your skin or the whites of your eyes (jaundice)
- An unexpected change in the amount of urine produced and/or its appearance or blood in your urine
- Bruising more easily than usual or frequent sore throats or infections
- Small red or purple spots on your skin
- Stiff neck, headache, disorientation, nausea and/or vomiting associated with fever
- Medicines such as Diclomax may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Diclomax and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain (frequency not known, cannot be estimated from the available data).

The side effects listed below have also been reported:

Common: may affect up to 1 in 10 people

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| – stomach pain | – diarrhoea |
| – nausea | – flatulence (excess wind) |
| – vomiting | – heartburn (indigestion) |
| – loss of appetite | – headache |
| – skin rash | – dizziness |
| – raised levels of liver enzymes in the blood | – vertigo (condition that affects balance) |

Rare: may affect up to 1 in 1,000 people

- liver problems, including hepatitis (inflammation of the liver)
- gastritis (inflammation or irritation of the stomach lining)
- asthma (including shortness of breath)
- oedema (water retention/swelling)
- raised itchy rash
- sleepiness

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

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| – problems with sight including blurred or double vision | – itch |
| – ringing in the ears (tinnitus) | – rapidly progressive hepatitis |
| – hearing loss | – liver damage and failure |
| – depression | – kidney problems including kidney failure and presence of blood or protein in the urine |
| – disorientation | – palpitations (fast or irregular heart beat) |
| – sleeplessness | – chest pain |
| – nightmares | – heart failure |
| – irritability | – hypertension (high blood pressure) |
| – mental disorders | – inflammation of blood vessels (vasculitis) |
| – loss of memory | |

- fits
- anxiety
- tremor
- taste changes
- “pins and needles” or numbness, tingling or itching of the skin
- various skin disorders including eczema, redness of the skin and increased sensitivity to sunlight
- angioedema (swelling under the skin, particularly around the eyes and lips)
- hair loss
- inflammation of the lungs (pneumonitis)
- inflammation of the colon (including worsening of ulcerative colitis or Crohn’s disease)
- constipation
- inflammation of the mouth (including mouth ulcers)
- inflammation of the tongue
- oesophageal disorders (causes symptoms such as difficulty swallowing)
- narrowing of the intestine
- inflammation of the pancreas (pancreatitis)

Not known: frequency cannot be estimated from the available data

- confusion
- hallucination (imagining something that is not really there)
- low numbers of white blood cells
- inflammation of the nerves in the eye
- worsened asthma or wheeze
- tiredness
- general feeling of being unwell (malaise)

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

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DICLOMAX

Keep this medicine out of the sight and reach of children.

Diclomax does not require any special storage conditions.

Do not use Diclomax after the expiry date which is stated on the carton and blister foil. The expiry date refers to the last day of that month.

Do not use Diclomax if you notice that the packaging or any of the capsules are damaged.

Medicines should not be disposed of via wastewater 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 Diclomax SR 75mg Capsules contain

The active substance is diclofenac sodium. Each Diclomax SR capsule contains 75mg of diclofenac sodium. The other ingredients are sucrose, maize starch, polyethylene glycol 6000, ammonio methacrylate copolymer type A, talc, lactose, polysorbate 80, gelatin, yellow iron oxide (E172), titanium dioxide (E171) and imprinting ink (shellac, black iron oxide (E172) and propylene glycol).

What Diclomax Retard 100mg Capsules contain

The active substance is diclofenac sodium. Each Diclomax Retard capsule contains 100mg of diclofenac sodium. The other ingredients are sucrose, maize starch, polyethylene glycol 6000, ammonio methacrylate copolymer type A, talc, lactose, polysorbate 80, gelatin, titanium dioxide (E171) and imprinting ink (shellac, black iron oxide (E172) and propylene glycol).

What Diclomax Capsules look like and contents of the pack

Diclomax SR 75mg Capsules are yellow capsules with “Diclomax SR 75mg” printed on them in black ink. They are available in blister packs of 4 and 56 capsules.

Diclomax Retard 100mg Capsules are white capsules with “Diclomax Retard” printed on them in black ink. They are available in blister packs of 4 and 28 capsules.

Marketing Authorisation Holder

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