

Motifene[®] 75 mg Capsules

diclofenac sodium

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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, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not give it to anyone else. 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.

What is in this leaflet:

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

1. WHAT MOTIFENE IS AND WHAT IT IS USED FOR

Diclofenac sodium, the active ingredient in Motifene, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) and is used to reduce pain and inflammation. Some of the pellets inside the Motifene capsule shell release diclofenac quickly to give a rapid effect (gastro-resistant pellets). The remainder of the pellets dissolve more slowly to produce a longer lasting effect (prolonged release pellets).

Motifene can be used for the treatment of pain and inflammation due to:

- Acute attacks of gout
- Acute musculo-skeletal disorders (for example frozen shoulder, inflamed tendons)
- Dental or other minor surgery
- Joint disorders (such as ankylosing spondylitis, osteoarthritis, rheumatoid arthritis)
- Traumatic conditions (including sprains, strains, dislocations, fractures)
- Low back pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MOTIFENE

Do not take Motifene:

- if you think you may be allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Motifene. (These are listed at the end 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
- if you have severe liver, kidney or heart failure
- if 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
- if you have or have had problems with your blood circulation (peripheral arterial disease)
- if you are in the last three months of pregnancy
- if you have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach (for example, passed black tarry or bloody stools or vomited blood or dark particles that look like coffee grounds), or have had two or more episodes of peptic ulcers, stomach bleeding or perforation.

If you think any of these apply to you, or you are unsure, do not take the capsules. Talk to your doctor first and follow the advice given.

Warnings and precautions

Talk to your doctor or pharmacist before taking Motifene, particularly if you have any of the following health problems:

- Smoking
- Diabetes
- Angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides

Talk to your doctor before taking Motifene

- if you are also taking other NSAIDs, as Motifene should not be used at the same time as other NSAIDs.
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Motifene or other pain medications.

If you have any of the following health problems, you may need to take special care while taking the medicine as your condition could get worse:

- Asthma, hay fever or other allergies, polyps in your nose, difficulty breathing (COPD), long term respiratory infections
- Crohn's disease or ulcerative colitis
- SLE (Systemic Lupus Erythematosus), an inflammation of the connective tissue
- Heart, kidney or liver problems (your doctor may want to carry out some tests while you are taking the capsules)
- High blood pressure
- Acute porphyria
- Blood clotting problems

Tell your doctor if you are about to have major surgery. Because Motifene is a NSAID, it can make the symptoms of an infection (such as fever, pain) less noticeable.

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

Medicines such as Motifene 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.

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

Older people

If you are older (65 years and over), your doctor may want to monitor you carefully while you are taking Motifene.

Children and adolescents

Motifene is not recommended for children and adolescents under the age of 18.

Other medicines and Motifene

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor or pharmacist about any of the following:

- Other painkillers or anti-inflammatory drugs (NSAIDs), including aspirin, or any other medicines used to prevent platelet clumping
- Medicines to lower blood pressure (anti-hypertensives)
- Anti-coagulants, such as warfarin (to "thin" the blood)
- Anti-diabetic tablets
- Certain antibiotics, such as ciprofloxacin
- Ciclosporin or tacrolimus (immunosuppressive medicines, used to dampen down the body's immune reactions)
- Corticosteroids
- Mifepristone (for early termination of pregnancy)
- Heart drugs, such as digoxin
- Diuretics ("water tablets"), including the potassium-sparing type
- Lithium (a medicine used to treat mood swings and some types of depression)
- Selective serotonin reuptake inhibitors (SSRIs) (medicines used to treat some types of depression)
- Methotrexate (a medicine used to treat arthritis and some types of cancer)
- Zidovudine (a medicine used to treat HIV and AIDs)
- Phenytoin (used to treat epilepsy)
- Colestipol or cholestyramine (medicines used to lower cholesterol levels)
- Voriconazole (used to treat fungal infections)
- Sulfinpyrazone (used to treat gout)

Taking Motifene with food and drink


Motifene is best taken with or after food.

Pregnancy and breast-feeding

Tell your doctor before taking Motifene if you are pregnant or breast-feeding. As with other non-steroidal anti-inflammatory drugs, Motifene 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.

Motifene must not be taken during the last three months of pregnancy (see "Do not take Motifene" above) as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

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You should not take Motifene during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Motifene can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring. Motifene should be avoided if you are breast-feeding, as small amounts of the medicine may pass into breast milk.

Driving and using machines

These capsules can cause some people to feel dizzy or giddy, drowsy or sleepy, tired or have problems with their vision. If this happens, do not drive or use machines until the symptoms wear off. Ask your doctor for advice.

3. HOW TO TAKE MOTIFENE

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one capsule of Motifene, once or twice a day as prescribed.

It is important that the second dose is taken 8 – 12 hours after the first dose and that no more than two capsules of Motifene are taken in any 24 hour period.

Motifene must be swallowed whole with a drink of water (about half a glass). Do not chew or break open the capsules. The capsules are best taken with or after food. It may help you to remember to take your capsules if you take them at the same time every day, perhaps with breakfast or an evening meal.

If you take more Motifene than you should

If you take more capsules than you should or if a child accidentally swallows some, go to your doctor or nearest emergency department immediately and take your medicine pack with you.

If you forget to take Motifene

If it is a little more than 12 hours since your previous dose, take the forgotten dose and then adjust the timing of your next dose to 8 – 12 hours later. Do not take a double dose to make up for the forgotten dose and do not take more than two capsules in 24 hours.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Taking the lowest effective dose for the shortest possible time will minimise side effects.

Some side effects can be serious. STOP taking Motifene and tell your doctor immediately if you have any of the following symptoms:

- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Motifene 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)
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- Stomach ulcer or duodenal ulcer
- Passing blood in your faeces (stools/motions)
- Bleeding from the stomach or intestines (e.g. passing black 'tarry' stools)
- Vomiting blood or dark particles that look like coffee grounds
- Stomach pains or other abnormal stomach symptoms
- Indigestion or heartburn
- Worsening of Crohn's disease or of ulcerative colitis
- Allergic reactions, which can include sudden wheeziness, difficulty in breathing, swelling of the face, lips, hands or fingers, skin rash, itching, bruising, painful red areas, peeling or blistering.

These are the other side effects known about so far with Motifene:

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

Headache, dizziness or giddiness, vertigo, sickness, feeling sick, flatulence, diarrhoea, loss of appetite, changes in blood test results, skin rashes.

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

Liver problems including hepatitis and jaundice (yellowing of the skin or whites of the eyes), sleepiness, rashes and spots, swelling caused by a build-up of fluid (known as 'oedema').

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

Memory problems, pins and needles, disorientation, impaired hearing, insomnia, irritability, fits, anxiety, nightmares, tremor, mood changes, psychotic reactions, changes in taste, stiff neck, depression, confusion, hallucinations, bleeding in the brain, feeling unwell, tiredness, tinnitus (ringing in the ears), blurred vision, double vision, eye pain, constipation (including blockages), problems swallowing, hair loss, eczema, unusual bruising, kidney problems, urinary problems (e.g. any change in the usual amount or colour of the urine), severe liver problems including liver failure, sensitivity to light, flaky skin, blisters on the skin and sore mouth/eyes, inflammation of the pancreas, swelling of the tongue, high blood pressure, inflammation of the blood vessels, chest pain, palpitations, heart failure, inflammation of the lungs, changes in blood cell levels.

Not known (frequency cannot be estimated from the available data)

An allergic skin reaction, that may include round or oval patches of redness and swelling of the skin, blistering, and itching (Fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur. Fixed drug eruption usually reoccurs at the same site(s) if the medication is taken again.

Medicines such as Motifene may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. 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 MOTIFENE

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

Motifene should not be stored above 25°C.

Do not use this medicine after the expiry date printed on the box and on the blister strip. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Motifene contains

The active substance is diclofenac sodium.

Each hard gelatin capsule contains 75 mg diclofenac sodium.

The other ingredients are:

Gastro-resistant pellets:

Microcrystalline cellulose, Povidone K25, colloidal anhydrous silica, methacrylic acid ethyl acrylate copolymer, propylene glycol, talc.

Prolonged-release pellets:

Microcrystalline cellulose, Povidone K25, colloidal anhydrous silica, ammonio methacrylate copolymer A and B, triethyl citrate, talc.

Capsule shell:

Indigocarmine (E132), titanium dioxide (E171), gelatin.

Capsule body:

Gelatin, ink (containing shellac, propylene glycol, titanium dioxide (E171)).

What Motifene looks like and contents of the pack

Motifene are blue and clear capsules and are marked 'D 75 M'.

The capsules are available in packs of 2, 4, 28, 30, 50 and 56.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Glenwood GmbH Pharmazeutische Erzeugnisse
Arabellastraße 17, 81925 Munich, Germany

Manufacturer

Swiss Caps GmbH
Grassingerstraße 9, 83043 Bad Aibling, Germany

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