Dufenac®

75 mg,

Diclofenac Sodium Dual Release Enteric-coated Capsules

B&O PHARM

Please read this leaflet carefully before taking this medicine as 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 drug has been prescribed for you personally. Do not give it to other people. It may harm them, even if the signs of their illness are the same as yours.
If you experience any side effects talk to your doctor, pharmacist or nurse. This includes any side effects not mentioned in this leaflet. See section 4.

What does this leaflet contain?
1. What is **DUFENAC** 75 mg, dual release enteric-coated capsules used for and when is it used?
2. What information should you know before taking **DUFENAC** 75 mg, dual release enteric-coated capsules?
3. HOW TO TAKE **DUFENAC** 75 mg, dual release enteric-coated capsules?
4. What are the possible side effects?
5. HOW TO STORE **DUFENAC** 75 mg, dual release enteric-coated capsules?
6. Package contents and other information.

1. WHAT IS DUFENAC 75 mg dual release enteric-coated capsules USE FOR AND WHEN IS IT USED ?
Pharmacotherapeutic Class • ATC Code: ANTI-INFLAMMATORY, ANTI-RHUMATIC, NON-STEROID. • M01AB05
DUFENAC 75 mg dual release enteric-coated capsules contains diclofenac, a substance that belongs to the family of non-steroidal anti-inflammatory drugs (NSAIDs). These drugs reduce inflammation, pain and fever.
DUFENAC 75 mg dual release enteric-coated capsules is for adults and teenagers over 15 years of age.
It is used in the symptomatic treatment of rheumatoid arthritis, osteoarthritis and ankylosing spondylitis, acute musculoskeletal disorders such as periarthritis, tendonitis, tenosynovitis, bursitis, sprains, strains and injuries, pain that follows surgery, lower back pain, acute gout, pain also arising in the management of pain and inflammation in orthopaedic, dental and minor surgery. In the management of dysmenorrhoea and associated menorrhagia.

2. WHAT INFORMATION SHOULD BE KNOWN BEFORE TAKING DUFENAC 75 mg dual release enteric-coated capsules?
Medical follow-up during treatment with DUFENAC 75 mg, dual release enteric-coated capsules
If you have liver or kidney problems or blood abnormalities, you will be asked to have blood tests during adjustment of your treatment.
Never take DUFENAC 75 mg dual release enteric-coated capsules:
If you are allergic to the active substance or any of the other components of this drug mentioned in section 6.
If you have a history of allergy (such as hives, angioedema, acute rhinitis, chest pain or asthma triggered by taking this drug or another medicine, including other non-steroidal anti-inflammatory drugs, especially acetylsalicylic acid (aspirin).
If you are pregnant, from the beginning of the 6th month of pregnancy (beyond 24 weeks of amenorrhea).
If there is a history of gastrointestinal bleeding or ulcers related to previous NSAID therapy.
In the case of an existing or recurring stomach or duodenal ulcer.
In case of gastrointestinal hemorrhage, cerebral hemorrhage or other ongoing hemorrhage.
In case of severe liver disease (liver failure).
In case of severe kidney disease (kidney failure).
If you have known heart disease and or cerebrovascular disease, such as a heart attack, stroke, transient ischemic attack (TIA) or blockage of the blood vessels supplying the heart or brain, or if you have had surgery to remove or bypass the blockage.
If there is any history of blood circulation disorders or active disorders (peripheral arterial disease).
Children under 15 years of age (due to inappropriate dosing of this medication).
If you are taking a medicine containing an active substance called mifamurtide to treat certain bone tumors.

Warnings and Precautions
Talk to your doctor, pharmacist or nurse before taking **DUFENAC 75 mg,** dual release enteric-coated capsules.
Drugs such as **DUFENAC** 75 mg, dual release enteric-coated capsules may increase the risk of heart attack ("myocardial infarction") or stroke. The risk is even greater the higher the doses used and the longer the duration of treatment.
Do not exceed the recommended doses or treatment duration.
If you are a woman **DUFENAC** 75 mg, dual release enteric-coated capsules may impair your fertility. Its use is not recommended for women who wish to conceive a child. For women who are having difficulty conceiving or are undergoing tests for reproductive function, talk to your doctor or pharmacist before taking **DUFENAC** 75 mg, dual release enteric-coated capsules.
Elderly subjects, especially frail or low body weight elderly patients, are at greater risk of adverse effects particularly for gastrointestinal hemorrhage, ulcers or perforation. Renal, hepatic and cardiac function should be closely monitored.

During treatment
Stop treatment and contact a doctor or the nearest hospital emergency room immediately.
If you have blood in your mouth, blood in your stool or your stool is colored black. This may be bleeding or bleeding in your stomach and/or intestine (gastrointestinal bleeding).
If you have a rash on your skin, itching, sudden swelling of the face and neck, difficulty breathing or chest pain. This may be an allergic to this medicine.
If you have swelling (edema) in your extremities, increased blood pressure, or shortness of breath.
If you have yellow discoloration of the skin or eyes.
Side effects can be minimized by using the lowest effective dose for the shortest time necessary.
DUFENAC 75 mg, dual release enteric-coated capsules may reduce the signs of infection (especially headache and fever) making it more difficult to diagnose and manage.

Infants
Do not use in children under 15 years of age (due to inappropriate dosage of this drug).

Other Medicines and DUFENAC 75 mg, dual release enteric-coated capsules
This drug contains a non-steroidal anti-inflammatory drug, **diclofenac.**
Do not take or not administer more than one non-steroidal anti-inflammatory drugs (and, like selective cyclooxygenase 2 inhibitors) and/or acetylsalicylic acid (aspirin) at the same time as this medication.
Read the package inserts of other medications you are taking carefully to make sure you do not take non-steroidal anti-inflammatory drugs and/or acetylsalicylic acid (aspirin) if you are already using these medications, you should not use **DUFENAC** 75 mg, dual release enteric-coated capsules unless your doctor tells you to.
Tell your doctor or pharmacist if you are taking, have recently taken, or may take any other medicines, including medicines obtained without a prescription, including the following medicines:
a drug to prevent blood clotting and to thin the blood (such as an anticoagulant K or heparin), if your doctor has instructed you to take any of these medications in addition to **DUFENAC** 75 mg, dual release enteric-coated capsules, digestive bleeding may occur.
a drug of the same family as **DUFENAC** 75 mg, dual release enteric-coated capsules (non-steroidal anti-inflammatory drugs such as aspirin or ibuprofen for example), to relief inflammation, pain and fever.
a drug containing an active substance called mifamurtide for treating certain bone tumors.
lithium – a drug used to treat certain psychiatric disorders.
a drug containing an active substance called methotrexate to treat certain rheumatism and cancer.
a drug containing an active substance called nicorandil to prevent or reduce the signs of pain caused by heart disease.
a drug containing an active substance called pemetrexed to treat certain cancers.

Pregnancy, Breastfeeding and Fertility
If you are pregnant or breastfeeding, think you may be pregnant, or are planning a pregnancy, ask your doctor or pharmacist for advice before taking any medication.

Pregnancy
Before the beginning of the 6th month of pregnancy (up to the 24th week of amenorrhea), you should not take this medication unless necessary as determined by your doctor, due to the potential risk of miscarriage or malformations. In this case, the dose should be as low as possible and the duration of treatment as short as possible.
From the beginning of the 6th month until the end of the pregnancy (beyond the 24th week of amenorrhea), the medicine is contraindicated, you must NOT take this drug and/or ANY circumstances because it exposes your child to risks: heart and lung toxicity, kidney dysfunction, in particular on the heart, lungs and/or kidneys, even with a single dose.

Breastfeeding
Because this drug passes into breast milk, it is not recommended to use it while breast-feeding.

Fertility
This drug, like all non-steroidal anti-inflammatory drugs (NSAIDs), may impair women's fertility and cause difficulties in becoming pregnant, which may be reversible if treatment is stopped. Harm your doctor if you are planning a pregnancy or have difficulty conceiving.

Driving and using machines
In rare cases, **DUFENAC** 75 mg, dual release enteric-coated capsules may cause dizziness, drowsiness and visual disturbances. You should avoid driving or operating machinery if you experience any of these effects.

3. HOW TO TAKE DUFENAC 75 mg, dual release enteric-coated capsules?
Dosage
If you are taking DUFENAC 75 mg, dual release enteric-coated capsules **for acute or occasional pain (attack treatment):** The recommended dose is 1 capsule at 75 mg, to be taken twice a day, morning and evening, for up to 7 days.
If you are taking DUFENAC 75 mg, dual release enteric-coated capsules **to prevent relapse (maintenance therapy):** The recommended dose is 1 capsule at 75 mg per day.
Mode of administration
This medicine should be taken through oral administration.
You should swallow the capsules as they are, with a full glass of water, preferably during meals.

Duration of treatment
If you are taking **DUFENAC** 75 mg, dual release enteric-coated capsules to treat acute or occasional pain or inflammation (before therapy), you should not exceed 7 days of treatment. The dosage should be as low as possible for the shortest time necessary to relieve symptoms.
If you have taken more DUFENAC 75 mg, dual release enteric-coated capsules than you should have taken
Overdose may cause the following symptoms: headache, nausea, vomiting, gastrointestinal ulcers, digestive bleeding, diarrhea, dizziness, buzzing or ringing in the ears (tinnitus), convulsions, restlessness, intoxication.
Consult your doctor or pharmacist immediately if you experience any of these symptoms.
If you forget to take DUFENAC 75 mg, dual release enteric-coated capsules
Do not take a double dose to make up for the dose you forgot to take.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?
Like all drugs, this is because this drug may cause side effects but they do not always occur in everyone.
The following side effects may occur:
Frequently (1 to 10 in 100 people): nausea, vomiting, diarrhea, abdominal pain, dyspepsia, loss of appetite, gas, headache, dizziness, lightheadedness, an increase in certain liver enzymes (elevation when blood is drawn), pimples or rashes on the body (skin rash).
Uncommon (1 to 10 in 1,000 people): heart attack, heart failure (characterized by shortness of breath, difficulty breathing when lying down, swelling of the legs or feet), palpitations, chest pain, abdominal cramps, stomach pain, burping.
Rarely (1 to 10 in 10,000 people): an allergic reaction, some of which can be severe with a drop in blood pressure, spasms of the bronchi or an accelerated heart rate (tachycardia), shock, digestive bleeding (bleeding discharge of blood through the mouth or in the stool, stool discoloration to black), cases of stomach and/or intestinal ulcer and/or perforation, stomach inflammation, yellow discoloration of the skin and eyes (jaundice), altered liver function which can be serious (hepatitis), itchy pimples (hives), asthma or shortness of breath, drowsiness.
Very rarely (less than 1 person in 10,000): skin detachment that can rapidly spread very seriously throughout the body, a strong skin reaction when exposed to the sun or UV rays, hair loss, or purple spots on the skin (purpura), itching, the appearance of small blisters on the skin that itch (eczema), redness of the skin and mucous membranes or red purple spots, hives, sweating, flaking, an allergic reaction with swelling of the tongue, throat and face, depression, anxiety, disorientation, difficulty in sleeping, nervousness, stress, delusions and hallucinations, tremor, trembling, inflammation of the meninges (the layers that surround the brain), convulsions, stroke, memory problems, altered taste, visual disturbances, blurred vision, double vision, ringing in the ears and decreased hearing, increased blood pressure, an inflammation of the small vessels, infection of the lungs, narrowing of the intestine, an inflammation of the large intestine, constipation, irritation or inflammation of the esophagus (tube connecting the stomach to the mouth), torque, mouth or pancreas, severe liver failure, or impairment, liver severe inflammation (hepatitis), more or less severe kidney disease (nephrosis or kidney failure), kidney inflammation, bleeding in the urine, protein or albumin in the urine, a decrease in blood, platelets, red and white blood cells, sometimes with fever, and/or other serious changes in the results of blood and urine tests may eventually occur (affecting liver and kidney, etc.).
The following adverse reactions have been reported but their frequency is unknown: rectal abscess (a pus in the rectum and surrounding tissues), necrotic shortly after initiation of treatment with **DUFENAC** 75 mg, dual release enteric-coated capsules and followed by rectal bleeding or bloody diarrhea usually within 24 hours of the onset of abdominal pain, swelling (edema), fatigue, a decrease in blood pressure, an allergic drug reaction, the amount of salt and water retained by your body with the possibility of swelling, an increase in the level of potassium in the blood, difficulty breathing, chest pain, which may be a sign of a potentially serious allergic reaction called Kounis syndrome.

5. HOW TO STORE DUFENAC 75 mg, dual release enteric-coated capsules?
Keep this medicine out of sight and reach of children.
Do not use this medicine after the expiry date stated on the package. The expiry date refers to the last day of that month.
Store at a temperature not exceeding 30°C and away from humidity.
Do not dispose of any medicines down the drain or with household waste. Ask your pharmacist to dispose of drugs you no longer use. This will help protect the environment.

6. PACKAGE CONTENTS AND OTHER INFORMATION
What DUFENAC 75 mg, dual release enteric-coated capsules contains
The active substance is:
Diclofenac sodium ..... 75.00 mg
for a dual release enteric-coated capsules
The other components are: Sugar spheres (Saccharose), Sodium hydroxide, Talc, Triethyl citrate, Ammonio methacrylate copolymer type A, Ammonio methacrylate copolymer type B, Copolymer dispersion of ethyl acrylate and methacrylate acid.
What is DUFENAC 75 mg, dual release enteric-coated capsules and contents of outer packager
Capsules in aluminium / aluminium blister pack. Packaging: 10 capsules / blister, 1 blister / box

Marketing Authorisation Holder
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Dufenac®

75 mg,

Diclofénac Sodique Gélules Gastrorésistantes à Double Libération

B&O PHARM

Veuillez lire attentivement cette notice avant de prendre ce médicament car elle contient des informations importantes pour vous.
Gardez cette notice. Vous pouvez avoir besoin de la relire.
Si vous avez d'autres questions, interrogez votre médecin, votre pharmacien ou votre infirmier/ère.
Ce médicament vous a été personnellement prescrit. Ne le donnez pas à d'autres personnes. Il pourrait leur être nocif, même si les signes de leur maladie sont identiques aux vôtres.
Si vous ressentez un effet indésirable, parlez-en à votre médecin, votre pharmacien ou votre infirmier/ère. Ceci s'applique aussi à tout effet indésirable possible non cité dans cette notice. Voir rubrique 4.

Que contient cette notice?
1. Quand et que **DUFENAC** 75 mg, gélules gastro-résistantes à double libération utilisé pour et dans quel cas est-il utilisé?
2. Quelles sont les informations à connaître avant de prendre **DUFENAC** 75 mg, gélules gastro-résistantes à double libération?
3. Comment prendre **DUFENAC** 75 mg, gélules gastro-résistantes à double libération?
4. Quels sont les effets indésirables éventuels?
5. Comment conserver **DUFENAC** 75 mg, gélules gastro-résistantes à double libération?
6. Contenu de l'emballage et autres informations.

1. QU'EST-CE QUE DUFENAC 75 mg, gélules gastro-résistantes à double libération ET DANS LQUELS CAS EST-IL UTILISÉ?
Classe pharmacothérapeutique • Code ATC: ANTI-INFLAMMATOIRES, ANTI-RHUMATISMAUX, NON STÉROÏDIENS • M01AB05
DUFENAC 75 mg, gélules gastro-résistantes à double libération contient du diclofénac, une substance qui appartient à la famille des médicaments anti-inflammatoires non stéroïdiens (AINS). Ces médicaments diminuent l'inflammation, la douleur et la fièvre.
DUFENAC 75 mg, gélules gastro-résistantes à double libération est réservé à l'adulte et à l'enfant de plus de 15 ans.
Il est utilisé dans le traitement symptomatique de la polyarthrite rhumatoïde, l'arthrose et la spondylarthrite ankylosante, les troubles musculo-squelettiques aigus tels que la périarthrite, la tendinite, la ténosynovite, la bursite, les entorses, les foulures et blessures, soulagement de la douleur consécutives à une chirurgie, douleurs au dos de la jambe aiguë, arthrite goutteuse aiguë, douleurs post-opératoires, douleurs de dentisterie et inflammation orthopédique dentaire et dans la chirurgie mineure. Dans le cas des dysménorrhées et ménorragies associées.

2. QUELLES SONT LES INFORMATIONS À CONNAÎTRE AVANT DE PRENDRE DUFENAC 75 mg, gélules gastro-résistantes à double libération?
Suivi médical au cours du traitement par DUFENAC 75 mg, gélules gastro-résistantes à double libération
Si vous avez des problèmes au niveau du foie, des reins ou des anomalies au niveau du sang, il vous sera demandé de faire des analyses de sang afin d'ajuster votre traitement.
Ne prenez jamais prendre DUFENAC 75 mg, gélules gastro-résistantes à double libération:
Si vous êtes allergique à la substance active ou à l'un des autres composants contenus dans ce médicament, mentionnés dans la rubrique 6.
En cas d'antécédent d'allergie (tel que urticaire, angio-œdème, rhinite aiguë, douleurs thoraciques ou d'asthme déclenché par la prise de ce médicament ou un médicament appartenant notamment à la famille des anti-inflammatoires non stéroïdiens, ou acide acétylsalicylique (aspirine).
Si vous êtes enceinte à partir du début du 6ème mois de grossesse (au-delà de 24 semaines d'aménorrhée).
En cas d'antécédents de saignements gastro-intestinaux ou d'ulcères liés à des traitements antérieurs par AINS.
En cas d'ulcère de l'estomac ou du duodénum ancien ou en évolution ou récidivant.
En cas d'hémorragie gastro-intestinale, hémorragie cérébrale ou autre hémorragie en cours.
En cas de maladie grave du foie (insuffisance hépatique).
En cas de maladie grave du rein (insuffisance rénale).
En cas de maladie cardiaque et/ou de maladie vasculaire cérébrale avérée (par exemple si vous avez été victime d'une crise cardiaque, d'un accident vasculaire cérébral (AVC), d'un accident ischémique transitoire (AIT) ou d'une obstruction des vaisseaux sanguins irriguant le cœur ou le cerveau ou si vous avez dû subir une opération pour obtenir un rétablissement.
En cas d'antécédents de troubles de la circulation sanguine ou de troubles actifs (artériopathie périphérique).
Enfant de moins de 15 ans (en raison du dosage inadapté de ce médicament).
Si vous prenez un médicament contenant une substance active appelée mifamurtide pour traiter certaines tumeurs osseuses.

Avertissements et précautions
Parlez avec votre médecin, pharmacien ou votre infirmier/ère avant de prendre **DUFENAC 75 mg,** gélules gastro-résistantes à double libération.
Les médicaments tels **DUFENAC** 75 mg, gélules gastro-résistantes à double libération pourraient augmenter le risque de crise cardiaque (« infarctus du myocarde ») ou d'accident vasculaire cérébral. Le risque est d'autant plus important que les doses utilisées sont élevées et la durée du traitement prolongée.
Ne pas dépasser les doses recommandées ni la durée de traitement.
Si vous avez une femme **DUFENAC** 75 mg, gélules gastro-résistantes à double libération peut altérer votre fertilité. Son utilisation n'est pas recommandée chez les femmes qui souhaitent concevoir un enfant. Chez les femmes qui peuvent avoir des difficultés pour concevoir ou chez lesquelles des examens sur la fonction de reproduction sont en cours, veuillez en parler à votre médecin ou votre pharmacien avant de prendre **DUFENAC** 75 mg, gélules gastro-résistantes à double libération.
Les sujets âgés, notamment les patients âgés fragiles ou de faible poids corporel, présentent un risque plus élevé de subir des effets indésirables, en particulier pour les hémorragies gastro-intestinales, ulcères et perforations. Les fonctions rénales, hépatiques et cardiaques doivent être strictement surveillées.

Pendant le traitement
Arrêtez le traitement et contactez immédiatement un médecin ou les urgences de l'hôpital le plus proche.
Si vous rejetez du sang par la bouche, si vous avez du sang dans les selles ou si vos selles sont colorées en noir (saignement gastro-intestinal).
Si vous avez des éruptions sur la peau des démangeaisons, un brusque gonflement du visage et du cou, une difficulté à respirer ou des douleurs thoraciques.
Si vous avez des gonflements (œdèmes) au niveau des membres, une augmentation de la tension artérielle ou si vous vous essoufflez plus vite.
Si vous avez une coloration jaune de la peau ou des yeux.
Les effets indésirables peuvent être minimisés en utilisant la dose efficace la plus faible pendant la durée la plus courte nécessaire.
DUFENAC 75 mg, gélules gastro-résistantes à double libération peut atténuer les signes d'une infection (en particulier les maux de tête et fièvre) rendant plus difficile son diagnostic et sa prise en charge.

Enfants
Ne pas utiliser chez l'enfant de moins de 15 ans (en raison du dosage inadapté de ce médicament).

Autres médicaments et DUFENAC 75 mg, gélules gastro-résistantes à double libération
Ce médicament contient un anti-inflammatoire non stéroïdien **le diclofénac.**
Vous ne devez pas prendre en même temps que ce médicament d'autres médicaments contenant des anti-inflammatoires non stéroïdiens y compris les inhibiteurs sélectifs de la cyclo-oxygenase 2 et/ou de l'acide acétylsalicylique (aspirine).
Les autres composants: Sucre sphères (Saccharose), Sodium hydroxide, Talc, Triethyl citrate, Ammonio methacrylate copolymère type A, Ammonio methacrylate copolymère type B, Copolymère dispersion d'éthyl acrylate et methacrylate acide.
Que trouve-t-on dans la boîte et quelle est le contenu de l'emballage extérieur
Gélules en blister aluminium / aluminium. Conditionnement: 10 gélules / blister, 1 blister / boîte.

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