This is a medicinal product for SELF MEDICATION which can be used to remedy minor, temporary conditions that are easily recognised and treatable without the need for a doctor. This product may therefore be purchased without a prescription but it must be used correctly to ensure its effectiveness and to reduce undesirable effects. For more information and advice, ask your pharmacist. Consult a doctor if the problem is not resolved after a short period of treatment.

WHAT IT IS
Moment belongs to the analgesic anti-inflammatory group, that is the group of medicinal products designed to relieve pain and inflammation.

WHAT IT IS USED FOR
Pain of various types and origins (headache, toothache, neuralgia, osteoarticular and muscular pain, menstrual pain). An adjunct treatment for the symptoms of fever and flu.

WHEN IT SHOULD NOT BE USED
• Hypersensitivity to the active substance (ibuprofen), to other antirheumatic drugs (e.g. acetylsalicylic acid etc.), or to any of the product excipients.
• In children aged under 12 years old
• In pregnancy and breastfeeding (see “What to do during pregnancy and breastfeeding”)
• Severe or active gastroduodenal ulcer or other gastric disease.
• History of gastrointestinal bleeding or perforation related to previous active treatments or history of recurrent peptic haemorrhage ulcer (two or more distinct episodes of established ulceration or bleeding).
• Severe heart failure.
• Severe liver or kidney disorders.

PRECAUTIONS FOR USE
• Ibuprofen should be taken with caution by asthmatic patients and especially subjects who have experienced bronchospasm following use of acetylsalicylic acid or other NSAIDs (nonsteroidal anti-inflammatory drugs), as well as by subjects with a history of gastrointestinal bleeding or ulcers.
• The concomitant use of Moment and NSAIDs, including selective COX-2 inhibitors, should be avoided.
• The undesirable effects can be minimised if the lowest effective dose to control the symptoms is used for the shortest possible treatment time.
• In adolescents suffering from dehydration, there is a risk of renal impairment.
• In the elderly and in patients with a history of ulcers, particularly where complicated by haemorrhage or perforation (see the section “When it should not be used”), the risk of gastrointestinal bleeding, ulceration or perforation is higher with higher doses of NSAIDs. These patients should start their treatment on the lowest dose available. The concomitant use of protecting agents (misoprostol or proton pump inhibitors) should be considered in treating these patients as well as in treating patients taking low doses of aspirin or other medications which can increase gastrointestinal risk (see below and the section “Medications and foods which could alter the effect of the medicinal product”).
• Patients with a history of gastrointestinal toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially gastrointestinal bleeding) particularly in the initial stages of treatment.
• NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn’s disease), as these conditions may be exacerbated (see “Undesirable effects”).
• If gastrointestinal bleeding or ulceration occurs in patients receiving Moment, the treatment should be withdrawn.

• Special attention should be paid to patients undergoing concomitant treatment with medications capable of increasing the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulant agents like warfarin, serotonin selective reuptake inhibitors or antplatelet drugs like aspirin (see the section “Medications and foods which could alter the effect of the medicinal product”).
• Medicines like Moment may lead to a slightly increased risk of heart attack (myocardial infarction) or stroke. This increased risk is more likely when using high doses and in long-term treatment. Do not exceed the recommended dose or treatment time (3 days).
• Consult a doctor or pharmacist about your treatment if you have heart problems, if you have ever had a stroke or if you think that you have an increased risk for these conditions (for example, if you have high blood pressure, diabetes, high cholesterol levels or if you smoke).

MEDICATIONS AND FOODS WHICH COULD ALTER THE EFFECT OF THE MEDICINAL PRODUCT
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription medicines.
• If undergoing a coumarin anticoagulant-based therapy (warfarin, dicumarol, etc.), only use Moment on medical advice.
• Do not use Moment concomitantly with acetylsalicylic acid or other NSAIDs.
• Corticosteroids: increased risk of gastrointestinal ulceration or bleeding (see “Precautions for use”).
• Anticoagulants: NSAIDs may enhance the effects of anticoagulants, such as warfarin (see “Precautions for use”).
• Antiplatelet agents and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding (see “Precautions for use”).
• Diuretics, ACE-inhibitors and angiotensin-II Antagonists: NSAIDs may reduce the effect of diuretics and other antihypertensive medicinal products. In some patients with compromised renal function (e.g. dehydrated patients or elderly patients with compromised renal function), the co-administration of an ACE-inhibitor or angiotensin-II antagonists and agents that inhibit the cyclo-oxygenase system may lead to further deterioration of renal function, including possible acute renal failure, which is usually reversible. These forms of interaction should be considered in patients undergoing concomitant treatment with Moment and ACE-inhibitors or angiotensin-II antagonists. Therefore, the combination should be administered with caution, especially in the elderly.
• Patients should be adequately hydrated and consideration should be given to monitoring renal function after initiation of concomitant therapy.
• Some medicinal products, such as anticoagulant and antiplatelet drugs (e.g. acetylsalicylic acid, warfarin, ticlopidine), high blood pressure treatments (ACE-inhibitors, such as captopril, beta-blockers, angiotensin II antagonists) and other drugs may interact with the ibuprofen treatment. Seek medical advice before using ibuprofen with other medications.

IMPORTANT INFORMATION
• As with any medication inhibiting the synthesis of prostaglandins and cyclo-oxygenase, the use of Moment is not recommended in women planning pregnancy.
• The administration of Moment should be discontinued in women with fertility disorders or who are undergoing investigations of infertility.
• Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation which may be fatal (see the section "How to use this medicinal product").
• Gastrointestinal bleeding, ulceration and perforation, which can be fatal, have been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious gastrointestinal events.
• Caution (a discussion with doctor or pharmacist) is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy.
• Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs (see the section "Undesirable effects"). Patients appear to be at the highest risk early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first month of treatment. Moment should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

When it should be used only on medical advice
• Asthmatic patients (see "Precautions for use").
• Patients with a history of gastroduodenal ulcers or haemorrhage (see "Precautions for use").
• Patients undergoing coumarin anticoagulant-based therapies (warfarin, dicumarol, etc.) (see "Medications and foods which could alter the effect of the medicinal product").

What to do during pregnancy and breastfeeding
In pregnant and breastfeeding women, Moment should only be used on medical advice and concordant assessment of the individual risk/benefit ratio.
Consult your doctor if you suspect that you are pregnant or if you are planning on becoming pregnant.

Pregnancy
Always consult your doctor or pharmacist before taking any medicinal product.
Inhibition of prostaglandin synthesis may adversely affect pregnancy and/or embryonic/foetal development.
Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastrochisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk of cardiac malformation increased from less than 1% up to approximately 1.5%. The risk was deemed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryofetal lethality.
In addition, increased incidence of various malformations, also of a cardiovascular nature, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.
During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose:
the foetus to:
- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction, which may progress to renal failure with oligohydramnios;
the mother and the neonate, at the end of pregnancy, to:
- possible prolongation of bleeding time and anti-aggregating effect which may occur even at very low doses;
- inhibition of uterine contractions resulting in delayed or prolonged labour.

Driving and using machines
The medicinal product does not usually alter the ability to drive or use machinery. However, subjects performing activities that require vigilance should use it with caution if they notice drowsiness, vertigo or depression during the treatment.

Important information about some of the excipients of Moment
Moment contains:
• 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.

Health education notes
All of us may experience various types of pain, of varying frequency and intensity, in our daily lives: headache, toothache, muscular and articular pain, menstrual pain.
Headache (or cephalea) is certainly one of the most common pains. There are three main types of primary headache (namely not due to other diseases): migraine, so called because the pulsating pain only affects one side of the head; the most commonly experienced tension headache, affecting the whole head and cluster headache, characterized by fits of shooting pain affecting an eye or a zygomatic headache.
In some cases, a headache may be a symptom of another disease (allergies, anaemia, myopia, poisoning, stomach troubles, cervical arthritis, sinusitis, constipation, head traumas). When suffering from headache, it is important that factors which may provoke it (irregular feeding habits, particular foods, smoking, alcohol, stress, over-intensive physical exertion, excessive exposure to sunlight, loud noises, heavy scents, etc.) be identified and prevented. In case of recurring fits of headache, it is, anyhow, advisable for you to consult your physician.
Menstrual pain (dysmenorrhoea) is a very common ailment; in addition to pain there are altered moods (sadness, easy irritability), breast tension and feeling of generalized fatigue. Eliminating substances like coffee, salt or chocolate from your diet or reducing them in favour of food rich in vitamins like fruit, as well as taking hot infusions and camomile tea, may help reduce these effects. Menstrual pain, at times quite intense, can be fought by using pain-relieving drugs that act to reduce the amount of prostaglandins, substances produced in the womb and considered largely responsible for this type of discomfort.

HOW TO USE THIS MEDICINAL PRODUCT
How much
Adults and adolescents above 12 years: 1-2 tablets, two-three times daily.

Warning: do not exceed the dose of 6 tablets a day without first consulting your doctor.
Elderly patients should follow the minimum dosage indicated above.

When and for how long
Take the drug on a full stomach (preferably after breakfast, lunch or dinner).
Consult a doctor if there are no clear signs of improvement after three days of treatment.
Consult your doctor if symptoms present themselves repeatedly or if you note any recent change in their nature.
Consult a doctor if use of the medicinal product is necessary in adolescents for more than three days or in case of worsening symptoms.

How
Swallow the tablet whole.

WHAT TO DO IN THE CASE OF AN EXCESSIVE DOSE OF THE MEDICINAL PRODUCT
In the case of accidental ingestion/assumption of an excessive dose of Moment, immediately notify a doctor or go to the nearest hospital. Take this package leaflet with you.
Note for healthcare professionals: in the case of an overdose, perform a gastric lavage and adjust blood electrolytes. There is no specific antidote for ibuprofen.
IF YOU HAVE ANY DOUBT WHATSOEVER ON THE USE OF Moment, ASK YOUR DOCTOR OR PHARMACIST.

UNDISCOVERABLE EFFECTS
Like all medicines, Moment can cause side effects, although not everybody will experience them.

Cutaneous effects
Allergy-based forms of cutaneous rash (erythema, pruritus, urticaria) may occasionally develop.
Blistering reactions including Stevens-Johnson syndrome and Toxic Epidermal Necrolysis (very rarely).

Gastrointestinal effects
The most commonly-observed adverse events are gastrointestinal in nature.
Peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal, particularly in the elderly, may occur (see "Important information").
The following effects have been reported after Moment has been administered: feeling of indigestion, nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melena, haematemesis, ulcerative stomatitis, Crohn’s disease and colitis exacerbation (see "Important information"). Less frequently, gastritis has been observed.

Cardiovascular effects
Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment. Medicines like Moment may entail a slightly increased risk of heart attack (myocardial infarction) or stroke. These events usually regress on discontinuation of treatment.

Following the indications provided in this package leaflet will reduce the risk of undesirable effects. If any of the effects become worse, or if you notice the appearance of any undesirable effect not listed on this package leaflet, inform your doctor or pharmacist.

SHELF LIFE AND STORAGE
Shelf life: Check the expiry date on the packaging.
Do not use the medicine after the expiry date indicated on the packaging.
The expiry date refers to the product in the original packaging, stored correctly.
Keep this medicine out of the reach and sight of children.
It is important that the information on the medicinal product is always available; therefore always keep the package and the package leaflet together.
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.

COMPOSITION
Each tablet contains: active ingredient: ibuprofen 200 mg. Excipients: maize starch, sodium carboxymethyl starch, povidone, colloidal anhydrous silica, talc, hydroxypropyl cellulose, gum arabic, sucrose, Macrogol 6000, light magnesium carbonate, titanium dioxide.

WHAT IT LOOKS LIKE
Moment 200 mg comes in the form of coated oral tablets.
Each pack contains 6, 10, 12, 20, 24, 30, 32 or 36 tablets. The pack of 6 coated tablets includes a blister pack protection.

MARKETING AUTHORISATION HOLDER
Viale Amelia, 70 - 00181 Rome - Italy.

MANUFACTURER
Famar Italia S.p.A., Via Zambelletti, 25 - 20021 Baranzate di Bollate (MI) - Italy.

REVIEW OF THE PACKAGE LEAFLET BY THE ITALIAN MEDICINES AGENCY (AIFA):
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Use the QR Code on the box or go to http://leaflet.angelini.it/L01 to read the updated package leaflet and in other languages.