

Rx

Due to the different legal status in different countries certain Rx information has been added to the PL. The Rx information is marked in grey shadings, If it is not indicated for Rx the grey shaded parts will be deleted in the national version.

Package Leaflet: information for the user**MOMENDOL, 220 mg film-coated tablets****Naproxen sodium**

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you

Keep this leaflet. You may need to read it again.

- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days for pain and 3 days for the treatment of fever

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

Rx

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

1. What MOMENDOL is and what it is used for

MOMENDOL is a non-steroidal analgesic-ant inflammatory-antirheumatic drug; this class of medications acts against pain, inflammation, fever and it is useful in the symptomatic treatment of rheumatic diseases.

MOMENDOL is used for short-term symptomatic treatment of mild to moderate pain such as joint and muscle pain, headache, toothache and menstrual pain. MOMENDOL may also be useful in the relief of fever.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days for pain and 3 days for the treatment of fever.

2. What you need to know before you take MOMENDOL**Do not take MOMENDOL**

- If you are allergic to naproxen sodium or any of the excipients (listed in section 6) or other chemically related substances.
- If you are suffering from allergic manifestations such as asthma, urticaria, rhinitis, nasal polyps, angioedema, allergic reactions induced by acetylsalicylic acid, analgesics, antinflammatory drugs and/or anti-rheumatic medicinal products
- If you have had previous gastro-intestinal bleeding or perforation, active or history of recurrent peptic ulcer, chronic inflammatory bowel diseases (ulcerative colitis, Crohn's disease), severe liver impairment, severe heart failure, severe renal impairment (creatinine clearance <30 ml/min) angioedema, during intensive care with diuretics and in subjects with current bleeding and at hemorrhagic risk under treatment with anticoagulants. (see "Taking other medicines" and "Take special care with MOMENDOL")

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- During pregnancy, as from the third trimester, and during breast-feeding (see Pregnancy and breast-feeding).
- The medicinal product cannot be administered to children under 12 years.

Warnings and precautions

Talk to your doctor or pharmacist before taking MOMENDOL:

- Because there is a strong relationship between dose and severe gastrointestinal adverse events. Therefore the lowest effective dose should always be used.
- Medicines such as MOMENDOL 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 (7 days for pain and 3 days for treatment of fever).
- When MOMENDOL is used in patients with a history of hypertension and/or in patients with heart failure and/or impairment of renal function. During treatment with MOMENDOL urine output and renal function should be closely monitored, particularly in the elderly, in patients with chronic heart disease, chronic renal failure and in patients on diuretic treatment, following major surgery having involved massive bleeding.
- If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.
- When MOMENDOL is used in patients with severe heart failure, worsening of the condition may occur.
- When MOMENDOL is used in patients with past or present signs of allergy, since the product may cause bronchospasm, asthma or other allergic manifestations and in patients with a previous gastrointestinal disease or hepatic impairment, caution should be taken.
- If skin rash, mucosal lesions or any other sign of allergy hypersensitivity occur MOMENDOL should be discontinued.
- If vision disorders occur MOMENDOL should be discontinued.
- Because naproxen, as any other antiinflammatory drug, may mask symptoms of underlying infectious disease.

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- Because in isolated cases an exacerbation of infective inflammations has been described in temporal connection with the use of antinflammatory drugs.
- If used in elderly patients, who generally present compromised renal, hepatic and cardiac function since this group of patients is more exposed to the risk of undesirable effects of antinflammatory drugs. Prolonged use of antiinflammatory drugs in the elderly is not recommended.
- Because Naproxen inhibits platelet aggregation and can prolong bleeding time. Patients who have coagulation disorders or are receiving drug therapy that interferes with coagulation should be carefully observed when MOMENDOL is administered.
- When MOMENDOL is used by daily consumers of high doses of alcohol there is a high risk of stomach bleeding.
- In case of pain from gastro-intestinal origin the use of the product is not recommended. It is known that bleeding in the stomach or gut can occur in patients taking NSAIDs.
- In asthmatic patients, the product is usually contraindicated.
- When MOMENDOL is used in combinations with other medicinal product that request caution, see “Taking other medicines”.

Children and adolescents

Under 16 years it is advisable to contact a physician.

Other medicines and MOMENDOL

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Naproxen administration with other antinflammatory drugs or corticosteroids is not recommended due to the increased risk of ulcers and gastrointestinal bleeding.

Naproxen increases the anticoagulant effect of cumarinic-like anticoagulants (e.g. warfarin, dicumarol) because it prolongs protrombin time and reduces platelet aggregation.

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The combination of naproxen and lithium should be avoided; when it is necessary, monitoring of lithium plasma levels should be reinforced and dosage should be adjusted.

Due to the high binding of naproxen with plasma proteins, treatment with hydantoic or sulphamidic drugs should be used with caution.

Special care should be used also in patients under treatment with cyclosporin, tacrolimus, sulfonyluria, loop diuretics, methotrexate, beta-blocking agents, ACE-inhibitors, probenecid, thiazide diuretics and digoxin.

Naproxen can alter bleeding time (may prolong bleeding time until 4 days after discontinuation of therapy), creatinine clearance (may decrease), BUN, serum creatinine and potassium concentrations (may increase), liver function tests (may have elevation of transaminases).

Naproxen may falsely increase urinary 17-ketosteroid values; may interfere with urinary assays for 5-hydroxy-indoleacetic acid.

Before testing adrenal function, Naproxen therapy should be discontinued for at least 72 hours.

MOMENDOL with food and drink

MOMENDOL should be administered preferably after meal.

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.

Pregnancy

As all antinflammatory drugs, MOMENDOL is contraindicated during the third trimester of pregnancy.

As all antinflammatory drugs, during the first five months of pregnancy, MOMENDOL should only be used where necessary and after consulting the physician and assessing with him the individual risk/benefit ratio. If you suspect or wish to plan a pregnancy, consult the physician.

Breast-feeding

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Since antiinflammatory drugs are excreted in breast milk, as a precautionary measure, the use of MOMENDOL is contraindicated during breast-feeding.

Fertility

MOMENDOL belongs to a group of medicines (NSAIDs, antiinflammatory drugs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

Driving and using machines

The medicinal product does not normally affect the capacity to drive and use other machinery. However, caution is recommended to those who perform a job requiring vigilance, should, in the course of therapy, they notice sleepiness, dizziness, depression.

MOMENDOL contains:

The product contains lactose: if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take MOMENDOL

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

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The recommended dose is:

Adults and adolescents over age 16: 1 film-coated tablet every 8-12 hours.

On the first day, if needed, a better effect may be obtained by starting with 2 film-coated tablets followed by 1 film-coated tablet after 8-12 hours.

In elderly and in patients with mild to moderate renal impairment dosages should not exceed 2 film-coated tablets in 24 hours.

Use in children and adolescents

Under 16 years it is advisable to contact a physician

MOMENDOL is contraindicated in children under 12 years of age.

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Swallow film-coated whole tablets with some water.

MOMENDOL should be administered preferably after meal.

Do not take for more than 7 days for pain and 3 days for the treatment of fever.

Patients should be advised to consult their physician if pain or fever persist or worsen.

If you take more MOMENDOL than you should

Overdose signs include numbness, heartburn, diarrhoea, nausea, vomiting, drowsiness, hypernatremia, metabolic acidosis, and convulsions.

In case of incidental or voluntary ingestion/administration of an overdose of the medicinal product, the physician should adopt the usual requested remedies for these cases. Keep this leaflet with you.

Emptying of the stomach and normal supportive measures are recommended. The prompt administration of an adequate amount of active carbon (active carbon is a medicinal product, ask your pharmacist, if necessary) can reduce medicinal absorption.

If you forget to take MOMENDOL

Do not take a double dose to make up for a forgotten tablet

4. Possible side effects

Like all medicines, MOMENDOL can cause side effects, although not everybody gets them.

The most commonly observed adverse events are gastrointestinal in nature.

The following adverse events have been reported with NSAIDs and with naproxen

Common: may affect up to 1 in 10 people

- headache, somnolence, dizziness.
- nausea, dyspepsia, vomiting, pyrosis, gastralgia, flatulence.

Uncommon (may affect up to 1 in 100 people):

- allergic reaction (including facial oedema and angioedema)
- sleep disturbances, excitation
- visual disturbances
- tinnitus, hearing disorders

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- bruise
- diarrhoea, constipation
- skin rash/pruritis
- kidney function abnormal
- chills, edema (including peripheral edema)

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

- peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease

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

- aplastic or hemolytic anemia, thrombocytopenia, granulocytopenia.
- meningitis-like reaction
- tachycardia, oedema, hypertension and cardiac failure have been reported in association with NSAID treatment
- dyspnea, asthma
- colitis, stomatitis . Less frequently, gastritis has been observed
- jaundice, hepatitis, impaired liver function
- photosensitivity, alopecia, bullous disorder including Stevens-Johnson syndrome and toxic epidermal necrolysis
- blood pressure increased

As with other NSAIDs, allergic reactions of anaphylactic or anaphylactoid nature may occur in patients with or without a previous exposure to this class of medicinal products. The typical symptoms of an anaphylactic reaction include: severe and sudden hypotension, acceleration or slowing down of the heart beat, unusual fatigue or weakness, anxiety, agitation, loss of consciousness, difficult breathing or swallowing, pruritus, urticaria with or without angioedema, skin reddening, nausea, vomiting, cramp-like abdominal pain, diarrhoea.

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

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

How to store MOMENDOL

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

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

Store in the original package in order to protect from light and moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. These measures will help to protect the environment.

6. CONTENT OF THE PACK AND OTHER INFORMATION**What MOMENDOL contains**

The active substance is naproxen 200 mg (as Naproxen sodium 220 mg)

The other ingredients are: Tablet core: Lactose monohydrate, Maize starch, Cellulose microcrystalline, Povidone (K25), Sodium starch glycollate, Sillica colloidal anhydrous, Magnesium stearate.

Tablet film-coating: Hypromellose, Macrogol 400, Titanium dioxide (E171), Talc

What MOMENDOL looks like and contents of the pack

MOMENDOL is a film-coated tablet white, round, biconvex

Aluminium/PVC blisters contain 12 film-coated tablets

Each lithographed cardboard box contains 12 or 24 film-coated tablets (1-2 blisters of 12 film-coated tablets each).

Not all pack-sizes may be marketed

Marketing Authorisation Holder and Manufacturer

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Marketing Authorisation Holder:

To be completely nationally

Manufacturer:

To be completely nationally

This medicinal product is authorised in the Member States of the EEA under the following names:

<i>AUSTRIA</i>	MOMENDOL 220 mg Filmtabletten
<i>DENMARK</i>	EOX filmovertrukne tabletter 220 mg
<i>FINLAND</i>	EOX 220 mg tabletti
<i>GERMANY</i>	MOMENDOL 220 mg Filmtabletten
<i>GREECE</i>	MOMENDOL 220 mg επικαλυμμένα με υμένιο δισκία
<i>IRELAND</i>	MOMENDOL 220 mg film-coated tablets
<i>ITALY</i>	MOMENDOL 220 mg compresse rivestite con film
<i>LUXEMBOURG</i>	MOMENDOL cpr. pellic. 220 mg
<i>THE NETHERLAND</i>	MOMENDOL filmomhulde tabletten 220 mg
<i>PORTUGAL</i>	MOMENDOL 220 mg comprimido revestido por película
<i>SWEDEN</i>	EOX filmdragerad tablett 220 mg

This leaflet was last revised in

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