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1. WHAT IS MOMENDOL AND WHAT IS IT USED FOR?
Momenpol belongs to the class of non-steroidal analgesic - anti-inflammatory - antirheumatic drugs, which are used against pain, inflammation and fever and are useful in treating the symptoms of rheumatic diseases.

Momenpol is used for the short-term treatment of symptoms of light-to-moderate pain such as muscle and joint pain (e.g. backache, torticollis), headache, toothache and menstrual pain.

Momenpol can also be used to treat fever.

2. BEFORE YOU TAKE MOMENDOL
Do not take MOMENDOL
- If you are allergic (hypersensitive) to the active ingredient or to any of the excipients or other chemically closely related substances.
- If you show any allergic reactions such as asthma, urticaria, rhinitis, nasal polyps, angioedema and allergic reactions induced by acetylsalicylic acid, analgesics, anti-inflammatory drugs and/or antirheumatic drugs.
- If you have had previous episodes of gastrointestinal bleeding or perforation, recurrent peptic ulcer in active phase or relative to previous episodes, chronic intestinal inflammatory diseases (ulcerative colitis, Crohn's disease), severe hepatic insufficiency, severe congestive heart failure, severe renal failure (creatinine clearance <30 ml/min), angioedema, during intensive treatment with diuretics, in subjects presenting haemorrhage or at risk of haemorrhage during treatment with anticoagulants. (See “Taking MOMENDOL with other medicinal products” and “Take special care with MOMENDOL above all”)
- In pregnancy, as from the third trimester, and during breastfeeding (See “Pregnancy and breastfeeding”).
- The product cannot be administered under 12 years of age; under 16 years of age, it should only be administered after having sought medical advice.
- As the product belongs to a class of drugs (NSAIDs, anti-inflammatory drugs) that can cause fertility problems in women. This effect is reversible on suspension of treatment.
- The product is generally contraindicated in asthmatic patients.
- When MOMENDOL is used in association with other drugs requiring caution, see “Taking MOMENDOL with other medicinal products”.

Take special care with MOMENDOL above all
- Because there is a close correlation between dosage and the onset of severe undesirable effects involving the gastrointestinal system. The smallest dose effective should therefore always be used.
- Medicines like MOMENDOL 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 [7 days for pain and 3 days for treating fever].
- When MOMENDOL is used in hypertensive patients and/or in patients with impaired heart and/or kidney function. During treatment with MOMENDOL, diuresis and renal function must be carefully monitored, in particular in the elderly, in patients with heart failure or chronic renal failure, in patients treated with diuretics, and following major surgery involving major blood loss.
- 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), consult your doctor or pharmacist about your treatment.
- When MOMENDOL is used in patients with severe heart failure, the conditions may worsen.
- When MOMENDOL is used in patients with a history of gastrointestinal disease or hepatic insufficiency and in patients presenting allergic manifestations or a prior history of such reactions since, in these patients, the medicinal product may induce bronchospasm, asthma or other allergic phenomena, particular caution is required.
- MOMENDOL should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.
- If visual disturbances arise, treatment with MOMENDOL must be discontinued.
- Like all anti-inflammatory drugs, naproxen may mask concomitant symptoms of infectious diseases.
- As in isolated cases, exacerbation of infection-related inflammations has been reported, coinciding with the use of anti-inflammatory drugs.
- If used in elderly patients, in whom renal, hepatic and cardiac function are generally comprised to some degree, as this group of patients is at greater risk of the onset of undesirable effects related to the use of anti-inflammatory drugs. Prolonged use of anti-inflammatory drugs in elderly patients is not recommended.
- As naproxen inhibits platelet aggregation and may prolong bleeding. Patients who have coagulation disorders or patients who are receiving drug therapy that interferes with coagulation should be carefully observed if MOMENDOL is administered.
- When MOMENDOL is used by heavy drinkers since, with alcohol, there is a high risk of stomach bleeding.
- This medicinal product must not be used to treat pain of gastrointestinal origin. It is in fact known that in patients taking anti-inflammatory drugs, bleeding can occur in the stomach or intestine.
- As the product belongs to a class of drugs (NSAIDs, anti-inflammatory drugs) that can cause fertility problems in women. This effect is reversible on suspension of treatment.
- The product is generally contraindicated in asthmatic patients.
- When MOMENDOL is used in association with other drugs requiring caution, see “Taking MOMENDOL with other medicinal products”.

Taking MOMENDOL with other medicinal products
The administration of naproxen with other anti-inflammatory drugs or corticosteroids is not recommended as it increases the risk of ulcers and gastroduodenal bleeding.
Naproxen increases the effect of coumarin-type anticoagulants (e.g. warfarin, dicumarol) because it prolongs prothrombin time and reduces platelet aggregation.

Use of naproxen in combination with lithium should be avoided; when this is necessary, plasma lithium levels must be carefully monitored and the dosage adjusted. Since naproxen binding to plasma proteins is high, caution is required in concomitant treatment with hydantoins and sulfonamides. Particular caution is also required in patients treated with cyclosporin, tacrolimus, sulfonlyureas, loop diuretics, methotrexate, beta-blockers, ACE-inhibitors, probenecid, thiazide diuretics and digoxin.

Naproxen may alter bleeding time (which can be increased up to 4 days after discontinuing treatment), creatinine clearance (which may decrease), azotaemia and blood creatinine and potassium levels (which may increase), and hepatic function test results (which may show increased transaminase).

Naproxen may lead to false positives in urine tests for 17-ketogenic steroid and 5-hydroxyindoleacetic acid. Naproxen treatment should be discontinued at least 72 hours before performing the adrenal cortical function test.

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

Taking MOMENDOL with food and drink
MOMENDOL should be taken on a full stomach.

Pregnancy and breastfeeding
Pregnancy
Just like other anti-inflammatory drugs, MOMENDOL is contraindicated during the third trimester of pregnancy. During the first five months of pregnancy, like other anti-inflammatory drugs, MOMENDOL should only be taken if necessary and after seeking medical advice and assessing the specific risk/benefits of your case. Consult your doctor if you suspect that you are pregnant or if you are planning on becoming pregnant.

Breastfeeding
As NSAIDs are excreted into breast milk, as a precautionary measure, avoid using them while breastfeeding. Always consult your doctor or pharmacist before taking any medicinal product.

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 MOMENDOL
The product contains lactose: if your doctor has told you that you are intolerant to any sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE MOMENDOL
Instructions for correct use of the medicinal product
Always take MOMENDOL exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The usual dose is:

Adults and adolescents above 16 years: 1 film-coated tablet every 8-12 hours.
If necessary, to achieve greater effect, treatment can be started on the first day with 2 film-coated tablets, followed by 1 film-coated tablet 8-12 hours later.

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

Do not use for more than 7 days when treating pain, 3 for fever. Seek medical advice if the pain and fever persist or worsen. Swallow the film-coated tablets whole with water or another drink.

If you take more MOMENDOL than you should
Signs of overdose may include numbness, heartburn, diarrhoea, nausea, vomiting, drowsiness, increased sodium levels in the blood, metabolic acidosis, convulsions.

If a large quantity of the product is ingested accidentally or intentionally, contact your doctor so that he can implement the measures normally applied in such cases. Take this package leaflet with you. Emptying of the stomach and the usual support measures are recommended. Prompt administration of an adequate amount of activated charcoal (activated charcoal is a medicinal product; if required, ask your pharmacist for it) can reduce absorption of the medicinal product.

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 will experience them.

The side effects seen most commonly are gastrointestinal in nature. As for other non-steroidal analgesics - anti-inflammatories, antirheumatic drugs (NSAIDs), naproxen may induce the following undesirable effects. The following rate values have been used: very common (>1/10); common (>1/100, <1/10); uncommon (>1/1000, <1/100); rare (>1/10,000, <1/1000); very rare (<1/10,000); unknown (the frequency cannot be established based on the available data).

Gastrointestinal disorders - Common: nausea, dyspepsia, vomiting, pyrosis, gastralgia, flatulence. Uncommon: diarrhoea, constipation. Rare: peptic ulcer, gastrointestinal perforation or bleeding, sometimes fatal, particularly in the elderly, haematemesis, ulcerative stomatitis, a worsening of colitis and Crohn's disease are also possible. Very rare: colitis, stomatitis. Less frequently, gastritis has been observed.


Hearing and vestibular system disorders - Uncommon: tinnitus, impaired hearing.

Eye disorders – Uncommon: vision disorders.

General disorders and administration site conditions - Uncommon: shivers, oedema (including peripheral oedema).

Immune system disorders – Uncommon: allergic reactions (including facial oedema and angioedema).


Renal and urinary disorders – Uncommon impaired kidney function.

Skin and subcutaneous tissue disorders - Uncommon: skin rash /itching. Very rare: photosensitivity, alopecia, blistering, including Stevens-Johnson syndrome and toxic epidermal necrolysis.


Blood and lymphatic system disorders - Very rare: aplastic or haemolytic anaemia, thrombocytopenia, granulocytopenia.

Cardiac disorders – Very rare: tachycardia, oedema, hypertension and congestive heart failure have been reported in association with NSAID treatment.

Hepatobiliary system disorders - Very rare: jaundice, hepatitis, impaired liver function.

Diagnostic investigations – Very rare: raised blood pressure.

Respiratory, thoracic and mediastinal disorders - Very rare: dyspnoea, asthma.

Like other non-steroidal analgesics - anti-inflammatories, antirheumatic drugs (NSAIDs), anaphylactic or anaphylactoid allergic reactions may arise in patients with or without prior exposure to drugs belonging to the same class of medicinal products.
The characteristic symptoms of anaphylactic reactions are: severe, sudden hypotension, accelerated or slowed heart rate, fatigue or unusual weakness, anxiety, agitation, loss of consciousness, difficulty breathing or swallowing, pruritus, urticaria with or without angioedema, reddening of the skin, nausea, vomiting, cramp-like abdominal pain, diarrhoea. Medicines like MOMENDOL may lead to a slightly increased risk of heart attack (myocardial infarction) or stroke.

If any of the side effects becomes serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. 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 box. The expiry date refers to the last day of that month. Store in the original package in order to protect it from light and moisture. Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. FURTHER INFORMATION
What MOMENDOL contains
The active ingredient is naproxen 200 mg (equivalent to 220 mg of naproxen sodium).

The excipients are: Tablet core: lactose monohydrate, maize starch, microcrystalline cellulose, povidone (K25), sodium carboxymethyl starch, anhydrous colloidal silica, magnesium stearate. Film-coating: hypromellose, macrogol 400, titanium dioxide (E 171), talc.

What MOMENDOL looks like and the contents of the pack
MOMENDOL is presented as white, round, biconvex film-coated tablets. Each pack contains 12 or 24 film-coated tablets.

Marketing authorisation holder and Manufacturer:
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This medicinal product is authorised in the Member States of the EEA under the following names:

Australia: MOMENDOL 220 mg Filmtabletten
Belgium: MOMENDOL 220 mg filmomhulde
Denmark: EOX 220 mg filmovertrukne
Finland: EOX 220 mg tabletti
Germany: MOMENDOL 220 mg Filmtabletten
Greece: MOMENDOL ΜΩΜΕΝΔΟΛ 220 mg επακλυμμένα με υμένιο δισκία
Ireland: MOMENDOL 220 mg comprimido revestido con film
Italy: MOMENDOL 220 mg compresse rivestite con film
Luxembourg: MOMENDOL CPR.PEL. 220 mg
Holland: MOMENDOL filmomhulde tabletten 220 mg
Portugal: MOMENDOL 220 mg comprimidos con cubierta pelicular
Spain: EKILID 220 mg comprimidos con cubierta pelicular
Sweden: EOX filmdragerad tablett 220 mg

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