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PATIENT INFORMATION LEAFLET:
INFORMATION FOR THE USER

NUROMOL®

PAIN RELIEF 200 mg/500 mg Film Coated Tablets

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to take it carefully to get the best results from it.
Nuromol Pain Relief 200 mg/500 mg Film Coated Tablets will be referred to as "this medicine" throughout this leaflet.

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- You **should not take the product for longer than 3 days**
- If symptoms persist or worsen consult your doctor
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What is this medicine and what is it used for

This medicine contains two active ingredients (which make the medicine work)**. These are Ibuprofen and Paracetamol.** Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs work by reducing pain, reducing swelling and lowering high temperatures. Paracetamol is an analgesic (pain killer) which works in a different way from ibuprofen to relieve pain and fever. This medicine is used for the temporary relief of mild to moderate pain associated with migraine, headache, backache, period pain, dental pain, rheumatic and muscular pain, pain of non-serious arthritis, cold and flu symptoms, sore throat and fever.

2. What you need to know before you take this medicine

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Immediately stop taking this medicine and contact your doctor or medical emergencies if you notice any of these signs.

Do not take this medicine if you:

- are already taking **any other paracetamol containing product.**
- are taking **any other pain relieving products** including **ibuprofen**, **high dose aspirin** (above 75 mg per day) or **other non-steroidal anti-inflammatory drugs** (NSAIDs) including cyclooxygenase-2 (COX-2) specific inhibitors
- are **allergic to ibuprofen, paracetamol** or any other ingredients in Nuromol Pain Relief 200 mg/500 mg Film Coated Tablets
- are **allergic to aspirin or other NSAID painkillers**
- have or ever had an **ulcer or bleeding in your stomach or duodenum** (small bowel)
- have **blood clotting (coagulation) disorder**
- suffer from **heart, liver or kidney failure**
- are in the **last 3 months of pregnancy**
- are **under 18** years old.

Take special care and check with a doctor or pharmacist before taking this medicine if you:

- are **elderly**
- have **asthma** or have suffered from asthma
- have **kidney**, **heart, liver or bowel** problems
- have **Systemic Lupus Erythematosus** (SLE) – a condition of the immune system affecting connective tissue resulting in joint pain, skin changes and disorder of other organs – **or other mixed connective tissue disease**
- have **gastrointestinal disorders or chronic inflammatory bowel disease** (e.g. ulcerative colitis, Crohn's disease)
- are in the **first 6 months of pregnancy** or are **breastfeeding**
- are **planning to become pregnant**
- have an **infection** - please see heading "Infections" below

Infections

This medicine may hide signs of infections such as fever and pain. It is therefore possible that this medicine may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Skin reactions

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalised exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using this medicine and seek medical attention immediately, if you notice any of the symptoms related to these serious skin reactions described in section 4.

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking this medicine if you:

- have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs of feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack 'TIA').
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Taking this medicine with other medicines: Do not take this medicine with:

- other **paracetamol containing** products
- other **NSAID containing products** such as aspirin, ibuprofen.

Some other medicines may also affect or be affected by the treatment of this medicine. **You should therefore always seek the advice of your doctor or pharmacist before you use this medicine with other medicines.** For example:

- **corticosteroid** tablets
- **antibiotics** (e.g. chloramphenicol or quinolones)
- **flucloxacillin** (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.
- **anti sickness** medicines (e.g. metoclopramide, domperidone)
- anti-coagulant medicines that are (i.e. **thin blood/prevent clotting** e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- **heart stimulants** (e.g. glycosides)
- medicines for **high cholesterol** (e.g. cholestyramine)
- **diuretics** (to help you pass water)
- medicines that **reduce high blood pressure** (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- medicines to **suppress the immune system** (e.g. methotrexate, ciclosporin, tacrolimus)
- medicines for **mania or depression** (e.g. lithium or SSRI's)
- **mifepristone** (for pregnancy termination)
- **HIV medicines** (e.g. zidovudine)
- **Isoniazid** (tuberculosis treatment), due to increased risk of liver damage with paracetamol overdose.

Taking this medicine with food

To reduce the likelihood of side effects, take this medicine with food.

- If you are taking this medicine for longer than the recommended time or at higher than recommended doses you are at risk of serious harm. These include serious harm to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking any medicine. Do not take this medicine if you are in the last 3 months of pregnancy 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. You should not take this medicine 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, this medicine can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the

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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. Take special care if you are in the first 6 months of pregnancy.
This medicine may make it more difficult to become pregnant. Ibuprofen belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Important information about some of the ingredients in this medicine

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'.

3. How to take this medicine

For oral use and for short term use only. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

You should not take this medicine for longer than 3 days. If your symptoms worsen or persist, consult your doctor.

Take 1 tablet to be taken with **water and food**, up to three times a day. Leave at least **6 hours between doses**.
If one tablet dose not control symptoms, then a maximum of 2 tablets may be taken up to three times a day.

Do not take more than six tablets in any 24 hour period (equivalent to 3000 mg paracetamol, 1200 mg ibuprofen a day).

Not for use by children under 18 years.

If you take more this medicine than you should

If you have taken more this medicine than you should, or if children have taken this medicine by accident, always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported. **Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.**

If you forget to take this medicine

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at least 6 hours later.

4. Possible side effects

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

STOP TAKING the medicine and tell your doctor if you experience:

- **Heartburn, indigestion**
- **Signs of intestinal bleeding** (severe stomach pain, vomiting blood or liquid with what looks like coffee granules, blood in the stools/motions, black tarry stools)
- **Signs of Inflammation of the brain lining such as**: stiff neck, headache, feeling or being sick, fever or feeling disorientated
- **Signs of a severe allergic reaction** (swelling of the face, tongue or throat, difficulty breathing or worsening of asthma).
- **Severe skin reaction known as DRESS syndrome** (frequency not known). Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- Signs of hypersensitivity and skin reactions such as reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localised on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis) (frequency not known) See also section 2.

Other possible side effects

Tell your doctor or pharmacist if you get any of the following side effects or any side effects not listed.

Common: may affect up to 1 in 10 people:

- stomach pain or discomfort, feeling or being sick, diarrhoea
- higher levels of liver enzymes (shown in blood tests)
- excessive sweating

Uncommon: may affect up to 1 in 100 people:

- headache and dizziness, wind and constipation, skin rashes, swelling of the face.
- reduction in red blood cells number or increase in platelets (blood clotting cells) number.

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

- reduction in blood cells (causing sore throat, mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding, bruising and nose bleeds)
- visual disturbances, ringing in the ears, spinning sensation,
- confusion, depression, hallucinations
- fatigue, generally feeling unwell
- severe skin reactions such as blistering
- high blood pressure, water retention
- liver problems (causing yellowing of the skin and whites of the eyes)
- kidney problems (causing increased or decreased urination, swelling of the legs)
- heart failure (causing breathlessness, swelling)

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

- skin becomes sensitive to light

Medicines such as Nuromol Pain Relief 200 mg/500 mg Film Coated Tablets may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke. (See section2).

Tell your doctor or pharmacist if you notice any of the following:

- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- Liver, kidney problems or difficulty urinating

This medicine, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 this medicine

Keep out of the reach and sight of children. This medicinal product does not require any special storage conditions.
Do not use this medicine after the expiry date which is stated on the blister and the carton. The expiry date refers to the last day of that month.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other

What this medicine contains

- The active substances are ibuprofen and paracetamol. Each film-coated tablet contains 200 mg of ibuprofen and 500 mg of paracetamol
- The other ingredients are croscarmellose sodium, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate, stearic acid. Film coating: polyvinyl alcohol, titanium dioxide, talc, macrogol, potassium aluminium silicate (E555), polysorbate.

What this medicine look like

Nuromol Pain Relief 200 mg/500 mg Film Coated Tablets are white to off-white, oval shaped, film-coated pearlescent tablets marked with an identifying helix. They are available in blister packs containing 4, 6, 8, 10, 12, 16, 20, 24, 32 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer

Licence holder: Reckitt Benckiser Healthcare (UK) Ltd, Slough, SL1 3UH, United Kingdom
Manufactured by Reckitt Benckiser Healthcare International Ltd, Nottingham, NG90 2DB
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