Package leaflet: Information for the user

Nuromol Dual Action Film-Coated Tablets
Paracetamol 500 mg
Ibuprofen 200 mg

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 has 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 or 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 3 days.

What is in this leaflet:

1. What Nuromol Dual Action film-coated tablets are and what they are 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, and swelling.

Paracetamol is an analgesic which works in a different way from ibuprofen to relieve pain. Nuromol Dual Action film-coated tablets is used in adults only for the short-term symptomatic treatment of mild to moderate pain associated with migraine, headache, backache, period pain, dental pain, muscular pain, cold and flu, and sore throat.

This medicine is especially suitable for pain which has not been relieved by ibuprofen or paracetamol alone.

2. What you need to know before you take Nuromol Dual Action film coated tablets

Do not take Nuromol Dual Action film-coated tablets if you:
- are allergic to ibuprofen, paracetamol or any of the other ingredients of this medicine (listed un section 6)
- are already taking any other paracetamol containing product.
- are taking any other pain-relieving products including ibuprofen, high dose acetylsalicylic acid (above

75 mg per day) or other non-steroidal anti-inflammatory drugs (NSAIDs) including cyclo-oxygenase-2 (COX-2) specific inhibitors.
- are allergic to acetylsalicylic acid 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.

Warnings and precautions

Talk with your doctor or pharmacist before taking this medicine if you:
- have an infection - please see heading "Infections" below.
- are elderly.
- have asthma or have suffered from asthma.
- have kidney, heart, liver or bowel problems. If you have a kidney or liver impairment, you may need a lower dose or less frequent doses.
- if you are of low body weight (less than 50 kg), or are malnourished, or suffer from alcoholism.
- if you have been told you suffer with a condition known as haemolyic anaemia (low levels of red blood cells), or are lacking an enzyme (a proten called glucose-6-phosphate dehydrogenase).
- 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.

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 generalized exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment.Stop using Nuromol Dual Action film-coated tablets 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 such as 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.

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. Stop immediately taking Nuromol Dual Action film-coated tablets and contact immediately your doctor or medical emergencies if you notice any of these signs.

Children and adolescents
This medicine is not intended for use in children and adolescents under 18 years of age.

Other medicines and Nuromol Dual Action film-coated tablets :

Do not take Nuromol Dual Action film-coated tablets with:
- other paracetamol containing products
- other NSAID containing products such as acetylsalicylic acid, ibuprofen.

Special care is required as some medicines may interact with this medicine, for example:
- corticosteroid tablets
- antibiotics (e.g. chloramphenicol or quinolones)
- anti sickness medicines (e.g. metoclopramide, domperidone)
- medicines to thin the blood or prevent clotting (e.g. warfarin, acetylsalicylic acid, ticlopidine)
- heart stimulants (e.g. glycosides)
- medicines for high cholesterol (e.g. cholestyramine)
- diuretics (to help you pass water)
- medicines for high blood pressure (e.g. ACE-inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan).
- medicines to suppress the immune system (e.g. methotrexate, ciclosporine, tacrolimus)
- medicines for mania or depression (e.g. lithium or SSRI's)
- mifepristone (for pregnancy termination)
- HIV medicines (e.g. zidovudine)
- 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.

Always seek the advice of your doctor or pharmacist before you take Nuromol Dual Action film-coated tablets with other medicines.

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.

Nuromol Dual Action film-coated tablets with food
To reduce the likelihood of side effects, take this medicine with food.

Pregnancy, breastfeeding 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
Do not take Nuromol Dual Action film-coated tablets
if you are in the last 3 months of your 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 Nuromol Dual Action film-coated tablets 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, Nuromol Dual Action film-coated tablets

can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the 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.

Breastfeeding
Only small amounts of ibuprofen and its metabolites pass into breast-milk. This may be taken during breastfeeding if it is used at the recommended dose and for the shortest possible time.

Female fertility
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.

Driving and using machines
This medicine may cause dizziness, impaired concentration and drowsiness.
If you are affected, do not drive and do not use any tools or machines.

Nuromol Dual Action film-coated tablets contains sodium

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

3.How to take Nuromol Dual Action film-coated tablets

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
Check with your doctor or pharmacist if you are not sure.
You should not take this medicine for longer than 3 days.
For oral use and for short term use only (not more than 3 days). . If your symptoms worsen or persist or if the medicine is required for more than 3 days, consult your doctor.

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).

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

The recommended dose is:

Adults: Take 1 tablet with water and food, up to three times a day. Leave at least 6 hours between doses.
If a one tablet dose does 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 1200 mg ibuprofen and 3000 mg paracetamol a day).

Use in children and adolescents
Not for use by children and adolescents under 18 years.

If you take more of Nuromol Dual Action film-coated tablets than you should
If you have taken more of 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.

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. Some patients have increased risk of liver damage following paracetamol overdose. These include patients with liver disease, are elderly or a child, on long term treatment with medicines used to treat convulsions (such as carbamazepine, phenobarbitone, phenytoin, and primidone), medicine used to treat tuberculosis (rifampicin and isoniazid), and St John's Wort (natural medicine to treat depression). Patients consuming excessive alcohol, patients with eating disorders, cystic fibrosis (lung disease), HIV infection, undernutrition, and severe weight loss are also at an increased risk of liver damage.

If you forget to take Nuromol Dual Action film-coated tablets
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: **s**tiff 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).
- 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].
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).

Other possible side effects

Common (may affect up to 1 in 10 people):
- stomach pain or discomfort, feeling or being sick, diarrhoea, indigestion
- excessive sweating
- swelling
- alanine aminotransferase increased, gamma-glutamyltransferase increased and liver function tests abnormal with paracetamol. Blood creatinine and blood urea increased.

Uncommon (may affect up to 1 in 100 people):
- headache and dizziness
- wind and constipation
- skin rashes, swelling of the face and itching
- peptic ulcers, exacerbation of ulcerative colitis and Crohn's disease, gastrointestinal perforation or bleeding, vomiting blood, inflammation of stomach lining, and inflammation of the pancreas
- reduction in red blood cells number or increase in platelets (blood clotting cells) number
- aspartate aminotransferase increased, blood alkaline phosphatase increased, blood creatine phosphokinease increased, haemoglobin decreased and platelet count increased

Rare (may affect up to 1 in 1000people)
- tingling, numbness or itching (pins and needles)

Very rare (may affect up to 1 in 10,000 people):
- haematopoietic disorders such as reduction in blood cells (causing sore throat, mouth ulcers, flulike symptoms, severe exhaustion, unexplained bleeding, bruising and nose bleeds)
- severe hypersensitivity reactions
- visual disturbances, ringing in the ears, spinning sensation
- confusion, depression, hallucinations
- inflammation of the meninges, optic nerve and drowsiness
- respiratory tract reactivity, including asthma, exacerbation of asthma, bronchospasm, shortness of breath
- 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).

Not known (frequency cannot be estimated from the available data)
- a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- a red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, tru nk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthema tous pustulosis). Stop using this medicine if you develop these symptoms and seek medical attention immediately (see section 2).
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- skin becomes sensitive to light.

Medicines such as this medicine may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke (see section 2).

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 (see details below).
By reporting side effects you can help provide more information on the safety of this medicine. HPRA Pharmacovigilance. Website: www.hpra.ie

5. How to store Nuromol Dual Action film-coated tablets

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

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nuromol Dual Action film-coated tablets contains

- The active substances are paracetamol and ibuprofen. Each film-coated tablet contains 500 mg paracetamol and 200 mg ibuprofen.
- The other ingredients are croscarmellose sodium, microcrystalline cellulose, colloidal anhydrous silica (E551), magnesium stearate, stearic acid. Film coating: polyvinyl alcohol (E1203), titanium dioxide (E171), talc (E553b), macrogol 4000 (E1521), potassium aluminium silicate (E555), polysorbate (E433).

What Nuromol Dual Action film-coated tablets look like and contents of the pack
Nuromol Dual Action film-coated tablets are white to off-white, oval shaped, film-coated pearlescent tablets marked with an identifying helix. Nuromol Dual Action film-coated tablets are available in blisters containing 4, 6, 8, 10, 12, 16, 20, 24 or 32 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Reckitt Benckiser Ireland Ltd, 7 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Manufacturer
RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL.

This medicine is authorised in the Member States of the European Economic Area under the following names:
Portugal - Nurofen Forte
Hungary - Nurofen Duo 200mg / 500 mg filmtabletta
Bulgaria - Duo Max 200 mg / 500 mg film-coated tablets
Romania - Nurofen Duo 200mg / 500 mg comprimate filmate
Poland - Nurofen Ultima
Ireland - Nuromol Dual Action Film-Coated Tablets, Paracetamol 500 mg, Ibuprofen 200 mg

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