LEAFLET TEXT

Package leaflet: Information for the use

NUROFEN DURANCE
200mg Medicated plaster
ibuprofen

For use in adults and adolescents aged 16 years and over
Ibuprofen

Information for the User

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

- Always us 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 5 days.**

What is in this leaflet:

1. WHAT NUROFEN DURANCE IS AND WHIAT IT IS USED FOR

The active substance is ibuprofen. Ibuprofen belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), which work by changing how the body responds to pain, swelling and high temperature. The medicated plaster locally delivers ibuprofen continuously at the site of pain over 24 hours of application.
Nurofen Durance is indicated for the short-term treatment of local pain in acute muscular strains, or sprains in benign traumas close to the joint of the upper or lower limb in adults and adolescents aged 16 years and older.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE NUROFEN DURANCE

Do not use Nurofen Durance if you:

- are **allergic to ibuprofen, aspirin** (acetylsalicylic acid), other **Non-Steroidal Anti-Inflammatory Drugs** (NSAIDs), or to any of the ingredients of this medicine (listed in section 6)

- have had a **previous allergic reaction after taking Non-Steroidal Anti-Inflammatory Drugs** (NSAIDs) or **aspirin** (acetylsalicylic acid); such as asthma, wheezing, itching, runny nose, skin rashes, swelling
- are in the **last three months of pregnancy**

Do not use Nurofen Durance **on injured skin** (such as skin abrasions, cuts, burns), **infected skin,** skin affected by **exudative dermatitis or eczema, eyes, lips or mucosa.**

Warnings and precautions

Talk to your doctor or pharmacist before using Nurofen Durance if you:
- have or have ever had **asthma** or suffer from **allergies**
- have gastric **ulcer, bowel, heart, kidney or liver problems**
- are in the first **6 months of pregnancy** or **breastfeeding**

Whilst using Nurofen Durance
- at the first sign of any **skin reaction** (rash, peeling, blistering) or other sign of an allergic reaction, **stop using** the medicated plaster and consult a doctor at once
- report any unusual abdominal symptoms (especially bleeding) to your doctor
- serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using Nurofen Durance and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4
- if you are elderly you my be more likely to have side effects
- if you do not get better, you get worse, or develop new symptoms, talk to a doctor
- **avoid exposing** the treated area to strong sources of natural and/or artificial light (e.g. tanning lamps) during treatment and for one day after removal of the medicated plaster, in order to reduce the risk of sensitivity to light

Children and adolescents
This medicine should not be used by children or adolescents under the age of 16 years.

Other medicines and Nurofen Durance
Please tell your doctor or pharmacist if you are taking or have recently taken, or might take any other medicines, especially if you are taking any of the following:
- medicines to **lower blood pressure**
- medicines to **thin the blood** e.g. warfarin
- acetylsalicylic acid or other NSAIDs – used for inflammation and pain

Pregnancy and breast-feeding

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 using this medicine.

Do not use Nurofen Durance if you are in **the last 3 months of pregnancy**.

You should not use Nurofen Durance during the first 6 months of pregnancy unless clearly necessary and advised by your doctor. If you need treatment during this period, the lowest dose for the shortest time possible should be used.
Oral forms (e.g. tablets) of ibuprofen can cause adverse effects in your unborn baby. It is not known if the same risk applies to Nurofen Durance when it is used on the skin.

No harmful effects are known when using this medicine whilst breast-feeding. However, as a precautionary measure do not apply a medicated plaster directly on to the breast if you are breast-feeding.

Medicines such as ibuprofen may temporarily affect fertility in women. However this is reversible on stopping treatment. It is unlikely that the occasional use of this medicine will affect your chances of becoming pregnant; however, tell your doctor before taking this medicine if you have problems becoming pregnant.

Driving and using machines
None known.

3. HOW TO USE NUROFEN DURANCE

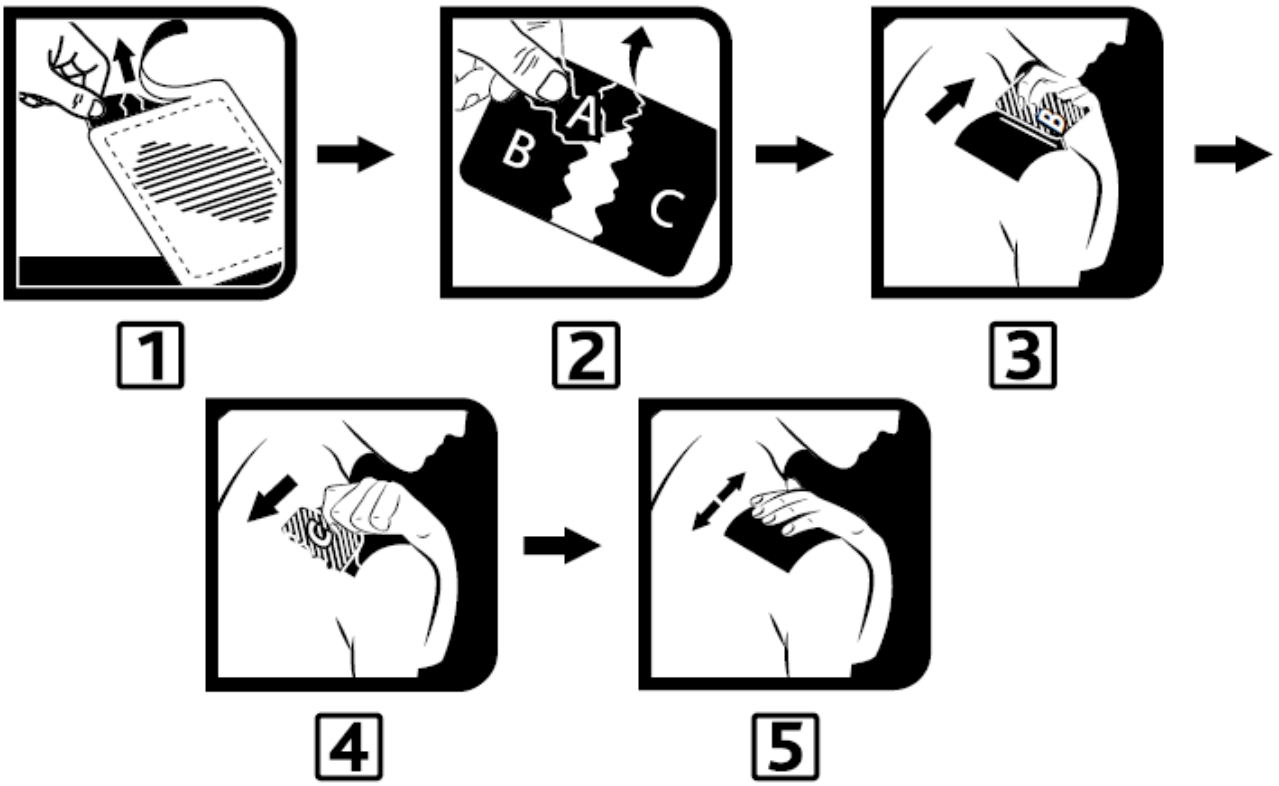
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

Recommended dose
Adults and adolescents aged 16 years and over:
One dose is equal to one medicated plaster. The maximum dose for a singe 24 hour period is one medicated plaster.

Do not use this medicine in children or adolescents under 16 years.

For cutaneous use on intact skin.
It is recommended to carefully wash and dry the area to be treated before applying the plaster.
The plaster can be applied at any time during the day or night, but should be removed and a new plaster re-applied at the same time on the following day.
The plaster is flexible and conformable, and if necessary can be applied on or near a joint and will allow for normal movement.

Do not:
- cut the plaster, it should be used whole
- apply to broken or damaged skin
- cover with other plasters or non-breathable dressings/bandages
- get the plaster wet



Method of application:

1. To remove a medicated plaster, tear or cut along the dotted line on the sachet.
2. Remove the plastic film marked (A) and place the adhesive strip over the middle of the pain area.
3. Remove plastic film marked (B) and stretching slightly, smooth this part of the medicated plaster onto your skin.
4. Remove plastic film market (C).
5. Stretching slightly, smooth the rest of the medicated plaster onto your skin.

Duration of Treatment

You should use as few doses as you need for the shortest time necessary to relieve your symptoms. Do not use this medicine for more than 5 days unless instructed to do so by your doctor.

If you use more Nurofen Durance than you should

Accidental overdose with the medicated plaster is unlikely. Seek medical advice.
Signs of overdose may include feeling sick or being sick, stomach ache or more rarely, diarrhoea. Ringing in the ears, headache and gastrointestinal bleeding is also possible.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

STOP USING this medicine and contact a doctor immediately if you develop:

- signs of an allergic reaction such as asthma, unexplained wheezing or shortness of breath, itching, runny nose, or skin rashes.
- signs of hypersensitivity and skin reactions such as redness, swelling, peeling, blistering, flaking or ulceration of skin
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of the 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)

Tell your doctor or pharmacist if you notice any of the following effects or any effects not listed:

Not known *(frequency cannot be estimated from the available data)*
- skin reactions such as redness, burning, itching, blistering, sore or weeping
- asthma, difficulty breathing, shortness of breath
- stomach pain or other stomach problems
- kidney problems
- skin becomes sensitive to light

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

5. HOW TO STORE NUROFEN DURANCE

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 sachet and carton after **EXP**. The expiry date refers to the last day of that month.
Do not store above 25ºC (2 patches per sachet).
Do not store above 30°C (4 patches per sachet).
Store in the original package in order to protect from light.
Shelf-life after first opening of the sachet: 6 months.
Do not flush the used plaster down the toilet.
Do not throw away medicines via wastewater or household waste. Ask your doctor or 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 Nurofen Durance contains:
The active substance is ibuprofen. One medicated plaster contains 200mg of ibuprofen.

The other ingredients are:
Adhesive layer: macrogol 400, Macrogol 20000, Levo-Menthol, Styrene-Isoprene-Styrene Block Copolymer, Polyisobutylene, Hydrogenated Rosin Glycerol Ester, Liquid Paraffin.
Backing layer: Woven Polyethylene Terephthalate (PET
Release liner: Silicone coated Polyethylene Terephthalate (PET).

What Nurofen Durance looks like and contents of the pack
The medicated plaster is comprised of colourless, self-adhesive formulation layer mounted onto a 10cm by 14cm flexible flesh-coloured woven support, with a release liner.
Pack size: 2, 4, 6, 8 or 10 medicated plasters.
Each sachet contains 2 or 4 medicated plasters.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Reckitt Benckiser Ireland Ltd., Citywest Business Campus, Dublin 24.
Manufacturer
RB NL Brands BV. Schiphol Blvd 207, 1118 BH Schiphol, NL.

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

Germany	Nurofen 24-Stunden Schmerzpflaster
Belgium	Nurofen Patch 200 mg Pleister
Ireland	Nurofen Durance 200mg Medicated Plaster
UK	Nurofen Joint & Muscular Pain Relief 200mg Medicated Plaster

This leaflet was last revised in: upon approval