

# NUROFEN<sup>®</sup>

## Nurofen Back Pain SR Capsules

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IBUPROFEN 300 mg

**PLEASE READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TO TAKE YOUR MEDICINE. Keep this leaflet. You may want to read it again.**

### WHAT IS IN NUROFEN BACK PAIN SR CAPSULES?

#### What is in the pack?

Contains 12 or 24 300 mg Nurofen Back Pain SR Capsules, which contain ibuprofen. The capsules are clear. Each capsule contains ibuprofen Ph.Eur 300 mg in a sustained release formulation.

Also contains: Sucrose and maize starch microgranules, polymethacrylates and methacrylate/acrylate copolymers, povidone, talc, silicon dioxide.  
Capsule shell contains gelatin, iron oxide ink.

Licence holder and manufacturer:

CROOKES HEALTHCARE LTD.

Nottingham NG2 3AA

Manufacturer:

Ethypharm Industries

78550 Houdan France

Product Licence No. PL00327/0101

### HOW DO NUROFEN BACK PAIN SR CAPSULES WORK?

Nurofen Back Pain SR Capsules contain ibuprofen which belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by changing the body's response to pain, swelling and high temperature.

The capsules have been specially designed to gradually release the active ingredient and so provide relief for up to 8 hours.

### What are Nurofen Back Pain SR Capsules for?

Nurofen Back Pain SR Capsules help provide relief from pain. It delivers effective and long lasting relief from muscle pain and stiffness such as **backache**.

### BEFORE YOU TAKE NUROFEN BACK PAIN SR CAPSULES:

Do Not take Nurofen Back Pain SR Capsules if you:

- have or have ever had a stomach ulcer, perforation or bleeding
- are allergic to ibuprofen, to any of the ingredients, or to aspirin or other painkillers
- are taking other NSAIDs pain killers, or aspirin with a daily dose above 75 mg
- are in the last 3 months of pregnancy
- are under 12 years of age.

Ask your doctor before taking Nurofen Back Pain SR Capsules if:

- you have asthma or have suffered from asthma
- you have kidney, heart, or liver or bowel problems
- have Systemic Lupus Erythematosus (SLE) - a condition of the immune system affecting connective tissue resulting in joint pains, skin changes and disorder of other organs
- you are taking any regular medication, especially:
  - aspirin at low dose (ie below 75 mg daily)
  - medicines for high blood pressure and water tablets (diuretics)
  - medicines for thinning the blood (anti-coagulants)
  - corticosteroids
  - Methotrexate (an anti-cancer agent)
  - Lithium (used to treat depression)
  - Zidovudine (an anti-viral drug)
- you are in the first 6 months of pregnancy or breast-feeding.

- Nurofen belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicines. It is unlikely that Nurofen, used occasionally, will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.

## **HOW TO TAKE NUROFEN BACK PAIN SR CAPSULES:**

### **Directions:**

Adults and children over 12 years: Initial dose 2 capsules taken with water and swallowed whole, then, if necessary, 1 or 2 capsules after at least 8 hours. Do not chew or suck the capsules. Do not exceed more than 4 capsules in 24 hours. Do not exceed the stated dose. If symptoms persist consult your doctor. Problems in overdose are rare, but if you accidentally take more than the recommended dose contact your doctor.

## **WHILST TAKING NUROFEN BACK PAIN SR CAPSULES:**

If you take too many Nurofen Back Pain SR Capsules by mistake, talk to your doctor or pharmacist as soon as possible. If symptoms persist or if the pain or fever worsen, or if new symptoms occur, talk to your doctor or pharmacist. This product is intended for short-term use only. You should take the lowest dose for the shortest time necessary to relieve your symptoms. You should not take Nurofen Back Pain SR Capsules for longer than 10 days unless your doctor tells you to.

Side-effects: Nurofen Back Pain SR Capsules are generally well tolerated by the majority of people, however, elderly patients are at increased risk of developing problems associated with side effects.

*Disorders of the stomach and intestines* including abdominal discomfort or pain, nausea, stomach ulcer, vomiting containing either blood or brown grit (like coffee grounds), black tarry stools, worsening of existing bowel diseases (ulcerative colitis or Crohn's disease)

*Blood disorders* resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, extreme pallor or weakness

*Allergic reactions* including worsening of asthma, unexplained wheezing or shortness of breath, swelling of the face and tongue, collapse. In addition, there may be skin reaction (including hives and itching): these can sometimes be severe with blistering and peeling of skin

**If you develop any of the symptoms above, stop the capsules and contact your doctor immediately**

*Liver disorders* that may be indicated by yellowing of the skin and eyes and/or pale stools and dark urine

*Kidney disorders* that may be indicated by passing less or more urine than normal, cloudy urine, blood in the urine, pain in the back and/or swelling (particularly of the legs)

*Nervous system disorders* indicated by severe headache, neck stiffness, disorientation, and light hurting the eyes

If you experience any of these, or have any other unusual symptoms or concerns, stop taking the product and see your doctor.

## **HOW SHOULD NUROFEN BACK PAIN SR CAPSULES BE STORED?**

Do not use after the expiry date shown on the pack.

Do not store Nurofen Back Pain SR Capsules above 25°C.

Store in the original packaging.

**Remember: Keep all medicines out of the reach and sight of children.**

## **HOW CAN YOU OBTAIN MORE INFORMATION ABOUT NUROFEN BACK PAIN SR CAPSULES?**

This leaflet gives you the most important patient information about Nurofen Back Pain SR Capsules. If you have any questions after you have read it, ask your doctor or pharmacist, who will give you further information.