What Nuprin is and what it is used for

Nuprin contains acetylsalicylic acid, which in low doses belongs to a group of medicines called anti-platelet agents. Platelets are tiny cells in the blood that cause the blood to clot and are involved in thrombosis. When a blood clot occurs in an artery it stops the blood flowing and cuts off the oxygen supply. When this happens in the heart it can cause a heart attack or angina, in the brain it can cause a stroke.

Nuprin is taken to reduce the risk of blood clots forming and therefore prevent further:

- heart attacks
- strokes
- cardiovascular problems in patients who suffer from stable or unstable angina (a type of chest pain).

Nuprin is also used to prevent the formation of blood clots after certain types of heart surgery in order to widen or to unblock the blood vessels.

This medicinal product is not recommended for use as a preventative treatment.

What you need to know before you take Nuprin

Do not take Nuprin if you:

- are allergic to acetylsalicylic acid or any of the ingredients of this medicine (see section 6)
- have high blood pressure
- have or have ever had problems with your stomach or small intestine or any other type of bleeding like a nosebleed
- high blood pressure
- are asthmatic, have hay fever, nasal polyps or other chronic respiratory diseases
- acetylsalicylic acid may induce an asthma attack
- have ever had a gastrointestinal bleeding
- have heavy menstrual periods
- have had an asthma attack or swelling of some parts of the body e.g. face, lips, throat or tongue (angioedema) after taking salicylates or NSAIDs.

- commonly have or have ever had an ulcer in your stomach or small intestine or any other type of bleeding like a nosebleed
- have ever had the problem of your blood not clotting properly
- have severe liver or kidney problems
- are in your last 3 months of pregnancy; you must not use higher doses than 100 mg per day (see section “Pregnancy and breast-feeding”)
- are taking a medicine called methotrexate (for cancer or rheumatoid arthritis) in doses higher than 15 mg per week

Liver and kidney problems

Talk to your doctor or pharmacist before taking Nuprin if you:

- have trouble with your kidneys, liver or heart
- have or have ever had problems with your stomach or small intestine
- have high blood pressure
- are asthmatic, have hay fever, nasal polyps or other

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 taking this medicine. Pregnancy Pregnant women should not take acetylsalicylic acid during pregnancy unless advised by their doctor. You should not take Nuprin if you are in the last 3 months of pregnancy, unless you are advised to do so by your doctor and then the daily dose should not exceed 100 mg (see section “Do not take Nuprin”).

Breast-feeding Breast-feeding women should not take acetylsalicylic acid at the same time as any other medicines for:}

- thinning of the blood/prevention of clots (e.g. warfarin, heparin, clopidogrel)
- rejection of organ after transplantation (cyclosporine, tacrolimus)
- high blood pressure (e.g. diuretics and ACE inhibitors)
- regulation of the heart beat (digoxin)
- manic-depressive illness ( lithium)
- pain and inflammation (e.g. NSAIDs such as ibuprofen, or steroids)
- gout (e.g. probenecid)
- epilepsy (valproate, phenytoin)
- glosceoma (acitretin)
- rheumatoid arthritis (methotrexate, in doses lower than 15 mg per week)
- diabetes (e.g. glibenclamide)
- depression (selective serotonin re-uptake inhibitors (SSRIs) such as sertraline or paroxetine)

Use as hormone replacement therapy when the adrenal glands or pituitary gland have been destroyed or to treat inflammation, including rheumatic diseases and inflammation of the intestines (colitides)

Nuprin with alcohol Drinking alcohol may possibly increase the risk of gastrointestinal bleeding and prolonging bleeding time.

Driving and using machines

Nuprin should not affect your ability to drive and use machines.
How to take Nuprin
Always take Nuprin exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults
Prevention of heart attacks:
• The recommended dose is 75-160 mg once daily.
• Prevention of strokes:
  • The recommended dose is 75-325 mg once daily.
  • Prevention of cardiovascular problems in patients who suffer from stable or unstable angina (type of chest pain):
  • The recommended dose is 75-160 mg once daily.
Prevention of blood clot after certain types of heart surgery:
• The recommended dose is 75-160 mg once daily.

Elderly
As for adults. In general, acetylsalicylic acid should be used with caution in elderly patients who are more prone to adverse events. Treatment should be reviewed at regular intervals.

Use in children and adolescents
Acetylsalicylic acid should not be administered to children and adolescents younger than 15 years, unless prescribed by a doctor (see section “Warnings and precautions”).

Method of administration
For oral use.

The tablets, should be swallowed whole with sufficient fluid (1/2 glass of water). The tablets have a gastro-resistant coating which prevents irritant effects on the gut, and should therefore not be crushed, broken or chewed.

If you take more Nuprin than you should
If you or someone else accidentally take too many tablets, you should tell your doctor or contact immediately the nearest casualty department. Show any left over medicine to the doctor. The tablets may affect up to 1 in 1000 people:

• Severe skin reactions such as rash known as erythema multiforme and it’s life threatening forms Stevens-Johnson syndrome or Lyell’s syndrome.
• Unusual bleeding, such as coughing up blood, blood in stool, nosebleeds, sexually, haemorrhages, low blood sugar, and shock.

If you forget to take Nuprin
If you miss a dose, wait until it is time for your next dose, then go on as normal.

Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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

If you notice any of the following serious side effects, stop taking Nuprin and contact a doctor immediately:
• Severe breathing difficulties, swelling of your lips, face, or body, rash, fainting or difficulty breathing (swelling allergic reaction).
• Difficulty swallowing,这个词 cannot be translated.
• Burning mouth or pharynx.
• Abdominal pain.
• Ringing in your ears (tinnitus) or reduced hearing ability.

If you notice any of the following side effects, stop taking Nuprin and contact a doctor immediately:
• Severe bleeding in the stomach or intestines, brain or body, or shock.
• Severe skin reactions such as rash known as erythema multiforme and it’s life threatening forms Stevens-Johnson syndrome and Lyell’s syndrome.
• Severe skin reactions such as sweating of e.g. lips, face, or body, or shock.
• Abnormal heavy or prolonged menstrual periods.

Side effects with unknown frequency (frequency cannot be estimated from the available data)
• Uncommon side effects (may affect up to 1 in 100 people):
  • Fainting.
  • Increased tendency for bleeding.
  • Blurred vision.

If you notice any of the following side effects, stop taking Nuprin and contact a doctor immediately:
• Diarrhoea.
• Burning mouth or pharynx.
• Uncommon side effects (may affect up to 1 in 100 people):
  • Severe bleeding in the stomach or intestines, brain or body, or shock.
  • Severe skin reactions such as rash known as erythema multiforme and it’s life threatening forms Stevens-Johnson syndrome and Lyell’s syndrome.
  • Severe skin reactions such as sweating of e.g. lips, face, or body, or shock.
  • Abnormal heavy or prolonged menstrual periods.

Side effects with unknown frequency (frequency cannot be estimated from the available data):
• Ringing in your ears (tinnitus) or reduced hearing ability.

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 HPA Pharmacovigilance, Earlsfort Terrace, IR - Dublin 2: 14.
• +353 1 6794971 / Fax: +353 1 6752517. Website: www.hpra.ie / E-Mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

How to store Nuprin
Keep this medicine out of the sight and reach of children.

Store below 25°C.

Tablet container:
Keep the container tightly closed in order to protect from moisture.

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Contents of the pack and other information
What Nuprin contains
The active substance is acetylsalicylic acid. Each gastro-resistant tablet contains 75 mg of acetylsalicylic acid.

The other ingredients are:
• Tablet core: microcrystalline cellulose, main starch, colophony anhydrous silica, stearic acid, silicon dioxide, magnesium stearate, gelatin, papaverine hydrochloride, acacia, hydroxypropyl cellulose, magnesium stearate.

What Nuprin looks like and contains of the pack
Nuprin gastro-resistant tablets 75 mg are oval, white, biconvex film-coated tablets, 9.2 ± 0.2 mm.

Pack size:
Blisters: 10, 20, 26, 30, 50, 56, 90, 100, 100 gastro-resistant tablets.
Tablet container:
Tablet container contains 10, 30, 50, 90, 100 gastro-resistant tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Actavis Limited, Actavis Group PTC ehf.
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland

Manufacturer
Actavis Limited
BLB 016, Babil Industrial Estate
Zejtun ZTN 3000
Malta

Balkanpharma Dupnitsa AD
3, Samokovsko Shosse Str.
2600 Dupnitsa
Bulgaria

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

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This leaflet was last approved in September 2016.