

PATIENT INFORMATION LEAFLET

Nu-Seals[®] 75mg
Gastro-resistant Tablets
aspirin (acetylsalicylic acid)

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

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1. What Nu-Seals 75mg is and what it is taken for

Nu-Seals 75mg contains aspirin. Aspirin is used:

- to prevent recurrence of heart attacks or strokes by thinning the blood. If someone who has previously had a heart attack or stroke takes Nu-Seals 75mg regularly, it reduces the risk of a blood clot occurring in the heart or brain. This can prevent further heart attacks or strokes.

If you take aspirin in high doses or over a long period of time, it can irritate your stomach lining. To prevent stomach irritation, these tablets have a special coating (called enteric) so that the aspirin is not released until it has passed through the stomach.

Aspirin is released slowly from these tablets, so Nu-Seals 75mg is not suitable for the short-term relief of pain, such as headaches or toothache.

2. What you need to know before you take Nu-Seals 75mg

Do not take Nu-Seals 75mg:

- if you are allergic to aspirin or any of the other ingredients in this medicine (listed in section 6)
- if you have had a cerebral haemorrhage (a type of stroke caused by bleeding in your brain)
- if you have ever had the problem of your blood not clotting properly or suffer from any bleeding problems
- if you have ever had an ulcer in your stomach or small intestine, or severe inflammatory bowel disease (Crohn's or ulcerative colitis)
- if you have ever had bleeding or perforation in the stomach or intestines related to aspirin or other non-steroidal anti-inflammatory drugs – NSAIDs (e.g. ibuprofen or naproxen)
- if you have severe heart problems (such as severe heart failure)
- if you are in your last 3 months of pregnancy, unless advised by your doctor.

Warnings and precautions

Before you take Nu-Seals 75mg tell your doctor if you:

- think you may be dehydrated (you may feel thirsty with a dry mouth)
- have trouble with your kidneys or liver
- you have or have had gout
- have high blood pressure
- have been told you have a lack of glucose-6-phosphate dehydrogenase (G6PD)
- are asthmatic, aspirin may induce an asthma attack
- are elderly.

When given to children aspirin may cause Reye's syndrome. Reye's syndrome is a very rare disease, which can be fatal. For this reason, aspirin should not be given to children aged under 16 years, unless on the advice of a doctor.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Nu-Seals 75mg.

Other medicines and Nu-Seals 75mg

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The effect of treatment may be influenced if aspirin is taken at the same time as some other medicines for:

- thinning of the blood/prevention of clots (e.g. warfarin)
- organ rejection after transplantation (e.g. ciclosporin, tacrolimus)
- high blood pressure (e.g. diuretics and ACE-inhibitors)
- pain and inflammation (e.g. anti-inflammatory medicines such as ibuprofen, or steroids)
- gout (e.g. probenecid)
- cancer or rheumatoid arthritis (e.g. methotrexate)

These other medicines may also affect or be affected by aspirin:

- insulin or any other drug to treat diabetes (e.g. sulfonylureas such as glibenclamide or tolbutamide)
- corticosteroids (used as hormone replacement therapy when the adrenal glands or pituitary gland have been destroyed or removed, or to treat inflammation, including rheumatic diseases and inflammation of the intestines)
- phenytoin or sodium valproate (used to control epilepsy)
- sulphonamides (a type of antibiotic) such as sulfamethoxazole
- medicines such as acetazolamide used to treat glaucoma
- antacids (indigestion medicine). Do not take antacids just before or after taking Nu-Seals 75mg as they may cause the aspirin to be released too soon
- antiplatelet drugs (such as clopidogrel and dipyridamole)
- diuretics (water tablets)
- cardiac glycosides (drugs which regulate the heart beat)
- lithium
- aminoglycosides (a group of antibiotics)
- gold, which is sometimes used in rheumatic conditions
- an anaesthetic called thiopental
- selective serotonin re-uptake inhibitors (SSRIs) for depression such as sertraline or paroxetine
- Metamizole (substance to decrease pain and fever) may reduce the effect of acetylsalicylic acid on platelet aggregation (blood cells sticking together and forming a blood clot), when taken concomitantly. Therefore, this combination should be used with caution in patients taking low dose aspirin for cardioprotection.

Before using aspirin, you should inform a healthcare professional about the medicines you are taking. If you are using aspirin regularly you should seek advice before taking any other medicine (including other medicines you may have bought).

If you have alcoholic drinks whilst taking Nu-Seals 75mg, you may increase the risk of causing bleeding in your stomach or intestines.

Tell your doctor that you are taking aspirin if you are to have a urine test, as it can sometimes interfere with the results.

Pregnancy, breast-feeding and fertility

Pregnant women should not take aspirin during pregnancy unless advised by their doctor. Regular or high dose aspirin therapy during late pregnancy can cause serious complications in the mother or baby. Do not take Nu-Seals 75mg if you are in your last three months of pregnancy.

Do not take Nu-Seals 75mg if you are breast-feeding because some of the aspirin may be in your breast milk and could harm your baby.

Do not take Nu-Seals 75mg if you are trying to become pregnant as aspirin may reduce female fertility.

Nu-Seals 75mg contains Benzyl Alcohol

This medicine contains 0.128 mg benzyl alcohol in each tablet.

Ask your doctor or pharmacist for advice if you have a liver or kidney disease, or are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

Benzyl alcohol may cause allergic reactions.

Ask your doctor or pharmacist for advice before taking any medicine.

3. How to take Nu-Seals 75mg

Always take Nu-Seals 75mg exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

- Prevention of heart attacks, angina or mini-strokes:
 - For your first dose - your doctor will tell you to chew two 75mg tablets. Chewing the tablets will help the aspirin start to work quickly.
 - After this first dose - The usual dose is one or two 75mg tablets each day. Sometimes your doctor may tell you to take a higher dose.

Apart from the first dose of Nu-Seals, swallow the tablets whole with water. Do not cut, crush or chew them as this will damage the special coating. If the coating is damaged the tablets are more likely to irritate your stomach.

If you may be taking this medicine for a long time, you should talk to your doctor about it.

What to do if you take more Nu-Seals 75mg than you should

If you (or someone else) accidentally take too many tablets, you should tell your doctor at once or contact the nearest casualty department. Show any left-over medicines or the empty packet to the doctor.

Common symptoms of an overdose include:

- vomiting
- dehydration
- ringing in the ears
- loss of balance (vertigo)
- deafness
- sweating
- warm hands and feet with a racing pulse

- unusually fast or deep breathing.

Less common symptoms of an overdose include:

- vomiting blood
- high fever
- alteration in blood platelets which may lead to an increased risk of bleeding or bruising
- lowering of blood sugar levels (typical early warning signs are feeling hungry, trembling or shakiness and sweating)
- low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm
- kidney failure (symptoms include swollen ankles, hands or feet and blood in the urine)
- fluid build-up in the lungs which can cause severe breathlessness.

If you forget to take Nu-Seals 75mg

Do not worry. 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.

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

4. Possible Side Effects

Like all medicines, Nu-Seals 75mg can cause side effects, although not everyone gets them.

Aspirin may cause hypersensitivity and you must tell your doctor immediately if you experience any of the following:

- skin rashes or itching or wheezing or coughing or difficulty breathing.

Side effects may be more serious in elderly patients.

When taking Nu-Seals 75mg you may suffer some more serious side effects, **tell your doctor immediately** if you get any of the following:

- signs of intestinal bleeding (bleeding in your stomach or intestines may be fatal), perforation or ulcers such as:
 - blood in your vomit
 - black stools

other side effects such as:

- heart problems which can cause shortness of breath or ankle swelling
- kidney stones (which can cause severe stomach or back pains)
- bruising with purple spots
- skin rash, skin peeling or blistering
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- blood in your urine
- coughing up blood (however small the amount)

- any swellings

Medicines such as Nu-Seals 75mg may be associated with a small increased risk of high blood pressure and fluid retention in the body.

Aspirin may sometimes cause asthma or bronchospasm (narrowing of the airways that causes wheezing or difficulty breathing).

Aspirin may cause bleeding, and you must tell your doctor if you experience any unusual bleeding such as:

- nosebleeds
- signs of bleeding in the brain: severe headache, nausea, vomiting, dizziness, loss of balance, weakness in the limbs.

Other side effects of aspirin include:

- nausea and vomiting
- ringing in your ears
- pain or discomfort in your stomach or lower chest after eating
- diarrhoea
- flatulence
- constipation
- worsening of colitis, Crohn's disease or irritation of your colostomy
- recurrent mouth ulcers
- liver problems with symptoms that may include a yellowing of the skin or whites of the eyes (jaundice), dark yellow urine and fatigue.

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 Nu-Seals 75mg

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

Do not use Nu-Seals 75mg after the expiry date which is stated on the carton, blister or container. The expiry date refers to the last day of that month.

Do not store above 25°C. Blister packs: Store in the original package in order to protect from moisture. Tablet container: For dispensing purposes only. Use within 8 weeks of opening. Keep the container tightly closed in order to protect from moisture. Do not take Nu-Seals 75mg if you notice the appearance has changed in any way.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Nu-Seals 75mg contains

The active ingredient in this medicine is aspirin (acetylsalicylic acid). Each tablet of Nu-Seals 75mg contains 75 milligrams (mg) of aspirin.

The other ingredients are maize starch, hypromellose, talc, methacrylic acid-ethyl acrylate (1:1) copolymer dispersion 30 percent, polyethylene glycol 3350, propylene glycol, benzyl alcohol, emulsion silicone. Printing ink containing shellac, iron oxide (E172), isopropyl alcohol, n-butyl alcohol, propylene glycol, ammonium hydroxide (E527) and simeticone.

What Nu-Seals 75mg looks like and contents of the pack

Nu-Seals 75mg is a white tablet, with 75 on it in red. Nu-Seals 75mg comes in either blister packs contained in a carton (28 or 56 tablets) or in a white container, with a child resistant closure (100 tablets).

Marketing Authorisation Holder and Manufacturer

The product licence holder is: Alliance Pharma (Ireland) Limited, United Drug House, Magna Drive, Dublin, D24 X0CT, Ireland.

Nu-Seals 75mg is manufactured by Chanelle Medical Unlimited Company, Dublin Road, Loughrea, Co Galway, H62 FH90, Ireland.

The information in this leaflet applies only to Nu-Seals 75mg. If you have any questions or you are not sure about anything, ask your doctor or a pharmacist.

This leaflet was last revised in April 2024

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