



PATIENT INFORMATION LEAFLET

Nu-Seals® 300mg
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.

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1. What Nu-Seals 300mg is and what it is taken for

Nu-Seals 300mg contains aspirin. Aspirin is used:

- as an anti-inflammatory analgesic which can relieve pain and swelling
- to bring down high body temperatures
- 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 300mg 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 300mg 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 300mg

Do not take Nu-Seals 300mg:

- if you are allergic to aspirin or any of the other ingredients in this medicine (listed in section 6)
- 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 had a cerebral haemorrhage (a type of stroke caused by bleeding in your brain)
- 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.

Warnings and precautions

Before you take Nu-Seals 300mg 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 300mg.

Medicines such as Nu-Seals 300mg may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke. Any risk is more likely with high doses, prolonged treatment or if you are elderly. Do not exceed the recommended dose or duration of treatment.

Other medicines and Nu-Seals 300mg

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 300mg 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).

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

Nu-Seals 300mg with alcohol

If you have alcoholic drinks whilst taking Nu-Seals 300mg, you may increase the risk of causing bleeding in your stomach or intestines.

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 300mg if you are in your last three months of pregnancy.

Do not take Nu-Seals 300mg 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 300mg if you are trying to become pregnant as aspirin may reduce female fertility.

Nu-Seals 300mg contains benzyl alcohol

This medicine contains 0.334 mg benzyl alcohol in each tablet.

Ask your doctor or pharmacist for advice if you have a liver or kidney disease. 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 300mg

Always take Nu-Seals 300mg exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

The usual dose is different in the following circumstances:

- Pain and swelling, or fever
Take up to three 300 mg tablets three or four times a day.
- Acute rheumatic disorders (joint and muscle problems)
Your doctor will tell you how many tablets to take and how often. You will usually take 4 to 8 grams of Nu-Seals 300mg a day.
- Prevention of heart attacks, angina or mini-strokes
The usual dose is one or two 75 mg tablets each day. Sometimes, your doctor may tell you to take one 300mg tablet each day.

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.

If you take more Nu-Seals 300mg 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 300mg

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 300mg 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 300mg 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:

- blood in your urine
- coughing up blood (however small the amount)
- 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
- any swellings.

Medicines such as Nu-Seals 300mg may be associated with a small increased risk of heart attack ('myocardial infarction'), stroke, 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 and 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 HPRC 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 300mg

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 bottle and carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep containers tightly closed. Do not take Nu-Seals 300mg if you notice the appearance has changed in any way.

If your doctor decides to stop your treatment, return any unused medicine to the pharmacist. Only keep it if your doctor tells you to.

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 300mg contains

The active ingredient in this medicine is aspirin (acetylsalicylic acid).

Each tablet of Nu-Seals 300mg contains 300 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 300mg looks like and contents of the pack

Nu-Seals 300mg is a white tablet, with 300 on it in red. Nu-Seals 300mg comes in bottles of 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 300mg is manufactured by Chanelle Medical, Loughrea, Co Galway, Ireland.

The information in this leaflet applies only to Nu-Seals 300mg. If you have any questions or you are not sure about anything, ask your doctor or a pharmacist.

This leaflet was last revised in June 2023

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