

Anadin Maximum Strength Hard Capsules

Aspirin 500 mg and Caffeine 32mg

PA0678/148/002

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. Always take this medicine exactly as described in the leaflet or as your doctor or pharmacist 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4. You must see a doctor if your symptoms worsen or do not improve in more than 3 days.

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1.What your medicine is and what it is used for

Each hard capsule of Anadin Maximum Strength contains Aspirin (Acetylsalicylic acid) 500mg and Caffeine 32mg.

Aspirin works by relieving pain and reducing high temperature and fever. Aspirin belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and has anti-inflammatory properties. In addition, the capsules contain caffeine, which increases the pain relieving effect of the product.

Your medicine is for the treatment of mild to moderate pain including, headache, period pain, neuralgia, dental pain, rheumatic pain, and symptoms of cold and flu.

2.What you need to know before you take your medicine

Please read the following information. Do not give to children under 16 years of age.

Do not take if you:

- are allergic to aspirin, caffeine, other NSAIDs or any of the other ingredients listed in this leaflet
- have or have ever had a stomach ulcer, perforation or bleeding
- suffer from bleeding disorders e.g. haemophilia or are taking medicines that thin the blood/prevent blood clots (e.g. Warfarin, heparin)
- are breast-feeding or are in the last 3 months of pregnancy
- suffer from heart disease
- have severe heart failure
- have renal failure
- have kidney failure
- take more than 15 mg of methotrexate a week (a medicine that could be used to treat rheumatoid arthritis, psoriasis or Chron's disease).
- are under 16 years of age

- If you have glucose-6-phosphate dehydrogenase (G-6-PD) deficiency (an hereditary condition leading to low red blood cell counts).

There is a possible association between aspirin and Reye's syndrome when given to children. 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.

Warnings and Precautions:

Take special care and talk to your pharmacist or doctor before taking this medicine if you:

- suffer from asthma, or have suffered from asthma.
- have heart, liver or kidney problems as NSAID's can deteriorate kidney function, therefore you may need to be monitored regularly.
- have stomach or intestinal problems (such as ulcerative colitis or Crohn's disease).
- have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes, high cholesterol or are a smoker).
- have had a head injury, unexplained bleeding, or raised intracranial pressure.
- are elderly. Elderly people are more likely to experience unwanted side effects with NSAIDs (including aspirin) such as stomach bleeding and perforation which may be fatal.
- are suffering from dehydration.

Aspirin can cause gout in patients with low uric acid excretion.

Excessive intake of caffeine should be avoided. Consumption of alcohol should be avoided.

Stomach or intestinal bleeding, ulceration or perforation, can occur when taking NSAIDs at anytime during treatment, with or without warning symptoms, or a previous history of these problems.

Medicines such as Anadin Maximum Strength Capsules may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses and prolonged treatment, do not exceed recommended dose or duration of treatment.

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs.

Stop taking the product immediately if you experience:

- unusual abdominal symptoms, vomiting blood or passing blood in the faeces
- skin rash, skin blisters or other signs of hypersensitivity such as an itchy, runny nose, swelling lips, face, tongue or throat.

Other medicines and Anadin Maximum Strength Hard Capsules:

Tell your pharmacist about the medicines you are taking. If you are using aspirin regularly you should seek advice before taking any other medicine (including OTC medicines).

- Do not use this medicine if you are taking water tablets, anticonvulsants (e.g. phenytoin or valproate), medicines for cancer or rheumatoid arthritis (e.g. Methotrexate), lithium, medicines for gout (e.g. probenecid), digoxin, metoclopramide, aminoglycosides (a type of antibiotic), medicines to breakdown blood clots (thrombolytics), medicines for indigestion (antacids), medicines for organ rejection after transplantation (e.g. cyclosporin, tacrolimus), medicines for diabetes, corticosteroids, medicines for high blood pressure (e.g. diuretics and ACE-inhibitors), medicines for pain and

inflammation (e.g. anti-inflammatory medicines such as ibuprofen, or steroids) or medicines for treatment of depression called selective serotonin reuptake inhibitors (SSRIs).

Pregnancy, breast feeding and fertility

Pregnancy - last trimester

Do not take Anadin Maximum Strength if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

Pregnancy – first and second trimester

You should not take Anadin Maximum Strength during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Anadin Maximum Strength can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breastfeeding

Do not use when breastfeeding.

Fertility

If you are pregnant or trying to become pregnant discuss with your pharmacist. The product belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine.

3.How to take your medicine

Adults and the elderly:

Take 1-2 capsules with a drink of water. Repeat every four to six hours as required.

Do not take more than 8 capsules in 24 hours.

Do not give to children and adolescents aged under 16 years, unless on the advice of a doctor.

Prolonged use without medical supervision could be harmful.

Use only when clearly necessary.

OVERDOSE

In case of overdose call your doctor or hospital immediately.

4. Possible Side Effects

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

Please note that using the smallest dose required can reduce the chances of experiencing side effects. Side effects may be more serious in elderly patients. If you experience any side effects

mentioned above or any other side effects, STOP taking this medicine immediately and consult your doctor.

Blood: the blood does not clot well, which may result in easy bruising or bleeding. A reduction in some components of the blood (red cells, white cells or platelets) may rarely occur.

Heart: raised blood pressure, swollen ankles and heart failure. Any risk is more likely with high doses and prolonged treatment.

Breathing: shortness in breath, wheezing and breathing difficulties may be triggered in patients suffering from or with a previous history of asthma.

Gastro-intestinal: abdominal pain, nausea, vomiting, indigestion, heartburn, diarrhoea, flatulence, constipation, ulceration of mouth, worsening of existing inflammatory bowel disease, peptic ulcer and bleeding or inflammation of the stomach or bowel shown by the vomiting of blood or dark particles that look like coffee grounds, or the passage of black stools, exacerbation of colitis and Crohn's disease

Skin: rashes, itching, fluid build-up in tissue below the skin and in mucous membranes which appears as spots or lumps, blood blisters and occasionally flaking of the skin or rarely changes in skin colour.

Allergic reactions: difficulty in breathing, skin rash, swollen facial features or a runny nose. Very rare cases of Stevens-Johnson syndrome have been reported.

Kidney problems: impaired kidney function, formation of kidney stones

Ear disorders: ringing in the ears or temporary hearing loss.

Musculoskeletal disorders: Gout (pain in the joints due to inflammation).

Circulation disorders: High blood pressure

Reye's Syndrome in children under 16 years, is a very rare disease which affects brain and liver.

High caffeine intake can result in tremor and palpitations. Aspirin may precipitate gout in susceptible individuals. Kidney stones and ringing in the ears have also been reported in patients taking aspirin.

Medicines such as Anadin Maximum Strength Capsules may be associated with a small increased risk of heart attack or stroke.

Please note that using the smallest dose required can reduce the chances of experiencing side effects. Side effects may be more serious in elderly patients.

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 your medicine

- Do not use this medicine after the expiry date which is stated on the blister and carton.
- The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Keep this medicine out of sight and reach of children.

- Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or house hold waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Content of the pack and other information

What does this medicine contain?

The active substances are aspirin and caffeine. Your medicine contains 500mg of Aspirin (Acetylsalicylic acid), and 32mg of Caffeine.

In addition to the above active ingredients, ANADIN MAXIMUMSTRENGTH HARD CAPSULES contain: Maize starch, dimethicone, gelatin, shellac, propylene glycol, ammonium hydroxide and colours - quinoline yellow(E104), titanium dioxide (E171), iron oxide (E172) and patent blue V (E131).

What your medicine looks like and contents of pack?

The capsules are hard gelatin capsules with green caps and yellow bodies containing a white powder/granule mix. Anadin 500 is printed longitudinally in black on each half.

Your medicine is available in pack sizes of 12 capsules.

Who makes this medicine?

Your medicine is manufactured by: Haleon Italy Manufacturing S.r.l., Via Nettunense 90, Aprilia, Italy

The marketing authorisation holder is Haleon Ireland Limited, Clocherane, Dungarvan, Co. Waterford, Ireland.

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