

Anadin

HALEON

ANALGESIC Film-coated Tablets

Aspirin 325 mg and Caffeine 15 mg

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 after 3 days.**

IN THIS LEAFLET:

1. What your medicine is and what it is used for
2. What you need to know before you take your medicine
3. How to take your medicine
4. Possible side effects
5. How to store your medicine
6. Contents of the pack and other information

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

Each Film-coated tablet contains 325 mg of Aspirin (Acetylsalicylic Acid), and 15 mg of Caffeine. Aspirin belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

These products relieve pain and inflammation and reduce fever. In addition, your medicine contains caffeine, which increases the pain-relieving effect of the product.

Your medicine is for relief of pain of: Headache, Neuralgia, Colds and Flu, Rheumatic Pain, Period Pain, Dental Pain and Toothache.

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

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

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

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

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. hemophilia or are taking medicines that reduce blood clotting e.g. warfarin, heparin.
- have severe heart failure.
- have severe renal failure.
- are pregnant or breast-feeding.
- suffer from heart disease or have high blood pressure.
- are under 16 years.
- are on a high dose of methotrexate.
- Do not take with **OTHER** aspirin or non-steroidal anti-inflammatory drugs.

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

- suffer from asthma, allergic disease, high blood pressure, heart failure, intracranial haemorrhage, bleeding diathesis, kidney or liver disease or any other bowel disorder (e.g. ulcerative colitis or Crohn's disease).
- are trying to become pregnant. The product belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine.
- are elderly. Elderly people are more likely to experience unwanted effects with NSAIDs (including aspirin), especially bleeding from the bowel or perforation of the bowel.
- Stop taking this medicine and contact your doctor if you experience any unusual abdominal pain or gastrointestinal bleeding.
- have glucose-6-phosphate dehydrogenase (G-6-PD) deficiency (an hereditary condition leading to low red blood cell counts).

Taking other medicines

Do not take this medicine if you are taking any of the following medicines: Medicines for thinning the blood / prevention of clots (e.g. warfarin, heparin), lithium, medicines for cancer or rheumatoid arthritis (e.g. methotrexate), medicines for organ rejection after transplantation (e.g. cyclosporin, tacrolimus), other NSAIDs or corticosteroids.

Talk to your doctor or pharmacist before taking this medicine if you are taking any of the following medicines: Water tablets, anticonvulsants (e.g. phenytoin or valproate), digoxin, aminoglycosides (a type of antibiotic), metoclopramide (treatment for nausea and vomiting), medicines for diabetes or medicines for treatment of depression called selective serotonin reuptake inhibitors (SSRIs), medicines to treat high blood pressure (e.g. diuretics and ACE-inhibitors), heart failure, gout (e.g. probenecid), medicines used to treat pain and inflammation (e.g. anti-inflammatory medicines such as ibuprofen and steroids).

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

3. How to take your medicine

For oral administration and short term use only.

Dosage: Adults and the elderly: The minimum effective dose should be used for the shortest time necessary to relieve symptoms. Take 2 tablets every 4 hours if necessary. Do not exceed 12 tablets in any 24 hour period. Tablets should be swallowed with a drink of water. Do not give to children and adolescents aged under 16 years, unless on the advice of a doctor. Do not exceed the stated dose. Use only when clearly necessary.

If symptoms persist for more than 3 days or you experience any other symptoms not related to the original condition discontinue treatment immediately and consult your doctor. Prolonged use, except under medical supervision, can be harmful.

If you take more tablets than you should:

In the case of accidental overdose contact your doctor or hospital immediately. Bring any remaining tablets and the package with you to show the doctor.

4. Possible Side Effects

Like all medicines, your medicine can cause side effects, although not everybody gets them. You can reduce the chances of experiencing side effects by using the minimum dose required. Elderly people are more likely to experience unwanted effects with NSAIDs, including aspirin.

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, indigestion, heartburn, diarrhoea, flatulence, constipation, ulceration of mouth, worsening of existing inflammatory bowel disease and Crohn's 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.

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.

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. 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.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. 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.

5. How to store your medicine

- Do not use this medicine after the expiry date on the blister and carton.
- Do not store above 25°C.
- Keep this medicine out of the sight and reach of children.

6. Contents of the pack and other information

What does this medicine contain?

The active substances are Aspirin and Caffeine. Your medicine contains 325 mg of Aspirin (Acetylsalicylic acid) and 15 mg of Caffeine.

The other ingredients are;

Quinoin sulfate, Microcrystalline Cellulose, Maize Starch, Calcium Stearate, Hypromellose and Macrogol.

What your medicine looks like and contents of the pack?

White capsule-shaped film coated tablets. Available in pack sizes of 12 and 24 tablets.

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, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

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