

## **Package leaflet: Information for the user**

Anadin Analgesic Film-coated Tablets Aspirin 325 mg and Caffeine 15 mg

Aspirin/Caffeine

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

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has 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 talk to a doctor if you do not feel better or if you feel worse.

### **What is 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. Content 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.
- have kidney failure.
- are pregnant or breast-feeding.
- suffer from heart disease or have high blood pressure.
- are under 16 years.
- take more than 15 mg of methotrexate a week (a medicine that could be used to treat rheumatoid arthritis, psoriasis or Chron's disease).

Do not take with OTHER aspirin or non-steroidal anti-inflammatory drugs.

**Warnings and precautions:**

Talk to your doctor, pharmacist or nurse 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).

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

Excessive intake of caffeine should be avoided.

Consumption of alcohol should be avoided.

**Other medicines and Anadin Analgesic Film-coated Tablets:**

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).

### **Pregnancy, breast feeding and fertility**

#### **Pregnancy - last trimester**

Do not take Anadin Analgesic 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 Analgesic 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 Analgesic 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

#### **Breast feeding**

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**

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

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 1-2 tablets every 4-6 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:**

Symptoms of overdose include vomiting, dehydration, tinnitus, vertigo, deafness, sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation.

In case of overdose call your doctor or hospital immediately.

**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, 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.

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, website: [www.hpra.ie](http://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**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date on the carton and blister after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What this medicine contains**

The active substances are aspirin and caffeine. Each film-coated tablet contains 325 mg of aspirin and 15 mg of caffeine.

Other ingredients: quinine 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.

#### **Marketing authorisation holder:**

Haleon Ireland Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland. This leaflet was last revised February 2025.

#### **Manufacturer:**

Haleon Italy Manufacturing S.r.l., Via Nettunense 90, Aprilia, Italy.

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