HALEON

Anadin EXTRA

CONTAINS ASPIRIN, PARACETAMOL AND CAFFEINE

Read this leaflet carefully because it contains important information for you
This medicine is available without a prescription, for you to treat a mild illness without a doctor's help. Nevertheless, you still need to use your medicine carefully to get the best results. Keep this leaflet. You may need to read it again. Ask your pharmacist if you need more information or advice. You must see a doctor if your symptoms worsen or do not improve.
If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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

Each tablet contains: 300 mg of Aspirin, 200 mg of Paracetamol and 45 mg of Caffeine.
Aspirin and paracetamol work 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, your medicine contains caffeine, which increases the pain-relieving effect of the product.
Your medicine is for effective relief from: mild to moderate pain including headache, migraine, sharp nerve pain (neuralgia), toothache, sore throat, period pains, symptomatic relief of sprains, strains, rheumatic pain, nerve pain of the lower back or legs (sciatica), lower back pain (lumbago), chronic muscle pain, sometimes with tiredness and skin sensitivity (fibrositis), muscular aches and pains, joint swelling and stiffness, influenza, feverishness and feverish colds.

2. Before you take your medicine

Please read the following information. 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 aged under 16 years, unless on the advice of a doctor.

Do not take if you:

- are allergic to aspirin, paracetamol, caffeine, or any of the other ingredients listed in this leaflet
- have or have ever had a stomach ulcer, perforation or bleeding
- suffer from haemophilia (your blood does not clot well) or from gout
- are breast-feeding.
- suffer from asthma caused by aspirin or other NSAIDs
- are in your 3rd trimester of pregnancy.

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

- suffer from asthma, allergic disease, dehydration, have a history of gout, liver or kidney disease (including alcoholic liver disease) or G-6-PD deficiency (an hereditary condition leading to low red blood cell counts).
- have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), suffer from malnutrition, chronic alcoholism or if you are taking flucloxacillin (antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when is taken together with flucloxacillin. Symptoms may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).
- are pregnant.
- Excessive intake of caffeine (e.g., coffee, tea and some canned drinks) should be avoided.
- Consumption of alcohol should be avoided.
  During treatment with Anadin Extra, tell your doctor straight away if you get a combination of these symptoms.

When taking acetylsalicylic acid, serious allergic reactions which may include chest pain and even heart attack (Kounis syndrome) have been reported (see section 4). Seek medical care immediately when you notice chest pain with allergic reactions (such as skin rashes, shortness of breath).

Taking other medicines

Anadin Extra should not be used together with other non-steroidal anti-inflammatory drugs (NSAIDs).
Please inform your doctor or pharmacist if you are taking:

- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

This medicine should also be used with caution when taking the following:

- Other NSAIDS and corticosteroids: Do not use in combination with other NSAIDs as these may increase the risk of adverse effects.
- medicines to treat blood clots (thrombolytics and anticoagulants) as there is an increased risk of bleeding.
- medicines used to treat gout (probenecid, sulfinpyrazone) as there may be an increase of aspirin in the patients plasma levels.
- medicines used to treat high blood pressure due to risk of kidney failure.
- anti-sickness medicines (metoclopramide) as it may increase the rate of absorption of aspirin.
- medicines used to treate seizures (phenytoin) as aspirin increases the serum level of phenytoin.
- medicines used to treat epilepsy and bipolar disorder (valproate) as aspirin inhibits the metabolism of valproate.
- methotrexate (to treat some kinds of cancer, arthritis or psoriasis). Use of methotrexate with aspirin, renal function should be measured.
- medicines used to treat diabetes (sulphonylureas) as aspirin can increase the hypoglycaemic effect.

- medicines used to treat indigestion (antacids) as use with this medicine may increase the excretion of aspirin.
- antidepressants (SSRIs) as there is a risk of bleeding in the abdomen.
- medicines to treat high cholesterol (cholestyramine). Paracetamol absorption is reduced.
- medicines used to treat nausea and vomiting (metoclopramide and domperidone) as paracetamol absorption is increased.
- medicines used to treat blood clots (warfarin) as there is an increased risk of bleeding.
- carbonic anhydrase inhibitors, such as acetazolamide (to treat glaucoma, seizure, or to increase urine production).

Consumption of alcohol and excessive caffeine intake should be avoided.

3. How to take your medicine

For oral administration and short term use only

Dosage: Adults, the elderly and young persons aged over 16:

The minimum effective dose should be used for the shortest time necessary to relieve symptoms. Take 2 tablets up to 4 times a day, as required. The tablets should be taken with water. Take only as much as you need to relieve your symptoms and leave at least 4 hours between each dose.

Do not take more than 8 tablets in any 24 hour period.

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

For migraine indication: not recommended for children and adolescents (under 18 years of age).

Do not take with any other paracetamol-containing products.

Do not exceed the stated dose.

If you take more tablets than you should:

Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Bring any remaining tablets 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 minimum dose required. Side effects may be more serious in elderly patients.

If you experience any of these effects then STOP taking this medicine immediately and contact your doctor or pharmacist:

The following side effects are all very rare:

- Breathing problems: Wheezing and breathing difficulties may be triggered in patients suffering from or with a previous history of asthma.
- Unexpected bleeding from the nose, gums, blood in the urine and bruising.
- Severe allergic reactions: Symptoms could include difficulty breathing, skin rash or swollen facial features.
- Serious skin reactions. Symptoms include skin reddening, blisters or rash.
- Chest pain with allergic reactions (such as skin rashes, shortness of breath); this can be a sign of a potentially serious allergic reaction (Kounis syndrome) (frequency not known).
- Liver dysfunction.

Other possible side effects

If any of the following side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist. The following side effects have Frequency "Not Known" (cannot be estimated from the available data):

- prolonged bleeding time.
- temporary hearing loss.
- fluid retention (swelling of the limbs).
- abdominal bleeding, abdominal discomfort, gastrointestinal ulceration, indigestion, nausea and vomiting.
- Reye's syndrome.
- Kidney dysfunction.
- Dizziness and headaches.
- Fluttering heartbeat.
- Insomnia, restlessness, anxiety, irritability and nervousness.
- Metabolic acidosis (serious condition that can make blood more acidic, see Section 2).

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 shown on the end of the carton.
- Do not store above 25ºC.
- Keep out of sight and reach of children.

6. Further Information

What does this medicine contain?

The active substances are Aspirin, Paracetamol and Caffeine. Your medicine contains 300 mg of Aspirin, 200 mg of Paracetamol and 45 mg of Caffeine.

Each tablet also contains: maize starch, microcrystalline cellulose (E460), hydrogenated vegetable oil, hypromellose (E464), macrogol, pregelatinised starch and povidone.

Your medicine is available in packs containing 8, 12, 16 or 32 tablets. The 32 tablet pack is available only from your pharmacy. Not all pack sizes may be marketed.

Manufacturer: Haleon Italy Manufacturing S.r.l., Via Nettunense, 90 - 04011 Aprilia (LT), Italy.
Marketing Authorisation Holder: Haleon UK Trading Limited, Weybridge, KT13 0NY, U.K.
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