

Anadin EXTRA

300mg/200mg/45mg Tablets

HALEON

CONTAINS ASPIRIN, PARACETAMOL AND CAFFEINE

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 pharmacist. If you get any side effects, talk to your pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

IN THIS LEAFLET:

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

Each tablet contains: Aspirin, Paracetamol and 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. What you need to know 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
- suffer from asthma caused by aspirin or other NSAIDs
- are breast-feeding
- are in your 3rd trimester of pregnancy.

Warnings and Precautions

Talk to your 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.
- Consumption of alcohol and excessive caffeine intake should be avoided.

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 (antibiotics), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

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 treat 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.
- medicines used to treat rheumatoid arthritis (methotrexate). 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.
- Consumption of alcohol and excessive caffeine intake should be avoided.

Pregnancy and breastfeeding

Talk to your doctor before taking this medicine if you are pregnant.

Do not take this medicine if you are in the 3rd trimester of pregnancy or if you are breastfeeding.

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 have Frequency "Not Known" (cannot be estimated from the available data):

- 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.
- 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.

- 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 25°C.
- Keep out of sight and reach of children.

6. Contents of the pack and other information

What your medicine contains The active substances are Aspirin, Paracetamol and Caffeine. Each tablet contains 300 mg of Aspirin, 200 mg of Paracetamol and 45 mg of Caffeine. The other excipients are: maize starch, microcrystalline cellulose (E460), hydrogenated vegetable oil, hypromellose (E464), macrogol, pregelatinised starch and povidone. Your medicine is white, capsule shaped tablet with a break bar on one side, with the letter 'A' and 'E' printed on the other. Your medicine is available only from your pharmacy in packs containing 24 or 32 tablets. Not all pack sizes may be marketed.

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