

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 in late stages of pregnancy
- are breast-feeding

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

- suffer from asthma, allergic disease, dehydration, liver or kidney disease (including alcoholic liver disease) or G-6-PD deficiency (an hereditary condition leading to low red blood cell counts).

Taking other medicines

Do not use this medicine if you are taking medicines that reduce blood clotting (warfarin) or for treatment of gout (sulphinpyrazone).

Talk to your doctor or a pharmacist if you are taking any water tablets, certain cancer treatments (methotrexate), treatment for diarrhoea caused by gall bladder disease, or a lipid lowering drug (cholestyramine), some antibiotics (chloramphenicol), anti-sickness treatments (metoclopramide, domperidone), steroid hormones (corticosteroids), treatments for epilepsy (phenytoin, valproate), blood pressure lowering treatments (ACE inhibitors), antacids, treatments for leg pain when walking (cilostazol), mifepristone, treatments for gout (probenecid), treatment of obesity (sibutramine), treatment of some depressive disorders (SSRIs, venlafaxine), and some asthma treatments (zafirlukast) or other NSAIDs.

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.

3. How to take your medicine (continued)

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:

- Stomach ulceration or perforation: Symptoms could include severe abdominal pain, vomiting blood (or liquid with what looks like coffee grounds), blood in the faeces (stools/motions) or passing black stools.
- Severe allergic reactions: Symptoms could include difficulty breathing, skin rash or swollen facial features.
- Breathing problems: Wheezing and breathing difficulties may be triggered in patients suffering from or with a previous history of asthma
- Very rare cases of serious skin reactions have been reported. Symptoms could include skin reddening, blisters or rash

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.

- Occasionally the blood does not clot well, which may result in easy bruising or bleeding.
- Rarely, a severe reduction in the number of white blood cells, which makes infections more likely.
- High caffeine intake can result in tremor (shaking) and palpitations (uncomfortable feeling in the chest caused by fluttering heartbeat). Aspirin may trigger gout in people prone to it.
- Other side effects include indigestion, heartburn, feeling or being sick, changes in skin colour, shortness of breath, and a runny nose.

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. 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. 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, hydroxypropyl methylcellulose (E464), polyethylene glycol, 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.

Who makes this medicine?

Your medicine is manufactured by: Pfizer Consumer Manufacturing Italy S.r.l., Via Nettunense, 90 - 04011 Aprilia (LT), Italy. The Marketing Authorisation Holder is: Pfizer Consumer Healthcare Ltd, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK.

If you have any queries or comments about your medicine or any other Pfizer Consumer Healthcare Ltd products, ring our customer Careline or e-mail us at carelineUK@pfizer.com