

## Patient Information Leaflet

**ANADIN EXTRA FILM-COATED TABLETS****Aspirin 300 mg****Paracetamol 200 mg****Caffeine 45 mg**

The full name of this medicine as listed above has been abbreviated throughout the leaflet for ease of reference to 'Anadin Extra.'

**Package leaflet: Information for the user.****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 Anadin Extra is and what it is used for
2. What you need to know before you take Anadin Extra
3. How to take Anadin Extra
4. Possible side effects
5. How to store Anadin Extra
6. Content of the pack and other information

**1. What Anadin Extra is and what it is used for**

Each film-coated tablet contains aspirin (acetylsalicylic acid) 300mg, paracetamol 200mg and caffeine 45mg. 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, the tablets contain caffeine, which increases the pain relieving effect of the product.

Anadin Extra is for the treatment of mild to moderate pain including, headache, period pain, toothache, sore throat, symptoms of influenza, joint swelling & stiffness, feverishness and colds, muscular aches and pains, rheumatic pain, and neuralgia.

**2. What you need to know before you take Anadin Extra**

Please read the following information. There is a possible association with aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease which 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, paracetamol, caffeine, other NSAIDs or any of the other ingredients of this medicine (listed in section 6).
- have or have ever had a stomach ulcer, perforation or bleeding.

## Patient Information Leaflet

- suffer from bleeding disorders e.g. haemophilia, or are taking medicines that thin the blood/prevent blood clots (e.g. Warfarin).
- are in the last trimester of pregnancy or breast-feeding.
- suffer from heart disease.
- are under 16 years of age.
- suffer from severe kidney or liver problems.

## Warnings and Precautions

### **Talk to a pharmacist or your doctor before taking this medicine if you:**

- are taking **any** other medicines including medicines containing aspirin or paracetamol,
- suffer from inflammatory bowel disease, blood clotting problems, asthma, or allergic disease.
- suffer, or have suffered from gastrointestinal bleeding, ulceration or perforation.
- are elderly. Elderly people are more likely to experience unwanted side effects with NSAIDs (including Aspirin) especially gastrointestinal bleeding or perforation.
- have a history of gastrointestinal disease (ulcerative colitis, crohn's disease) as your condition may worsen, if taking NSAIDs.
- have rheumatoid arthritis.
- have had an ulcer.
- are hypersensitive, as aspirin may induce asthmatic attacks in hypersensitive patients
- have a history of stomach or intestinal problems, particularly if elderly, you should report any unusual stomach or bowel symptoms to your doctor especially if you have vomited blood, or have had a bloody bowel movement, or have black, tarry stools.
- have intracranial haemorrhage (bleeding in the skull) or a tendency to bleed in general as NSAIDs may interfere with platelet function.
- are pregnant.
- have glucose-6-phosphate dehydrogenase (G-6-PD) deficiency (a hereditary condition leading to low red blood cell counts).
- suffer from kidney, heart or liver disease (particularly non-cirrhotic liver disease). Caution is required as kidney function may be impaired if taking NSAIDs.
- are trying to become pregnant as NSAIDs may impair female fertility although this is reversible on withdrawal of treatment.
- suffer from high blood pressure and/or heart failure as fluid retention and swelling has been reported during treatment.

Anadin Extra tablets should be discontinued at the first appearance of skin rash, skin lesions, blisters or any other sign of hypersensitivity.

## **Other medicines and Anadin Extra**

- Tell your doctor or pharmacist if you are taking other medication, especially water tablets, anticonvulsants (e.g. phenytoin or valproate), medicines for cancer or rheumatoid arthritis (e.g. methotrexate), lithium, chloramphenicol, medicines for gout (e.g. probenecid), digoxin, aminoglycosides, (a type of antibiotic), medicines for organ rejection after transplantation (e.g. cyclosporin, tacrolimus), medicines for diabetes, corticosteroids (e.g. prednisolone), medicines for high blood pressure (e.g. diuretics and ACE-inhibitors), medicines for pain and inflammation (e.g. medicines such as paracetamol, ibuprofen, and steroids, medicines for treatment of depression called selective serotonin reuptake inhibitors (SSRIs), a lipid lowering drug (cholestyranine or anti-sickness treatments (metoclopramide, domperidone)).

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

## Patient Information Leaflet

OTC medicines). Stop taking the product if you experience unusual abdominal symptoms or gastrointestinal bleeding. Prolonged use without medical supervision could be harmful.

Use when clearly necessary.

### **Pregnancy, breastfeeding and fertility:**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### **Pregnancy:**

Do not take Anadin Extra if you are pregnant or planning to have a baby, unless on the advice of a doctor. It is particularly important not to take Anadin Extra during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.

Anadin Extra contains caffeine, it is advised to limit your caffeine intake (less than 200 mg per day) during pregnancy as too much could harm your unborn child.

#### **Breast-feeding**

Aspirin appears in breast milk therefore do not breastfeed while taking this medicine due to the possible risk of Reye's syndrome to the infant. Caffeine also appears in the breast milk which may cause irritability and poor sleeping patterns in infants.

#### **Fertility**

Taking medicines containing aspirin may make it more difficult to become pregnant. This effect is reversible once you stop taking the medicine

### **3. How to take Anadin Extra**

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

For oral administration and short term use only.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

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

The minimum effective dose should be used for the shortest time necessary to relieve symptoms.

Take 1-2 tablets with a drink of water. Repeat every 4 hours as required.

Do not take more than 6 tablets in 24 hours.

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

Do not take with any other paracetamol-containing products.

Do not exceed the stated dose.

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 a pharmacist or your doctor.

#### **If you take more tablets than you should:**

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of 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.

## Patient Information Leaflet

You can reduce the chances of experiencing side effects by using the minimum dose required. If you experience any of the following serious side effects STOP taking this medicine immediately and contact your doctor or pharmacist;

- **Skin:** Rashes, itching fluid build-up in tissue below the skin and the mucous membranes which appear as spots or lumps, blood blisters and occasional flaking of the skin or rarely, changes in skin colour. Very rare cases of serious skin reactions have been reported. Symptoms could include skin reddening, blisters or rash.
- **Allergic reactions:** Difficulty in breathing, skin rash, swollen facial features or a runny nose. High caffeine intake can result in tremor or palpitations. Aspirin may cause gout in susceptible individuals. Side effects may be more serious in elderly patients.
- **Breathing:** Shortness in breath, wheezing, breathing difficulties may be triggered in patients suffering from or with previous history of asthma.
- **Gastro-intestinal:** Abdominal pain, nausea, indigestion, heartburn, diarrhoea, flatulence, constipation, ulceration of the 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.
- **Blood:** The blood does not clot well which may result in bruising and 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.

### 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 HPRAPharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Anadin Extra

- Do not use this medicine after the expiry date which is stated on the carton and foil < EXP: MM YYYY >. The expiry date refers to the last day of the month.
- Do not store above 25°C.
- Keep this medicine out of sight and reach of children.
- Store in the original package and protect from moisture.

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. Content of the pack and other information

### **What does this medicine contain?**

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 ingredients are maize starch, microcrystalline cellulose, hydrogenated vegetable oil (stertex), pregelatinised starch and povidone. The tablet coating contains hypromellose (methocel E5 and E15), and macrogol (carbowax 3350).

### **What Anadin Extra looks like and contents of pack?**

Patient Information Leaflet

The tablets are white in a capsule shape with a break bar on one side and with 'A' and 'E' debossed on the other side. Anadin Extra is available in pack sizes of 6, 8, 12 and 24 tablets.

Not all pack sizes may be marketed.

**Manufacturer:** Pfizer Consumer Manufacturing Italy S.r.l., Via Nettunense 90, Aprilia, Italy.

**Marketing Authorisation Holder:** Pfizer Healthcare Ireland, Citywest, Dublin 24.

This leaflet was last revised in October 2019.

PA 822/166/1