Aspirin (Acetylsalicylic acid) Gastro-resistant Tablets 75mg 28pk and 56pk PIL - UK

• are arthritic, have hayfever, nasal polyps or other chronic respiratory disorders; acetylsalicylic acid may induce an asthma attack
• have ever had gout
• have heavy menstrual periods.

You must immediately seek medical advice, if your symptoms get worse or if you experience severe or unexpected side effects e.g. unusual bleeding symptoms, serious skin reactions or any other sign of sensitivity (see section “Possible side effects”).

Inform your doctor if you are planning to have an operation (even a minor one, such as tooth extraction) since acetylsalicylic acid is blood-thinning there may be an increased risk of bleeding.

Acetylsalicylic acid may cause Reye’s syndrome in children. Reye’s syndrome is a very rare disease which affects the brain and liver and can be life threatening. For this reason, Aspirin tablets should be given to children under 16 years, unless on the advice of a doctor.

You should take care not to become dehydrated (you may feel thirsty with a dry mouth) since the use of acetylsalicylic acid at the same time may result in deterioration of kidney function.

This medicinal product is not suitable as a pain killer or fever reducer.

The effect of treatment may be influenced if acetylsalicylic acid is taken at the same time as some other medicines for:
• Thrombosis (the prevention of clots (e.g. warfarin, heparin, clopidogrel))
• Rejection of organ transplantation (e.g. ciclosporin, tacrolimus)
• High blood pressure (e.g. diuretics and ACE-inhibitors)
• Regulation of the heat (diabetes)
• Mannic depressive illness (lithium)
• Pains in the stomach (e.g. NSAIDs such as ibuprofen, or steroids)
• Gout (e.g. probenecid, colchicine)
• Depression (selective serotonin re-uptake inhibitors—SSRIs such as paroxetine) or panic attacks
• Rehabilitation after replacement therapy when the adrenal glands or pituitary gland have been destroyed or removed, or to treat inflammation, including rheumatoid arthritis, or thinning of the blood/prevention of clots (e.g. warfarin, heparin, clopidogrel)

Taking Aspirin tablets with food and drink

Drinking alcohol may possibly increase the risk of gastrointestinal bleeding and prolong bleeding time.

Pregnancy and breast-feeding

Ask your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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**4. Possible side effects**

If you take more Aspirin tablets than you should:

- **Uncommon side effects** (may occur in 1 to 10 out of 10,000 patients):
  - Severe bleeding in the stomach or intestines, brain haemorrhage; altered number of blood cells
  - Nausea and vomiting
  - Cramps in the lower respiratory tract, asthma attack

- **Common side effects** (may occur in 10 to 100 out of 10,000 patients):
  - Sudden swelling of your ears, breathing problems, cramps in the lower respiratory tract, asthma attack

- **Rare side effects** (may occur in 1 to 10 out of 10,000 patients):
  - Severe bleeding in the stomach or intestines, brain haemorrhage; altered number of blood cells
  - Nausea and vomiting
  - Cramps in the lower respiratory tract, asthma attack

Blood, blood in your vomit or urine, or severe joint pain and redness and swelling (severe allergic reaction)

- **Severe side effects** (may occur in 1 to 100 out of 10,000 patients):
  - Impaired liver function
  - Impaired kidney function
  - Prolonged bleeding time
  - Severe bleeding in the stomach or intestines, brain haemorrhage; altered number of blood cells
  - Sudden swelling of your ears, breathing problems, cramps in the lower respiratory tract, asthma attack

If you have any further questions on the use of this product, ask your doctor or pharmacist.

**6. Further information**

**What Aspirin tablets look like and contain**

The active substance is acetylsalicylic acid. Each gastro-resistant tablet contains 75mg of acetylsalicylic acid.

- The other ingredients are:
  - Tablet core: microcrystalline cellulose, maize starch, coloydithium sesilica, stearic acid; film-coating: methacrylic acid – ethyl acrylate copolymer (1:1), polyethylene glycol 40, sodium lauryl sulphate, triethyl citrate, talc.

**What Aspirin tablets should be used with caution in**

- Children
- Elderly

**Prevention of cardiovascular problems in**

- Prevention of strokes:
  - The recommended dose is 75-160mg once daily.

- Prevention of heart attacks:
  - The recommended dose is 75-160mg once daily.

**How to store**

- Keep out of the reach of children. Store below 25°C.
- Keep the original package in order to protect from moisture.
- Do not take any further questions on the use of this product, ask your doctor or pharmacist.

**Possible side effects**

- Uncommon side effects:
  - Rash
  - Runny nose
  - Asthma attack

**What Aspirin tablets contain**

- Acetylsalicylic acid should not be administered to children and adolescents younger than 16 years, unless prescribed by a doctor. (Take special care with Aspirin tablets.)
- The tablets should be swallowed whole with sufficient fluid (1/2 glass of water). The tablets cannot be crushed, broken or chewed.
- The tablets can be taken with or without food, but they are therefore not be crushed, broken or chewed.
- The tablets are oval, white, biconvex film-coated tablets, measuring 9.2 x 5.2 mm.
- The tablets do not contain any gluten, lactose, sugar or colorings/plates.
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**Technical Approval**

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