

# Package leaflet: Information for the user

## Aspirin 75mg Gastro-resistant Tablets

### Aspirin

#### 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 this leaflet or as your doctor, pharmacist or nurse have 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 talk to a doctor if you do not feel better or if you feel worse after 3 days.

The name of your medicine is Aspirin 75mg Gastro-resistant Tablets. In the rest of this leaflet, it is called Aspirin Tablets.

#### What is in this leaflet

1. What Aspirin Tablets are and what they are used for
2. What you need to know before you take Aspirin Tablets
3. How to take Aspirin Tablets
4. Possible side effects
5. How to store Aspirin Tablets
6. Contents of the pack and other information

#### 1. What Aspirin Tablets are and what they are used for

The active ingredient in your medicine is Aspirin. Aspirin belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Aspirin thins the blood which helps to reduce the likelihood of having a heart attack. These tablets have been specially coated (enteric coating) to help minimise stomach upset and feeling sick (sometimes experienced as side effects of these tablets – see Section 4).

Aspirin Tablets are used to reduce the likelihood of further heart attacks or strokes in patients with a previous history of these conditions, when taken regularly. They can also be taken following bypass surgery. Due to the slow release of Aspirin, this product is not useful for relieving acute pain.

#### 2. What you need to know before you take Aspirin Tablets

**There is a possible association between 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 aged under 16 years, unless on the advice of a doctor.**

#### Do not take Aspirin Tablets if you:

- are allergic (hypersensitive) to aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen, or any of the other ingredients of this medicine (listed in section 6). Symptoms may include rhinitis (runny nose), swollen face, mouth or tongue, itchy rash or asthma attack
- have or have had a stomach ulcer
- have a condition where your blood does not clot properly (e.g. haemophilia)
- have or have had gout
- are in the last three months of your pregnancy, you must not use higher doses than 100mg per day (see section "Pregnancy, breast-feeding and fertility").

#### Warnings and Precautions

##### Talk to your doctor, pharmacist or nurse before taking Aspirin Tablets

- if you have asthma, or suffer from allergies
- if you have problems with your heart, kidneys or liver
- if you are taking medicines to thin your blood such as warfarin
- if you are dehydrated
- if you have nasal polyps (inflamed swellings inside the nose)
- if you suffer from indigestion (dyspepsia)
- if you have an infection
- if you have high blood pressure
- if you have a lack of glucose 6-phosphate dehydrogenase (G6PD)
- if you are elderly
- if you are diabetic.

You should let your doctor know you are taking aspirin tablets, particularly if you are going to have an operation, as you may need to stop taking your tablets several days before the operation.

Your blood, kidney and liver should be monitored during prolonged use of aspirin as blood, kidney and liver disorders may develop.

#### Other Medicines and Aspirin Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The following medicines can affect or be affected by Aspirin:

- **Mifepristone** (used to terminate pregnancy). You should not take aspirin until eight to twelve days after mifepristone. If taken with aspirin this medicine may not be as effective
- **Non-steroidal anti-inflammatory (NSAIDs)** e.g. ibuprofen or diclofenac sodium (used for pain relief and to treat inflammation) or **Corticosteroids** e.g. prednisolone and betamethasone (used to treat allergy or inflammation): if taken with aspirin you may have more severe side effects e.g. increased risk of bleeding or ulcers in the stomach. If you suddenly stop taking corticosteroids you may develop aspirin poisoning
- **Metoclopramide** (used to treat nausea and vomiting): it may increase the effect of aspirin
- **Adsorbents** e.g. kaolin (for diarrhoea) and **Antacids** e.g. aluminium hydroxide and magnesium carbonate (used to treat indigestion): these medicines may reduce the effect of aspirin
- **Medicines known to affect the clotting of your blood:** if you take one of these medicines below with aspirin you may increase the likelihood of bleeding
- **Coumarins** e.g. warfarin, phenindione, streptokinase or heparins (blood thinning medicines)
- **Clopidogrel and ticlopidine** (used to prevent strokes and heart attacks)
- **Calcium channel blockers** such as verapamil, used to treat high blood pressure
- **ACE Inhibitors or Angiotensin-II Receptor Antagonists** e.g. captopril, enalapril maleate, valsartan, losartan (used to lower high blood pressure) taken with aspirin these medicines may not be as effective and you may suffer from kidney problems
- **Antidepressants** (used to treat depression) e.g. Selective Serotonin Re-uptake Inhibitors (SSRIs) (such as venlafaxine): if taken with aspirin you may increase the likelihood of bleeding
- **Medicines to control epilepsy** e.g. phenytoin and valproate: aspirin may increase the effect of these medicines. If you take sodium valproate with aspirin you may increase the likelihood of bleeding
- **Zafirlukast** (used to prevent or treat asthma)
- **Spironolactone** (diuretic) water tablets, **Probenicid** or **Sulfinpyrazone** (used to treat gout) and diuretics used to treat high blood pressure: if taken with aspirin these medicines may not be as effective. Phenylbutazone may reduce the effect of aspirin
- **Methotrexate** (used in the treatment of rheumatoid arthritis, Crohn's disease and cancer) or **Carbonic anhydrase inhibitors** e.g. acetazolamide (used in the treatment of glaucoma, epilepsy and excess water retention): if taken with aspirin the side effects of these medicines may become more severe
- **Thiopental** (used as an anaesthetic)
- **Gold compounds** (used to treat rheumatoid arthritis)
- **Insulin** and other drugs used to treat diabetes
- **Sulphonamides**, such as sulphamethoxazole, used to treat infections
- **Vitamin C**
- **Cilostazol** (for leg pain that occurs when walking due to poor circulation): the dose of aspirin should not be greater than 80mg a day
- **Metamizole** (substance to decrease pain and fever) may reduce the effect of acetylsalicylic acid on platelet aggregation (blood cells sticking together and forming a blood clot), when taken concomitantly. Therefore, this combination should be used with caution in patients taking low dose aspirin for cardioprotection.

Aspirin may affect the results of thyroid function tests.

## Aspirin Tablets with alcohol

Avoid drinking alcohol while taking Aspirin.

## Pregnancy, breast-feeding 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.

Taking this medicine may impair the fertility in women. This effect is reversible on stopping the medicine.

If you continue or start treatment with Aspirin during pregnancy per instruction of the physician, then use Aspirin as advised by your doctor and do not use a higher dose than is recommended.

## Pregnancy - last trimester

Do not take Aspirin higher than 100mg per day if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

If you take Aspirin at low doses (up to and including 100mg per day), you need strict obstetric monitoring as advised by your doctor.

## Pregnancy - first and second trimester

You should not take Aspirin during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Aspirin can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligocephalism) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

## 3. How to take Aspirin Tablets

For oral use.

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

### Adults (including the elderly and children over 16 years):

The recommended dose for long-term use is one or two tablets once daily. The tablets should be swallowed whole with water. Do not chew, crush or break the tablets. In some circumstances your doctor may advise a higher dose of up to four tablets daily.

Take the tablets with or immediately after food to reduce the risk of getting stomach and bowel irritation.

Do not take more medicine than the label tells you to.

If you do not get better for more than three days, talk to your doctor.

### Children and Adolescents

Do not give to children under 16 years of age unless your doctor tells you to.

### If you take more Aspirin Tablets than you should

If you take more Aspirin Tablets than your doctor has prescribed contact your nearest hospital casualty department or doctor immediately. Take the medicine or this leaflet with you to show the doctor.

Symptoms of an overdose include vomiting, dehydration, tinnitus, vertigo, headache, nausea, dizziness, restlessness, heart failure, breathing failure, deafness, sweating, warm extremities with racing pulse, increased breathing rate and hyperventilation.

### If you forget to take Aspirin Tablets

- If you forget to take a dose, do not worry. Take the next dose when it is due
- Do not take a double dose to make up for a forgotten dose.

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

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### If you experience the following side effects while taking your medicine, you

## should stop taking your tablets and tell your doctor straight away:

- allergic reaction (hypersensitivity) which may include lumpy skin or hives, skin rash, swelling of eyelids, face, lips, mouth or tongue, or sudden wheeziness, or induce or worsen asthma attacks
- you suffer from severe or persistent indigestion, stomach upset or pain, you may develop ulcers or bleeding from the stomach which can cause severe stomach pain, bloody or black tarry stools or vomiting blood
- Signs of bleeding in the brain (sudden severe headache, nausea, vomiting, dizziness, loss of balance, weakness in the limbs).

## Other possible side effects:

- stomach upset and feeling sick
- an increased tendency to bleed
- anaemia and other blood disorders
- mouth ulcers
- you may succumb to infections more easily
- you may bruise more easily
- slight blood loss which may result in iron-deficiency anaemia during long term use
- diarrhoea
- blood in the urine
- Stevens-Johnson syndrome (fever, rash, sore mouth and eyes, joint and muscle aches)
- severe skin problem with shedding of upper layer.

Some patients have developed liver problems (particularly with high doses).

## 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](http://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 Aspirin Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label.

Do not store above 25°C. Store in the original container in order to 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. Contents of the pack and other information

### What Aspirin Tablets contain

The active substance is aspirin. Each gastro-resistant tablet contains 75mg of aspirin. The other ingredients are potato starch, calcium hydrogen phosphate, microcrystalline cellulose, talc, methacrylic acid copolymer (also contains sodium lauryl sulfate and polysorbate), macrogol and simethicone.

### What Aspirin Tablets look like and contents of the pack

Aspirin Gastro-resistant Tablets are white, circular tablets, which are plain on both sides. Each pack of Aspirin Gastro-resistant Tablets contain 28, 32, 56 or 84 tablets. Packs of 32, 56 or 84 tablets are only available from your pharmacist. Not all pack sizes are marketed.

### Marketing Authorisation Holder

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

### Manufacturer

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK

### Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	Reference number
Aspirin 75mg Gastro-Resistant Tablets	29831/0014

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