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Information for the user PILXXXX

Aspirin 75 mg Gastro-resistant tablets

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription to treat minor conditions. However, you still need to take it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- 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.

What this medicine is for

This medicine belongs to a group of medicines called antiplatelet agents that help prevent blood cells sticking together. It can be used to help prevent further heart attacks and strokes in patients who have had a history of these conditions. It can also be used after by-pass surgery. It should not be used for pain relief or to reduce fever.

Before you take this medicine

This medicine can be taken by adults aged 16 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first. If you are taking this medicine for the first time, talk to your doctor to make sure it is suitable for you.

Do not take:

- If you are allergic to aspirin or any of the other ingredients of this medicine (listed in section "What is in this medicine").
- If you are allergic to other salicylates or nonsteroidal anti-inflammatory drugs (NSAIDs). NSAIDs are often used for arthritis or rheumatism and pain
- If you have had an asthma attack or swelling of some parts of the body (e.g. face, lips, throat or tongue (angioedema) after taking salicylates or NSAIDs)
- If you have, or ever had, an ulcer** in your stomach or intestine
- If you have, or ever had, a bleed in your stomach or intestines** (you may have been sick and it contained blood or dark particles that looked like coffee grounds and/or passed blood in your stools or passed black tarry stools)
- If you have had other types of bleeding** like a stroke
- If you have a blood clotting disorder** (e.g. haemophilia or thrombocytopenia) or are taking medicines to thin your blood
- If you are taking more than 15 mg per week of methotrexate**
- If you have gout**
- If you have severe kidney or liver problems**
- If you are in your last 3 months of pregnancy;** you must not use higher doses than 100mg per day (see section "Pregnancy, breast-feeding and fertility")

Talk to your pharmacist or doctor:

- If you have asthma or other allergic disease (have hay fever, nasal polyps or other chronic respiratory diseases) aspirin may induce asthma attack
- If you have other kidney, liver or heart problems (see "Do not take")
- If you have high blood pressure (your doctor may want to monitor you more closely)
- If you are dehydrated
- If you have a condition called glucose-6-phosphate dehydrogenase deficiency
- If you are elderly (your doctor may want to monitor you more closely)
- If you are pregnant and in the first 6 months of pregnancy
- If you have or have ever had problems with your stomach or small intestine
- If you have heavy menstrual periods.
- have ever had gout

Other important information

If you have surgery (even minor surgery such as tooth extraction) or any blood tests, tell your doctor or hospital staff that you are taking this medicine. If you get any unusual bleeding symptoms, talk to your doctor.

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 under the age of 16 years unless on the advice of a doctor.

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 serious allergy (see section "Possible side effects").

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

If you drink alcohol (wine, beer, spirits) when you are taking these tablets, it may make your stomach more sensitive to aspirin.

Other medicines and Aspirin Tablets

Before you take these tablets, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time, particularly the following: The effects of treatment may be influenced if aspirin is taken at the same time as other medicines for:

- Thinning of the blood/prevention of clots (e.g. warfarin, heparin, phenindione and clopidogrel)
- Medicines for depression
- Methotrexate (for cancer, skin problems, rheumatic problems, Crohn's disease)
- Ciclosporin or tacrolimus (given after transplant surgery, or psoriasis or rheumatism)
- Other non-steroidal anti-inflammatory medicines, like ibuprofen (to relieve pain, reduce swollen joints, muscles and ligaments)
- Use as hormone replacement therapy when the adrenal glands or pituitary gland have been destroyed or removed, or to treat inflammation, including rheumatic diseases and inflammation of the intestines (corticosteroids).
- Phenytoin and sodium valproate (for epilepsy)
- Medicines for diabetes, such as glibenclamide, glipizide (sulphonylureas) or insulin
- Medicines used to treat high blood pressure like ACE inhibitors (e.g. ramipril, captopril)
- Water tablets (diuretics e.g. spironolactone and acetazolamide)
- Probenecid and sulfapyrazone (for gout)
- Lithium (for severe mental problems)
- Medicines for heart problems (e.g. digoxin)
- Acetazolamide (for glaucoma)
- 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.

Before taking 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 medicine you may have bought).

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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.

Pregnancy

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 100 mg 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 100 mg 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 (oligohydramnios) 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.

Breast-feeding

Breast-feeding women should not take Aspirin unless advised by their doctor.

Stevens-Johnson syndrome or Lyell's syndrome

- Allergic skin reactions such as itchy, red, raised rash (which can sometimes be severe and include peeling, blistering and lesions of the skin)
- Unusual bleeding which may cause blood in the urine, coughing up blood or a stroke due to bleeding in the brain

If you get any of the following side effects see your pharmacist or doctor:

Common side effects (may affect 1 to 10 people in 100)

- Heartburn
- Increased tendency for bleeding

Uncommon side effects (may affect 1 to 100 people in 1000)

- Runny nose, breathlessness
- Hives

Rare side effects (may affect 1 to 1000 people in 10,000)

- Feeling sick, being sick, stomach irritation and pain
- Difficulty in breathing, asthma attacks
- Inflammation of blood vessels
- Heavy periods
- Unusual bruising, or infections such as sore throats - this may be a sign of very rare changes in the blood

Side effects with unknown frequency (cannot be estimated from available data)

- Increased bleeding time, e.g. when you have a nose bleed, bleeding gums (if bleeding is severe or lasts for a long time, talk to your doctor straight away)
- Blood problems such as anaemia
- Headache, feeling dizzy (vertigo)
- Reduced hearing, ringing in the ears
- Diarrhoea, ulcers and perforation in the stomach or gut
- High levels of uric acid in the blood
- Water retention
- Kidney problems including kidney stones
- Liver problems

How to take this medicine

Check the foil is not broken before use. If it is, do not take that tablet.

Age	How many to take	How often to take
Adults of 16 years and over	One or two	Once a day

The usual dose for the long-term management of cardiovascular disease (disease affecting the blood supply to the heart) or cerebrovascular disease (disease affecting the blood supply to the brain) or following by-pass surgery is 1 to 2 tablets, once a day.

In some cases your doctor may advise you to take more tablets. In this case follow your doctor's instructions.

Swallow the tablet whole with water. Do not cut, chew or crush the tablet.

Do not give to children under 16 years, unless your doctor tells you to. Do not take more than the amount recommended above.

If you take too many tablets: Talk to a doctor straight away.

Possible side effects

Most people will not have problems, but some may get some.

If you get any of these serious side effects, stop taking the tablets. See a doctor at once:

- You are sick and it contains blood or dark particles that look like coffee grounds
- Pass blood in your stools or pass black tarry stools
- Difficulty in breathing, asthma, swelling of the face, neck, tongue or throat, runny nose (severe allergic reactions) This could be erythema multiforme,

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