

Aspirin 300mg Gastro-resistant Tablets

(acetylsalicylic acid)

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Aspirin 300mg Gastro-resistant Tablets but will be referred to as Aspirin 300mg throughout the rest of this leaflet.

What is in this leaflet:

- 1 What Aspirin 300mg is and what it is taken for
- 2 What you need to know before you take Aspirin 300mg
- 3 How to take Aspirin 300mg
- 4 Possible side effects
- 5 How to store Aspirin 300mg
- 6 Contents of the pack and other information

1 What Aspirin 300mg is and what it is taken for

Aspirin 300mg contains aspirin. Aspirin is used:

- as an anti-inflammatory analgesic which can relieve pain and swelling
- to bring down high body temperatures
- to prevent recurrence of heart attacks or strokes by thinning the blood. If someone who has previously had a heart attack or stroke takes Aspirin 300mg regularly, it reduces the risk of a blood clot occurring in the heart or brain. This can prevent further heart attacks or strokes.

If you take aspirin in high doses or over a long period of time, it can irritate your stomach lining. To prevent stomach irritation, these tablets have a special coating (called enteric) so that the aspirin is not released until it has passed through the stomach.

Aspirin is released slowly from these tablets, so Aspirin 300mg is not suitable for the short-term relief of pain, such as headaches or toothache.

2 What you need to know before you take Aspirin 300mg

Do not take Aspirin 300mg:

- if you are allergic to aspirin or any of the other ingredients in this medicine (listed in section 6)
- if you have ever had the problem of your blood not clotting properly or suffer from any bleeding problems
- if you have had a cerebral haemorrhage (a type of stroke caused by bleeding in your brain)
- if you are in the last three months of your pregnancy or are breastfeeding (see section "Pregnancy, breast-feeding and fertility")
- if you have ever had an ulcer in your stomach or small intestine.

Warnings and precautions

Before you take Aspirin 300mg tell your doctor if you:

- think you may be dehydrated (you may feel thirsty with a dry mouth)
- have trouble with your kidneys or liver
- have high blood pressure
- have been told you have a lack of glucose-6-phosphate dehydrogenase (G6PD)
- are asthmatic, aspirin may induce an asthma attack
- have ever had inflammatory bowel disease (Crohn's or ulcerative colitis)
- have or have had gout.

Children

When given to children aspirin may cause Reye's syndrome. 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.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Aspirin 300mg.

Other medicines and Aspirin 300mg

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The effect of treatment may be influenced if aspirin is taken at the same time as some other medicines for:

- thinning of the blood/prevention of clots (e.g. warfarin)
- organ rejection after transplantation (e.g. ciclosporin, tacrolimus)
- high blood pressure (e.g. diuretics and ACE-inhibitors)
- pain and inflammation (e.g. anti-inflammatory medicines such as ibuprofen, or steroids)
- gout (e.g. probenecid)
- cancer or rheumatoid arthritis (e.g. methotrexate).
- 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.

These other medicines may also affect, or be affected by aspirin:

- insulin or any other drug to treat diabetes
- corticosteroids (used 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)
- phenytoin or sodium valproate (used to control epilepsy)
- sulphonamides (a type of antibiotic) such as sulfamethoxazole
- medicines such as acetazolamide used to treat glaucoma
- an anaesthetic called thiopental
- gold, which is sometimes used in rheumatic conditions
- antiplatelet drugs (such as clopidogrel and dipyridamole)
- selective serotonin re-uptake inhibitors (SSRIs) for depression such as sertraline or paroxetine
- antacids (indigestion medicine). Do not take antacids just before or after taking Aspirin 300mg as they may cause the aspirin to be released too soon.

Aspirin with alcohol

If you consume excessive amounts of alcohol whilst taking Aspirin 300mg, you may increase the risk of causing bleeding in your stomach or intestines.

Tell your doctor that you are taking Aspirin 300mg if you are to have a urine test, as it can sometimes interfere with the results.

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 other medicines you may have bought).

Pregnancy, breast-feeding and fertility

Pregnant women should not take aspirin during pregnancy unless advised by their doctor.

If you continue or start treatment with Aspirin 300mg during pregnancy per instruction of the physician, then use Aspirin 300mg as advised by your doctor and do not use a higher dose than is recommended.

Pregnancy - last trimester

You must not take Aspirin 300mg if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. Regular or high dose aspirin therapy during late pregnancy can cause serious complications in the mother or baby. 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.

Pregnancy - first and second trimester

You should not take Aspirin 300mg 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 300mg 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.

Do not take Aspirin 300mg if you are breast-feeding because some of the aspirin may be in your breast milk and could harm your baby.

The product belongs to a group of medicines which may impair the fertility in women. This effect is reversible on stopping the medicine.

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

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Patient Information Leaflet (continued)

Aspirin 300mg contains benzyl alcohol

This medicine contains 0.334 mg benzyl alcohol in each tablet.

Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

Benzyl alcohol may cause allergic reactions

3 How to take Aspirin 300mg

Always take Aspirin 300mg exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

The usual dose is different in the following circumstances:

- Pain and swelling, or fever
Take up to three 300mg tablets three or four times a day.
- Acute rheumatic disorders (joint and muscle problems)
Your doctor will tell you how many tablets to take and how often. You will usually take 4 to 8 grams of Aspirin 300mg a day.
- Prevention of heart attacks, angina or mini-strokes
The usual dose is one or two 75mg tablets each day. Sometimes, your doctor may tell you to take one 300mg tablet each day

Swallow the tablets whole with water. Do not cut, crush or chew them as this will damage the special coating. If the coating is damaged the tablets are more likely to irritate your stomach.

If you may be taking this medicine for a long time, you should talk to your doctor about it.

If you take more Aspirin 300mg than you should

If you have taken too many tablets, you should go to your nearest accident and emergency department or contact your doctor immediately. Take any leftover medicines or the empty packet to the doctor to show what you have taken.

The following effects may occur; nausea, vomiting, loss of appetite, dizziness, dehydration, ringing in ears or deafness, loss of balance, sweating, headache, tiredness, confusion, warm hands/feet with a fast heart rate, unusually fast or deep breathing.

Less common effects include; vomiting blood, high fever, bleeding or bruising, increased hunger, increased thirst, trembling/shakiness, muscle weakness, twitching, abnormal heart rhythm, difficulty concentrating, swollen ankles/hands/feet, blood in urine/reduced production of urine, severe breathlessness, seizures, coma, cessation of breathing or heartbeat.

If you forget to take Aspirin 300mg

Do not worry. If you miss a dose, wait until it is time for your next dose, then go on as normal. DO NOT take a double dose.

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

4 Possible side effects

Like all medicines, Aspirin 300mg can cause side effects, although not everyone gets them.

Aspirin may cause allergic reactions and you must STOP taking this medicine and tell your doctor immediately if you experience any of the following:

- skin rashes or itching or wheezing or coughing or difficulty breathing.

When taking Aspirin 300mg, you may suffer some more serious side effects; STOP taking this medicine and tell your doctor immediately if you experience any of the following:

- vomiting blood
- blood in your urine
- bruising with purple spots
- coughing up blood (however small the amount)
- any swellings
- black stools

- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- kidney stones (which can cause severe stomach or back pains).

Aspirin may sometimes cause asthma or bronchospasm (narrowing of the airways that causes wheezing or difficulty breathing).

Aspirin may cause bleeding, and you must tell your doctor if you experience any unusual bleeding.

Other side effects of aspirin include:

- nausea and vomiting
- ringing in your ears
- pain or discomfort in your stomach or lower chest after eating.
- liver problems with symptoms that may include a yellowing of the skin or whites of the eyes (jaundice), dark yellow urine and fatigue.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the internet at 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 300mg

- * KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- * Do not store above 25°C.
- * Keep the container tightly closed in order to protect from moisture.
- * Do not take this medicine after the expiry date which is stated on the bottle label or carton. The expiry date refers to the last day of that month. If your doctor tells you to stop taking the medicine, take any remaining medicine back to the pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
- * If your medicine becomes discoloured or shows any other signs of deterioration, ask your pharmacist who will advise you what to do.
- * Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Aspirin 300mg contains

Each gastro-resistant tablet contains 300mg of aspirin (also known as acetylsalicylic acid).

The other ingredients are maize starch, hypromellose, talc, methacrylic acid-ethyl acrylate (1:1) copolymer dispersion 30 percent, polyethylene glycol 3350, propylene glycol, benzyl alcohol, emulsion silicone. Printing ink containing shellac, iron oxide (E172), isopropyl alcohol, n-butyl alcohol, propylene glycol, ammonium hydroxide (E527) and simeticone.

What Aspirin 300mg looks like and contents of the pack

Aspirin 300mg are white, gastro-resistant tablets marked 300 in red and plain on the other side.

Each bottle contains 100 gastro-resistant tablets.

Manufacturer and Licence Holder

Manufactured by Chanelle Medical, Loughrea, Co Galway, Ireland and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

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in a format suitable for you.