ASPAR
Aspirin 300 mg Tablets POM

Docment Information

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Package leaflet: Information for the patient

POM

Aspirin 300 mg Tablets

(acetylsalicylic acid)

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 again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Aspirin 300 mg Tablets are and what they are used for
2. What you need to know before you take Aspirin 300 mg Tablets
3. How to take Aspirin 300 mg Tablets
4. Possible side effects
5. How to store Aspirin 300 mg Tablets
6. Contents of the pack and other information

1. What Aspirin 300 mg tablets are and what they are used for

Aspirin 300 mg Tablets contain Aspirin (acetylsalicylic acid). An analgesics and antipyretics (used to relieve pain, swelling and high temperature). It is used to treat headaches, migraine, neuralgia, toothache, sore throat, period pains, aches and pains, symptomatic relief of influenza and feverish colds relief of sprains, strains, rheumatic pain, sciatica, lumbago, muscle aches, fibrositis, joint swelling and stiffness in adults and children over 16 years of age.
You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

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

Do not take Aspirin 300 mg tablets if you:

- Are allergic to Aspirin, other non-steroidal anti-inflammatory drugs (NSAIDs), or any of the other ingredients listed in section 6, or have previously experienced asthma attacks, angioedema, urticaria (hives) or rhinitis when taking aspirin or other NSAIDs.
- Have a stomach ulcer or have had problems with ulcers in the past.
- Suffer from haemophilia or any other bleeding condition.
- Suffer from gout or have suffered from gout in the past.
- Are in the last 3 months of pregnancy or are breast feeding. (See section "Pregnancy, breast-feeding and fertility").

When taking acetylsalicylic acid, serious allergic reactions which may include chest pain and even heart attack (Kounis syndrome) have been reported (see section 4). Seek medical care immediately if you notice chest pain with allergic reactions (such as skin rashes, shortness of breath).

Warning and Precautions:
Talk to your doctor or pharmacist before taking Aspirin 300 mg Tablets if you:

- Have asthma or have ever had it in the past.
- Have dehydration.
- Have been told you are deficient in glucose-6-phosphate dehydrogenase.

Children and Adolescents
Do not give this medicine to children under the age of 16 unless your doctor tells you.
This is because 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.

Other medicines and Aspirin 300 mg Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including:

- Metoclopramide (for sickness and digestive disorders).
- Blood thinning medicines such as Heparin, Warfarin or nicoumalone.
- Corticosteroids e.g., hydrocortisone (which can be used for arthritis, asthma and inflammatory conditions).
- Anti-inflammatory medicines or steroids for pain and inflammation e.g., ibuprofen.
- High blood pressure medicines e.g., diuretic/water tablets, Angio-II receptor antagonists or ACE inhibitors.
- Epilepsy medicines e.g., Phenytoin, Sodium valproate.
- Methotrexate (for psoriasis, arthritis or tumours).
- Antacids for indigestion.
- Probenecid or sulphinpyrazone for gout.
- Anti-depressants, selective serotonin reuptake inhibitors (SSRIs) e.g., citalopram.

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

Pregnancy - last trimester
Do not take Aspirin 300 mg Tablets 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 you 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 300 mg Tablets 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 300 mg Tablets 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
Do not take this medicine if you are breastfeeding.

Aspirin 300 mg Tablets contain Lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.



3. How to take Aspirin 300 mg tablets

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

Use in adults and children over the age of 16 years:
The recommended dose is to take 1 to 3 tablets with water, every 4 hours. Do not take more than 4 doses in any 24 hours.
Do not take more medicine than the label tells you to.
If symptoms persist for more than 3 days consult your doctor.

Use in elderly:
A lower dose is recommended for the elderly.

Use in children and adolescents:
Do not give to children aged under 16 years unless told to by your doctor.

If you take more Aspirin 300 mg Tablets than you should
Seek medical attention IMMEDIATELY
Symptoms of overdose include vomiting, dehydration, tinnitus, vertigo, deafness, sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation.
Less common symptoms include vomiting blood, high fever, low blood sugar, low levels of potassium in the blood, low blood platelet count (thrombocytopenia), decreased rate of blood clot formation, renal failure and non-cardiac pulmonary oedema. Effects on the central nervous system include confusion, disorientation, coma and convulsions, which are more common in children.

If you forget to take Aspirin 300 mg Tablets
Do not take a double dose to make up for a forgotten dose.

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



4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
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.
- Stomach problems including pain, indigestion or heartburn.
- Allergic reactions such as skin rash, swelling of the face, neck or throat, worsening of asthma, difficulty in breathing.
- Bleeding on the brain which may cause a severe headache or stroke.
- Frequency not known: Acute myocardial ischemia (painful heart condition caused by lack of blood flow to the heart) with or without myocardial infarction (heart attack) occurring as part of an allergic reaction (Kounis syndrome).

These other side effects are less serious. If they bother you talk to a pharmacist:
- Feeling sick, being sick, changes to the stomach lining (swelling or ulcers).
- Increased bleeding time when you cut yourself, bleeding under the skin which may look like bruising.
- Nose bleeds (if a nose bleed is severe or lasts for a long time, talk to a doctor straight away).
- Hearing problems (e.g. ringing in the ears) feeling dizzy (vertigo), feeling confused.

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 Yellow Card Scheme, Website: 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 300 mg 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 carton or label after EXP.
The expiry date refers to the last day of that month.
Store below 25˚C.
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 300 mg Tablets contain
The active substance is Aspirin (acetylsalicylic acid). Each tablet contains Aspirin 300 mg.

The other ingredients are potato starch, lactose, and talc.

What Aspirin 300 mg Tablets looks like and contents of the pack
White, round, uncoated tablets. They are biconvex (rounded on top and bottom) with a break line on one side and plain on the other side. The break-line can be used to break the tablet for ease of swallowing but not to divide it into equal doses.

Aspirin 300 mg tablets are available in blister packs of 48, 50, 96 or 100 tablets and they are also available in container packs of 50, 100, 250, 500, 1000 or 5000 tablets. (Not all pack sizes are marketed).

Marketing Authorisation Holder and Manufacturer
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