

Aspirin 300mg Suppositories

Acetylsalicylic acid (Aspirin)

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, please ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you. 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Aspirin Suppositories are and what they are used for

Aspirin Suppositories belong to a group of medicines which have analgesic (pain relieving), anti-inflammatory (inflammation reducing) and antipyretic (temperature reducing) properties.

Aspirin Suppositories are used for:

- the relief of mild to moderate pain caused by headaches, neuralgia or sore throat.
- the relief of a high temperature (fever) due to a cold or flu
- the relief of pain and swelling due to rheumatic disease, arthritis or sciatica.

2. What you need to know before you use Aspirin Suppositories

Do not take Aspirin Suppositories and tell your doctor if:

- you are allergic to acetylsalicylic acid (aspirin), salicylates or to any other similar medicines (NSAIDs), or any of the other ingredients of this medicine listed in section 6.
- you suffer from nasal polyps associated with asthma
- you suffer from an allergy or have previously suffered from an allergic reaction with symptoms such as swelling, itching or a runny nose.
- you suffer from a blood disorder known as haemophilia
- your blood has difficulty clotting or are taking medicines to thin the blood
- you are suffering or have previously suffered from a stomach ulcer
- you suffer from severe liver or severe kidney problems or severe heart failure
- you are in the last 3 months of pregnancy
- you are a child under 16 years old
- you are taking methotrexate (15mg a week)

Warnings and precautions

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 e.g. for Kawasaki's Disease.

Tell your doctor or nurse before taking Aspirin Suppositories if you:

- have asthma or allergies
- have heart, liver or kidney problems or gout
- have an overactive thyroid gland
- are dehydrated (you may feel thirsty and have a headache, dry mouth and lips)
- have anaemia or suffer from a deficiency of the enzyme glucose6-phosphate dehydrogenase (G6PD) this can cause episodes of anaemia after eating certain foods such as fava beans (favism)
- have systemic lupus erythematosus (SLE) or other connective tissue disease
- are elderly
- have had any disorders affecting blood vessels in the brain
- have received a varicella (chickenpox) vaccination within the last 6 weeks
- are planning to become pregnant
- have heavy bleeding during your periods

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- have a history of stomach ulcers
- have chronic respiratory disease
- have hypertension
- taking deferasirox (a medicine to remove excess iron from the body)

Do not use Aspirin Suppositories for a prolonged period of time.

Other medicines and Aspirin Suppositories

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Especially:

- warfarin, coumarin, heparin, dipyridamole and clopidogrel (used to prevent blood clotting)
- metoclopramide or domperidone (to prevent sickness)
- diuretics ("water tablets") such as spironolactone, furosemide, acetazolamide (to treat high blood pressure)
- medicines which make your urine more alkaline such as antacids, citrates
- probenecid (to treat gout)
- methotrexate (to treat some cancers, psoriasis and rheumatic disease)
- sulfonylureas (antidiabetics)
- phenytoin or sodium valproate (to treat epilepsy)
- corticosteroids (to suppress the immune system)
- mifepristone (to induce abortion)
- other non-steroidal anti-inflammatory drugs - NSAIDs (such as ibuprofen or naproxen)
- vancomycin (medicines which can cause hearing problems)
- medicines to treat high blood pressure such as ACE inhibitors (e.g. enalapril, lisinopril, perindopril), Calcium channel blockers (e.g. amlodipine, diltiazem, nifedipine)
- SSRIs such as sertraline or paroxetine (medicines to treat depression)
- varicella (chickenpox) vaccine. Aspirin should be avoided for 6 weeks after vaccination
- herbal medicines containing ginkgo biloba
- digoxin (to treat heart problems)
- lithium (to treat depression)
- acetazolamide (to treat glaucoma)
- cyclosporine, tacrolimus (used to prevent organ rejection)
- alcohol

If you have any doubts as to whether Aspirin Suppositories are suitable for you please consult your doctor.

Aspirin Suppositories with alcohol

Avoid alcohol whilst taking this medicine.

Pregnancy and breast-feeding:

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. Avoid taking Aspirin Suppositories during pregnancy, especially in the last 3 months of pregnancy or whilst breast-feeding.

Surgery and tests

If you need to have an operation including having your teeth removed or blood and urine tests, tell your doctor or dentist you are taking this medicine.

3. How to use Aspirin Suppositories

Always use Aspirin Suppositories exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

1. If you need to empty your bowels this should be done before inserting the suppository.
2. Wash hands before opening individual packaging. If the suppository is too soft, it may be chilled in the refrigerator or under cold running water before unwrapping
3. To remove a suppository, tear one from the strip along the perforations then peel it from the plastic wrapping by grasping the two halves of the wrapping at the tip of the suppository and pulling them gently apart. The tip should be moistened with a little cold water to aid insertion
4. Lie on your left side (if you are right handed) and draw your knees up towards your chest, with the right leg drawn up more than the left.
5. Using your index finger or middle finger, whichever you



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find easier, gently push the suppository into the rectum (back passage), making sure the rounded end of the suppository is inserted first.

6. The suppository should be inserted as far as possible, pushing the end of the suppository sideways to ensure contact with the wall of the bowel.

7. Lower your legs to a comfortable position to help you to hold the suppository in place.

The recommended dose is

Adults, the elderly and children over 16 years

The usual dose is 2-3 suppositories every 4 hours. You should not use more than 12 suppositories in 24 hours.

Children under 16 years

Not recommended for children under 16 years.

Prolonged use of Aspirin Suppositories is not recommended.

If you use more Aspirin Suppositories than you should

If these suppositories are swallowed or if you have exceeded the stated dose of your medicine contact your doctor or pharmacist.

4. Possible Side Effects

Stop taking this medicine and contact a doctor immediately if you have any of the following:

- Difficulty breathing
- Severe allergic reactions (blistered skin, swelling of the face, lips, throat or tongue, difficulty breathing, worsening of asthma, shock)
- Severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (Lyells syndrome) or severe rash, blisters, or red patches on the skin (Stevens-Johnson syndrome)
- Bleeding on the brain (sudden severe headache, fit, changes in vision, speaking, understanding or coordination, weakness in an arm or leg)
- Stomach ulcers or bleeding which can be severe (you may develop bloody or black tarry stools, severe stomach pain and vomit blood), stomach irritation (mild stomach pain, heartburn and feeling or being sick) and inflammation of the liver
- Salicylism - if you take large doses for a long time you may develop symptoms of salicylism, these include: dizziness, ringing or buzzing in the ear, deafness, sweating, feeling or being sick, headache and confusion.
- Hepatitis (inflammation of the liver causing yellowing of the skin or eyes or tiredness, pain in abdomen, joint or muscles)

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Common: may affect up to 1 in 10 people

- Increase in the number of nose bleeds, longer bleeding time or notice that you bruise more easily or have more infections talk to your doctor.
- Indigestion

Uncommon: may affect up to 1 in 100 people

- Runny nose
- Itchy skin rash caused by allergic reaction- pale or red irregular raised patches with severe itching (hives)

Rare: may affect up to 1 in 1,000 people

- Anaemia, changes in numbers and types of blood cells and enzymes seen in blood tests
- Difficulty breathing or wheezing, worsening of asthma
- Heavy periods
- Irregular red patches on the skin of the hands and arms (erythema multiforme)
- Disorder characterised by blood spots, bruising and discolouring to skin (Purpura)
- Bleeding in the skin, mucous membranes
- Red tender lumps developing under the skin (Erythema nodosum)

Not known: frequency cannot be estimated from the available data

- Gout (high levels of uric acid in the blood)- causing crystals to deposit in joints of hands/feet causing pain (Hyperuricemia)
- Nosebleeds, bleeding of the gums, which may be prolonged. (Please advise doctor or dentist if surgery is planned)
- Reduction of red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia), Reduction in red blood cells which cause pale yellow skin and weakness or breathlessness (haemolytic anaemia)

Continued overleaf

blood disorder resulting in impaired blood clotting leading to an increased risk of bleeding, reduced number in red and white blood cells, blood loss, elevated blood enzymes levels (as seen in blood test)

- Headache
- Feeling of dizziness or spinning
- Hearing loss, Ringing or buzzing in the ears
- Liver problems
- Reduced kidney function

Additional side effects in children

Aspirin may be associated with the development of a condition called Reye's Syndrome, which causes severe liver and brain damage.

Reporting of side effects

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

Keep this medicine out of the sight and reach of children

Do not use Aspirin Suppositories after the expiry date on the carton label. The expiry date refers to the last day of that month. The doctor or nurse will check that the product has not passed this date.

Do not store above 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 to protect the environment.

6. Contents of the pack and other information

What Aspirin Suppositories contain

The active ingredient is Acetylsalicylic acid (Aspirin) 300mg
The other ingredient is hard fat (suppository base)

What Aspirin Suppositories look like and contents of the pack:

Aspirin Suppositories are smooth, white suppositories supplied in a plastic cavity in strips of 5. Each pack contains 10 suppositories.

Marketing Authorisation Holder:

Martindale Pharmaceuticals Limited
Bampton Road, Harold Hill
Essex, RM3 8UG
United Kingdom

Manufacturer:

Phoenix Healthcare Limited.,
Cookstown Industrial Estate, Tallaght, Dublin 24, Ireland.

Product License Number:
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DEVELOPMENT ARTWORK

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Prod: Aspirin 300mg UK
Suppositories pil

Paper Size: 88 x 300mm

Version Control	Date	By
Version A:	01/11/18	SS
Version B:	05/06/20	NF
Version C:	09/06/20	NF
Version D:	12/06/20	NF
Version E:	16/06/20	NF
Version F:	12/01/24	LB
Version G:	17/01/24	LB
Version H:		
Version I:		
Version K:		
Version L:		
Version M:		
Version N:		
Version O:		

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