

Dispersible Aspirin 300mg tablets

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Index

1. **What Dispersible Aspirin tablets are and what they are used for**
2. **Before you take**
3. **How to take**
4. **Possible side effects**
5. **How to store**
6. **Further information**

1. **What Dispersible Aspirin tablets are and what they are used for**

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

These tablets may be used for the relief of:

- headache, toothache, migraine, neuralgia (nerve pain), sore throat or period pains.
- symptoms of influenza, feverishness, rheumatic pains, sciatica (nerve pain of the leg/back), lumbago (lower back pain), fibrositis (muscular rheumatism), muscular aches and pains.

2. **Before you take**

Do not take Dispersible Aspirin tablets and **tell** your doctor if you have:

- an **allergy** (hypersensitivity) to aspirin, salicylates or non-steroidal anti-inflammatory drugs (NSAIDs) or other ingredients in the product. You may have developed difficulty breathing, a runny nose, itchy skin or swelling after taking aspirin or a NSAID previously (see section 6)
- a **stomach ulcer** or a history of ulcers or **indigestion**
- **bleeding** in the **stomach** and/or **intestines**, or other kinds of bleeding such as **bleeding** from the **blood vessels of the brain**
- **nasal polyps** associated with **asthma**
- **haemophilia** or other **blood clotting** disorder or are taking medicines to thin the blood.
- **severe** liver, kidney or heart failure
- are in the **third** trimester of pregnancy
- taking **methotrexate** (more than 15mg a week)
- a child **under 16** years old.

Important warning:

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.**

Check with your doctor or pharmacist before taking Dispersible Aspirin tablets if you:

- **have asthma, chronic respiratory disease or allergies**
- experience heavy **periods**

- **have hypertension** (high blood pressure)
- have a history of **stomach ulcers** or **excessive bleeding**
- **have heart, liver or kidney** problems or **gout**
- **have severe skin rash** with flushing, fever, blisters or ulcers (Stevens Johnson syndrome). **Treatment should be stopped immediately.**
- have an **overactive thyroid** gland
- **have dehydration**
- **have anaemia** or suffer from a deficiency of the enzyme glucose-6-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

Other important warnings:

- taking **painkillers** for **headaches** too often or for too long can make them worse.

Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- medicines to prevent blood clotting such as warfarin, dipyridamole, clopidogrel and heparin
 - deferasirox (for patients with excessive iron levels following blood transfusion)
 - digoxin (for heart problems)
 - metoclopramide or domperidone (to prevent sickness)
 - diuretics “water tablets” 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)
 - medicines to treat diabetes
 - phenytoin or sodium valproate (to treat epilepsy)
 - corticosteroids, tacrolimus and ciclosporin (to suppress the immune system)
 - mifepristone (to induce abortion)
 - other non-steroidal anti-inflammatory drugs – NSAIDs used for pain (eg ibuprofen or naproxen)
 - medicines which can cause hearing problems (vancomycin)
 - medicines to treat high blood pressure (ACE inhibitors, Calcium channel blockers)
 - medicines to treat depression such as lithium or SSRIs (e.g. paroxetine)
 - varicella (chickenpox) vaccine. Aspirin should be avoid for 6 weeks after vaccination
- herbal medicines containing ginkgo biloba.

Pregnancy and breast-feeding

Avoid taking Dispersible Aspirin tablets during pregnancy especially in the last 3 months of pregnancy or whilst breast-feeding. Ask your doctor or pharmacist for advice before taking this medicine.

Sugar intolerance

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a type of sugar called lactose.

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 take

Always take Dispersible Aspirin tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Avoid alcohol whilst taking this medicine.

Disperse the tablet(s) in a glass of water and drink.

Doses:

Adults, including the elderly: 1 or 2 tablets every 4 hours as required. No more than 8 tablets in any 24 hour period.

Children under 16 years old: Not recommended.

If you take more than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include ringing in the ears, hearing problems, headache, dizziness, confusion, feeling or being sick, stomach pain, high temperature, dehydration, sweating, feeling restless, fits, hallucinations, low blood sugar, severe chest pain, difficulty breathing, unconsciousness.

If you forget to take the tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time. Do not take more than one dose in any 4 hour period.

4. Possible side effects

Like all medicines, Dispersible Aspirin tablets can cause side effects, although not everybody gets them.

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

- Severe allergic reactions (blistered skin, swelling of the face, lips, throat or tongue, difficulty breathing, shock)
- itchy skin rash caused by allergic reaction- pale or red irregular raised patches with severe itching (hives/urticaria)
- 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), irregular red patches on the skin of the hands and arms (erythema multiforme)
- 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). Fatalities have occurred.

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

Common: may affect up to 1 in 10 people

- increased bleeding tendencies,
- indigestion

Uncommon: may affect up to 1 in 100 people

- runny nose

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

- anaemia, changes in numbers and types of blood cells as seen in blood tests
- difficulty breathing or wheezing, asthma attacks.
- heavy periods
- feeling or being sick
- disorder characterised by blood spots, bruising and discolouring to skin (hemorrhagic vasculitis or purpura)
- red tender lumps developing under the skin (Erythema nodosum)

Not known: frequency cannot be estimated from the available data

- nosebleeds, bleeding of the gums, which may be prolonged. (Please advise doctor or dentist if surgery is planned)
- reduction in red blood cells which cause pale yellow skin and weakness or breathlessness
- low levels of protein in the blood (can be caused by nephritic syndrome)
- reduced number of red and white blood cells, increased blood enzyme levels (as seen in blood test).
- Gout (high levels of uric acid in the blood)- causing crystals to deposit in joints of hands/feet causing pain (Hyperuricemia)
- headache
- feeling of dizziness or spinning (vertigo)
- hearing loss, Ringing or buzzing in the ears
- swelling of blood vessels resulting from loss of blood. (characterised by rash, fever, sweating, fatigue, weight loss) worsening of asthma
- liver problems including hepatitis (inflammation of the liver causing yellowing of the skin or eyes or tiredness, pain in abdomen, joint or muscles)
- reduced kidney function
- 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.

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.

If you are concerned about any side-effects or have any other unusual effects, tell your doctor immediately and seek advice.

5. How to store

Keep out of the reach and sight of children.

Store the tablets below 25°C in a dry place.

Do not use Dispersible Aspirin tablets after the expiry date stated on the label/carton/bottle.

The expiry date refers to the last day of that month.

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. Further information

What Dispersible Aspirin tablets contain

- The active substance (the ingredient that makes the tablets work) is 300mg aspirin (also known as acetylsalicylic acid).
- The other ingredients are citric acid, lactose, maize starch, saccharin sodium, calcium carbonate (E170).

What Dispersible Aspirin tablets look like and contents of the pack

Dispersible Aspirin are circular, white, uncoated tablets.

Pack sizes are 100 tablets.

Marketing Authorisation Holder and manufacturer

Actavis, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in November 2013

**PARTICULARS TO APPEAR ON <THE OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>
{NATURE/TYPE}**

1. NAME OF THE MEDICINAL PRODUCT

DISPERSIBLE ASPIRIN TABLETS BP 300mg

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 300mg Aspirin.

3. LIST OF EXCIPIENTS

Also contains lactose. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

White uncoated tablets.

Pack sizes are 100 tablets.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

Dosage: as directed by practitioner.

To be dispersed in water for oral use.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Peel here do not remove leaflet

Do not take if you have a stomach ulcer

If symptoms persist for more than 3 days, consult your doctor

Medicines should not be taken in pregnancy without consulting your doctor

Keep out of the reach of children

Do not give to children aged under 16 years, unless on the advice of a doctor.

8. EXPIRY DATE

Two years from the date of manufacture.

9. SPECIAL STORAGE CONDITIONS

Keep tightly closed and store below 25°C in a dry place.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Not applicable.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Actavis UK Limited

(Trading styles: Actavis)

Whiddon Valley

BARNSTAPLE

N Devon EX32 8NS

12. MARKETING AUTHORISATION NUMBER(S)

PL 0142/5519 R

13. BATCH NUMBER<, DONATION AND PRODUCT CODES>

To be completed

14. GENERAL CLASSIFICATION FOR SUPPLY

To be completed

15. INSTRUCTIONS ON USE

Read the package leaflet before use

16. INFORMATION IN BRAILLE

To be completed