# Package leaflet: Information for the user

# Aspirin 300mg Dispersible Tablets

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- The full name of this medicine is Aspirin 300mg Dispersible Tablets but within this leaflet it will be referred to as aspirin dispersible tablets.

## What is in this leaflet

- 1. What aspirin dispersible tablets are and what they are used for
- 2. What you need to know before you take aspirin dispersible tablets
- 3. How to take aspirin dispersible tablets
- 4. Possible side effects
- 5. How to store aspirin dispersible tablets
- 6. Contents of the pack and other information

# 1. What aspirin dispersible tablets are and what they are used for

Aspirin dispersible 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. What you need to know before you take aspirin dispersible tablets

Do not take aspirin dispersible tablets and tell your doctor if you:

- are allergic to aspirin, salicylates or Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or any of the other ingredients of this medicine (listed in section 6). You may have developed difficulty breathing, a runny nose, itchy skin or swelling after taking aspirin or a NSAID previously.
- have a **stomach ulcer** or a history of ulcers or **indigestion**
- have **bleeding** in the **stomach** and/or **intestines**, or other kinds of bleeding such as **bleeding** from the **blood vessels of the brain**
- have **nasal polyps** associated with **asthma**
- have **haemophilia** or other **blood clotting** disorder or are taking medicines to thin the blood.
- have severe liver, kidney or heart failure
- are in the **third** trimester of pregnancy
- are taking **methotrexate** (more than 15mg a week)
- are 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 aspirin dispersible 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.

# Other medicines and aspirin

Please **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:

- 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.

• 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 cardio protection.

#### Aspirin with alcohol

Avoid alcohol whilst taking this medicine.

#### **Pregnancy and breast-feeding**

Avoid taking aspirin dispersible 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 aspirin dispersible tablets

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

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

#### The recommended dose is:

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 aspirin dispersible tablets 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 aspirin dispersible 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, aspirin dispersible 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 (Lyell's 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.

## **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: <a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a> 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 dispersible tablets

Keep out of the sight and reach of children.

Store the tablets below 25 C in a dry place.

Do not use aspirin dispersible tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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 dispersible 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 aspirin dispersible tablets look like and contents of the pack

Aspirin Dispersible Tablets are circular, white, uncoated tablets.

Available in pack sizes of 28, 30 and 32 tablets.

Not all pack sizes may be marketed.

## Marketing Authorisation Holder and manufacturer

Accord, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in January 2021.

# If you would like a leaflet with larger text, please contact 01271 385257.