

Applicant: Unimed Healthcare (Pty) Ltd.

Product Name: Aspirin 300 Unimed

Dosage form and strength: Each tablet contains 300 mg Aspirin

Patient Information Leaflet (PIL)

for Medicines for Human Use

ASPIRIN 300 UNIMED (Tablets)

SCHEDULING STATUS: S0

ASPIRIN 300 UNIMED tablet

Aspirin

Contains sugar: Sucrose 2,94 mg per tablet

Contains a preservative: Benzoic acid 0,0014 % w/w

Read all of this leaflet carefully because it contains important information for you

ASPIRIN 300 UNIMED is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ASPIRIN 300 UNIMED carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ASPIRIN 300 UNIMED with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet:

1. What ASPIRIN 300 UNIMED is and what it is used for
2. What you need to know before you take ASPIRIN 300 UNIMED
3. How to take ASPIRIN 300 UNIMED
4. Possible side effects
5. How to store ASPIRIN 300 UNIMED
6. Contents of the pack and other information



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1. What ASPIRIN 300 UNIMED is and what it is used for

The active ingredient aspirin has analgesic (reduces pain), antipyretic (reduces fever) and anti-inflammatory (reduces inflammation) actions.

ASPIRIN 300 UNIMED is indicated for the relief of mild to moderate pain and fever.

2. What you need to know before you take ASPIRIN 300 UNIMED

Do not take ASPIRIN 300 UNIMED

- if you have stomach ulcers,
- if you have a bleeding disorder such as haemophilia,
- if you suffer from severe kidney impairment,
- if you are taking oral anti-coagulant medicines (medicines that prevent the blood from clotting),
- if you have an intolerance or are hypersensitive (allergic) to aspirin or to any of the other ingredients in ASPIRIN 300 UNIMED (listed in section 6),
- if you have or have had severe heart problems,
- if you have a history of stomach or intestinal perforation, ulcers or bleeding due to previous NSAIDs use, including ASPIRIN 300 UNIMED,
- if you suffer from or have suffered from a recurring ulcer, bleeding or perforation,
- if you are pregnant or breastfeeding your infant,
- if you are under 12 years of age (see Warnings and precautions).

Warnings and precautions

You should not use ASPIRIN 300 UNIMED continuously for longer than ten (10) days without consulting your doctor.

Take special care with ASPIRIN 300 UNIMED:

- when given to children or teenagers ASPIRIN 300 UNIMED may cause Reye's syndrome. Reye's syndrome is a rare but serious illness in children and teenagers



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with chickenpox and flu. For this reason, ASPIRIN 300 UNIMED should not be given to children aged under the age of 12 years and teenagers, unless on the advice of a doctor (see Do not take ASPIRIN 300 UNIMED),

- if you continue to take large amounts of ASPIRIN 300 UNIMED it may cause anaemia, abnormal conditions or diseases of the blood, gastrointestinal bleeding, stomach ulcers and kidney damage,
- if you develop serious skin reactions, skin rash, chest tightness, wheezing or difficulty breathing, you should stop taking ASPIRIN 300 UNIMED immediately.

Tell your doctor or pharmacist before taking ASIPRIN 300 UNIMED:

- if you have high blood pressure and/or suffer from heart problems. ASPIRIN 300 UNIMED may be associated with a small increased risk of heart failure,
- if you are elderly, as you may be more susceptible to the side effects of ASPIRIN 300 UNIMED,
- if you have a history of stomach ulcers or are of advanced age, the risk of internal bleeding of the stomach or intestines or ulcers is higher if you take large amounts of ASPIRIN 300 UNIMED,
- if you suspect that you have an ulcer, treatment with ASPIRIN 300 UNIMED should be stopped and you should consult your doctor,
- if you have a history of stomach and intestinal diseases e.g. inflammatory disease of the stomach and intestine, stomach pushing up into the chest, digestive disorder which affects the lower gut sphincter and vascular malformation of the gut, as these conditions may worsen,
- if you are scheduled for a surgical procedure. You must stop using ASPIRIN 300 UNIMED several days before your surgery,
- if you have a history of allergic reactions to NSAIDs, including attacks of asthma, swelling of your face, lips and tongue, hives, itchy skin or runny nose,



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- if you have other allergies or asthma,
- if you suffer from kidney problems,
- if you suffer from indigestion,
- if you have anaemia or suffer from a deficiency of the enzyme glucose-6-phosphate dehydrogenase (G6PD),
- if you are dehydrated (you may feel thirsty and have a headache, dry mouth and lips),
- if you develop symptoms such as a high body temperature, widespread rash, swollen glands or facial swelling. This reaction can also include kidneys, liver, and heart dysfunction as well as abnormal blood test results (for example an abnormal increase in the number of disease-fighting white blood cells).

Other medicines and ASPIRIN 300 UNIMED

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

It is especially important to tell your doctor if you are taking the following medicines:

- other non-steroidal anti-inflammatory drugs - NSAIDs (such as ibuprofen, naproxen, fenbufen, indomethacin and piroxicam),
- corticosteroids (to suppress the immune system),
- SSRIs such as sertraline or paroxetine (medicines to treat depression),
- medicines used to prevent blood clotting such as warfarin,
- oral antidiabetic medicines (medicine you take by mouth for the treatment of diabetes),
- sulphonamides (medicine used to treat infections),
- methotrexate (to treat some cancers, psoriasis and rheumatic disease),
- phenytoin or sodium valproate (to treat epilepsy),
- zarfirlukast (to treat asthma),
- medicines used to treat gout such as probenecid and sulfinpyrazone,



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- barbiturates and other sedatives (medicines to induce sleep),
- medicines which make your urine more alkaline such as antacids,
- mifepristone (to induce abortion),
- dipyridamole (medicine used to treat heart or blood conditions),
- metoclopramide (medicines used for nausea and vomiting),
- metoprolol (to treat angina),
- acetazolamide (to treat glaucoma).

ASPIRIN 300 UNIMED may interfere with some blood and urine tests. If you need to have blood and urine tests, tell your doctor you are taking ASPIRIN 300 UNIMED.

ASPIRIN 300 UNIMED with food, drink and alcohol

You should not drink alcohol while you are taking ASPIRIN 300 UNIMED.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ASPIRIN 300 UNIMED.

You should not take ASPIRIN 300 UNIMED during pregnancy or while you are breastfeeding your baby.

Taking ASPIRIN 300 UNIMED while you are 20 weeks or more than 20 weeks pregnant, may cause serious kidney problems in your unborn baby. This may cause a delay in your baby's lung development, as well as result in limb disabilities.

Regular use of ASPIRIN 300 UNIMED may result in increased blood pressure in your baby's lungs. The onset of labour may be delayed and its duration increased.

Driving and using machines



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It is not always possible to predict to what extent ASPIRIN 300 UNIMED may interfere with the daily activities of a patient. Since side effects such as dizziness have been reported with the use of ASPIRIN 300 UNIMED, you should be aware of how you react to ASPIRIN 300 UNIMED before you drive or operate machinery.

ASPIRIN 300 UNIMED contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this ASPIRIN 300 UNIMED.

3. How to take ASPIRIN 300 UNIMED

Do not share medicines prescribed for you with any other person.

Always take ASPIRIN 300 UNIMED exactly as directed in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

Use the lowest effective dose for the shortest possible duration of treatment.

Adults: Take one or two tablets every four hours with water.

Do not use continuously for longer than ten (10) days without consulting your doctor.

If you take more ASPIRIN 300 UNIMED than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of an overdose include ringing in the ears, spinning sensation, deafness, sweating, nausea, headache, vomiting, confusion, fast breathing rate, fever, coma and heart failure.

In children, serious signs of overdose may develop rapidly.

If you forget to take ASPIRIN 300 UNIMED

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If you missed a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the tablets at the usual time. Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

ASPIRIN 300 UNIMED can have side effects.

Not all side effects reported for ASPIRIN 300 UNIMED are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ASPIRIN 300 UNIMED, please consult your health care provider for advice.

If any of the following happens, stop taking ASPIRIN 300 UNIMED and tell your doctor immediately or go to the casualty department at your nearest hospital:

- you have an allergic reaction. The signs may include a skin rash, swallowing or breathing problems, wheezing, worsening of asthma, swelling of your lips, face, throat or tongue,
- you get blistering, peeling, bleeding, scaling or fluid filled patches on any part of your skin. You may have a serious skin problem,
- you have a fever and yellowing of the skin or whites of the eyes, feel tired, weak or generally unwell, loss of appetite (anorexia), feeling sick (nausea), being sick (vomiting). These may be early signs of liver problems,
- 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),
- if you develop flu-like symptoms with a high body temperature, widespread rash, swollen glands, facial swelling and abnormal blood results (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

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These are all very serious side effects. If you have them, you may have had a serious reaction to ASPIRIN 300 UNIMED. You may need urgent medical attention or hospitalisation.

Other side effects include:

- longer bleeding time,
- blood does not clot well, which may result in easy bruising or bleeding,
- dizziness,
- swelling,
- high blood pressure and heart failure,
- stomach ulcers,
- bleeding from the gastrointestinal tract,
- nausea (feeling sick), vomiting (being sick), diarrhoea,
- indigestion, constipation, stomach pain,
- vomiting blood or blood in your stool,
- worsening of inflammatory bowel diseases,
- liver problems,
- itchy skin rash caused by allergic reaction, pale or red irregular raised patches with severe itching (hives),
- blistering, peeling, bleeding, scaling or fluid filled patches on any part of the skin,
- runny nose,
- difficulty breathing or wheezing, worsening of asthma.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under 20.04.2023 (v1)

Initial:



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SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ASPIRIN 300 UNIMED.

5. How to store ASPIRIN 300 UNIMED

- Store in a well closed container, at or below 25 ° C. Exposure to air should be minimum.
- Store in the original package.
- Do not use after the expiry date stated on the pack.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Store all medicines out of reach of children.

6. Contents of the pack and other information

- The active substance is aspirin. Each tablet contains 300 mg aspirin.
- The other ingredients are maize starch, purified talc and sugar and starch granules consisting of benzoic acid (preservative), dicalcium phosphate, gelatin, maize starch, sucrose (powdered).

What ASPIRIN 300 UNIMED looks like and contents of the pack

Round, white, biconvex tablet with a break line on one side, 9,5 mm in diameter. Odourless or having a faintly acidic odour.

Round, amber PVC bottle, with white LDPE snap on cap, 0,5 g silica gel sachet and absorbent paper containing 100 tablets.

White polypropylene securitainer, with white LDPE serrated concap lid, 0,5 g silica gel sachet and small foam insert containing 100 tablets.

Round, amber/white PVC bottle, with white HDPE screw on cap, 0,5 g silica gel sachet and absorbent paper containing 500 or 1000 tablets.

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Blue/white HDPE bucket, lined with a polyethylene plastic bag, with white polypropylene lid,
0,5 g silica gel sachet containing 5000 tablets.

White LDPE patient ready packs containing 10 or 20 tablets.

Not all pack sizes and types may be marketed.

Holder of Certificate of Registration

Unimed Healthcare (Pty) Ltd

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Anchorville,

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