

AspriVIT™ tablets

Acetylsalicylic acid, caffeine and vitamin B1

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicine and its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep Medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

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

- Follow the instructions contained in this leaflet exactly, or your doctor's or pharmacist's instructions, on how to take the medicine.
- Please keep this leaflet as you may need to read it again.
- Please ask your doctor or pharmacist if you have any further questions.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet:

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

1. WHAT ASPRIVIT™ IS AND WHAT IT IS USED FOR

The combination of acetylsalicylic acid, caffeine and thiamine hydrochloride (vitamin B1) is effective in reducing fever and pain.

AspriVIT™ is prescribed for the symptomatic relief of occasional mild or moderate pain, such as headaches, dental pain, menstrual pain, muscle (contractures) or back (low back) pain. Febrile states.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ASPRIVIT™ Do not take AspriVIT™:

- if you are allergic to acetylsalicylic acid, caffeine or thiamine hydrochloride, or any of the other ingredients in this medicine (listed in Section 6).
- if you have or have had a gastric or duodenal ulcer or recurrent gastric conditions.
- if you have had asthma-like allergic reactions (shortness of breath, choking, bronchial spasms and any cases of coughing or wheezing when breathing) when taking anti-inflammatories, acetylsalicylic acid, other painkillers or the colouring agent tartrazine.
- if you have or have had asthma with or without nasal polyps, rhinitis or hives after taking acetylsalicylic acid.
- if you suffer from haemophilia or other blood clotting conditions that make you prone to internal bleeding.
- if you are being treated with medications to prevent blood clotting (oral anticoagulants).
- if you suffer from a severe kidney and/or liver disease (kidney and/or liver failure).
- if you are under 16, since the use of acetylsalicylic acid has been associated with Reye's Syndrome, a serious, albeit rare, disease. Moreover, this preparation contains caffeine, and should not be given to children.
- If you are more than six months pregnant.

Warnings and precautions

Talk to your doctor or pharmacist before taking AspriVIT™:

- if you have recently undergone surgery, including dental surgery.
- if you are due to undergo surgery, including dental surgery, within the next seven days.
- if you are taking anti-inflammatories or other medications, since certain drugs may interact with AspriVIT™ and produce undesirable effects (see "Other medicines and AspriVIT™").
- if you have high blood pressure, reduced kidney, heart or liver function, blood clotting disorders or are being treated with anticoagulants.
- if you are allergic to other anti-inflammatory or anti-rheumatic drugs.
- if you have glucose-6-phosphate dehydrogenase deficiency.
- if you suffer from rhinitis and/or hives.
- if you have recently been vaccinated.
- if you have diabetes, since caffeine can increase blood glucose levels.
- if you have previously suffered from hypersensitive reactions to other medications for asthmatic patients, such as aminophylline or theophylline.

Children and adolescents

This medicine is not suitable for children or adolescents under 16.

Other medicines and AspriVIT™

Some medicines may interact with AspriVIT™, so they should not be taken without first talking to your doctor. This is particularly important in the case of:

- Painkillers and non-steroidal anti-inflammatory drugs used to treat pain and/or muscle swelling, because they increase the risk of digestive bleeding.
- Corticosteroids, because they may increase the risk of digestive bleeding.
- Diuretics.
- Some antidepressants, such as selective serotonin reuptake inhibitors, because they increase the risk of bleeding.
- Medicines for blood clotting (oral anticoagulants), because they increase the risk of bleeding.
- Certain medicines for controlling high blood pressure.
- Medicines to reduce blood sugar levels.
- Cyclosporin, used in organ transplants.
- Vancomycin, an antibiotic used for some infections.
- Interferon alfa.
- Lithium, used in certain psychiatric disorders.
- Methotrexate, used to treat cancer and rheumatoid arthritis.
- Medicines used to treat gout.
- Antacids.
- Digoxin, used for heart conditions.
- Barbiturates, drugs used as sedatives for sleep disorders and to treat seizures.
- Zidovudine, used in the treatment of HIV infections.
- Phenytoin and valproic acid, drugs used for epilepsy.

Consuming alcohol while taking acetylsalicylic acid will increase the risk of digestive bleeding.

Always tell your doctor or pharmacist about all the medicines you are taking, have recently taken or may have to take.

You should avoid taking this medicine with beverages containing caffeine or other medicines containing caffeine or stimulating the central nervous system, as this could induce insomnia, excitability or irritability. Tell your doctor or pharmacist if you are taking or have recently taken other medicines, including non-prescription and homeopathic drugs, medicinal plants and other health-related products, as they may need to be suspended or their dosage adjusted.

This is particularly important in the case of:

- Medicines used to prevent transplant rejection, such as cyclosporin and tacrolimus.
- High blood pressure (diuretics and ACE inhibitors).
- Cancer, rheumatoid arthritis (methotrexate).
- Other painkillers or non-steroidal anti-inflammatory drugs (used to treat pain and/or muscle swelling).
- Anticoagulants (drugs used to "thin" the blood and prevent clot formation), such as Warfarin.
- Medicines used to treat gout (probenecid).

AspriVIT™ with food and drink

Take this medicine with or after food.

If you regularly consume alcohol (beer, wine, spirits...), taking AspriVIT™ may cause stomach bleeding.

Taking this medicine with beverages containing caffeine may cause overstimulation of the central nervous system, inducing excitability, irritability or insomnia.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, you think you could be pregnant or intend to become pregnant, tell your doctor or pharmacist before taking this medicine.

AspriVIT™ should not be taken during the last three months of pregnancy or while breast-feeding.

Driving and using machines

No effects have been reported.

Use in the elderly

Elderly people should not take this medicine without asking their doctor as they are more likely to suffer from its adverse effects.

Use in athletes

Athletes are advised that this medicine contains an ingredient that may determine a positive doping control analysis result.

AspriVIT™ contains corn starch

This medicine contains corn starch, equivalent to more than 20 ppm of gluten, which should be taken into account by coeliac patients.

Patients who suffer from wheat allergy (different from coeliac disease) should not take this medicine.

Interference with diagnostic tests:

If you are due to undergo any diagnostic test (including blood, urine or other tests), advise your doctor that you are taking this medicine, since it could alter the results.

3. HOW TO TAKE ASPRIVIT™

Follow your doctor's or pharmacist's instructions exactly on how to take this medicine. In case of doubt, ask your doctor or pharmacist again.

The recommended dose for adults and children over the age of 16 is one tablet every 46- hours, if needed. In no event, should you take more than 8 tablets in 24 hours (1 day).

Patients with liver or kidney conditions should talk to their doctor because their dose should be reduced.

AspriVIT™ should be taken orally with or after food. It is recommended that the tablet be removed from its carton immediately before use.

Always use the smallest effective dose.

Administration of the preparation depends on the onset of pain or fever symptoms. Once these disappear the medication should be suspended.

If the pain persists for more than 10 days, or the fever for more than 3 days, or the symptoms worsen or new symptoms appear, you should suspend treatment and contact your doctor.

If you think the action of AspriVIT™ is too strong or too weak, tell your doctor or pharmacist.

If you take more AspriVIT™ than you should

If you accidentally exceed the prescribed dose or ingest this medicine, contact your doctor or pharmacist or go to your medical center immediately, stating which medicine and amount you took.

The main symptoms of an overdose are: headache, dizziness, ringing in the ears, blurred vision, drowsiness, nausea, vomiting and occasionally diarrhoea. Symptoms of excitement, restlessness, perspiration and insomnia caused by caffeine may also occur.

If you forget to take AspriVIT™

Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Due to its effect on platelet aggregation, acetylsalicylic acid may increase the risk of bleeding.

Common side effects (may affect 1 to 10 in 100 patients):

- Gastric ulcer, duodenal ulcer, gastrointestinal bleeding, abdominal pain, gastric disorders, nausea, vomiting.
- Shortness of breath, bronchial spasm, rhinitis.
- Hives, skin rash, angioedema.
- Hypoprothrombinemia (with high doses).

Uncommon side effects (may affect 1 to 10 in 1,000 patients):

- Reye's syndrome in children under 16, with feverish states, flu or chickenpox (see "What you need to know before you take AspriVIT™").
- Liver disorders, particularly in patients with juvenile arthritis.

In long-term treatments with high doses, dizziness, ringing in the ears, deafness, perspiration, headache, confusion and kidney disorders may occur. Treatment should immediately be suspended if the patient becomes aware of an episode of deafness, ringing in the ears or dizziness.

In patients who have shown an allergic reaction to acetylsalicylic acid or other nonsteroidal anti-inflammatories, anaphylactic or anaphylactoid reactions may occur. This could also occur in patients who have shown no prior hypersensitivity to these drugs.

Reporting of side effects

If you get any kind of side effect talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE ASPRIVIT™

Keep this medicine out of the sight and reach of children.

Keep the original package tightly closed.

Do not store above 25°C.

Do not use AspriVIT™ if you notice visible signs of deterioration.

Do not use AspriVIT™ after the expiration date, which is printed after EXP. on the carton: The expiration 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

Composition of AspriVIT™ tablets

The active substances are acetylsalicylic acid, caffeine and thiamine hydrochloride (vitamin B1).

Each tablet contains 500 mg of acetylsalicylic acid, 50 mg of caffeine, and 2 mg of thiamine hydrochloride (vitamin B1).

The other ingredients (excipients) are wheat starch, magnesium stearate and talc.

What the product looks like and contents of the package

AspriVIT™ are round, white tablets marked C/V on both sides.

They are packed in 10- and 20-tablet cartons and 200-tablet hospital cartons.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer:

Pharmex Advanced Laboratories, S.L.

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