

Aldomet®

250 mg and 500 mg film-coated tablets
Methylodopa

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.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

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1. WHAT ALDOMET® IS AND WHAT IT IS USED FOR

Aldomet® belongs to a group of medicines called anti-hypertensives, which lower the blood pressure. Methylodopa tablets are used to treat high blood pressure (hypertension).

2. BEFORE YOU TAKE ALDOMET®

Do not take Aldomet®

- If you are allergic (hypersensitive) to methylodopa or any of the other ingredients (see section 6).
- If you have liver disease.
- If you have high blood pressure due to a tumor near the kidney (phaeochromocytoma).
- If you suffer from depression.
- If you are taking MAOIs (monoamine oxidase inhibitors) for depression.

Take special care with Aldomet®

Check with your doctor or pharmacist before taking your medicine:

- If you have had liver disease.
- If you have kidney disease.
- If you or a relative have a genetic/inherited disorder of the red blood pigment hemoglobin (porphyria).
- If you have damaged or diseased blood vessels in your brain.

Taking Aldomet® with 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 (including herbal medicines). This is because Aldomet® can affect the way some other medicines work. Also some medicines can affect the way Aldomet® works.

Please tell your doctor if you are taking any of the following medicines. They can make Aldomet® work less well:

- NSAIDs (non-steroidal anti-inflammatory drugs) which are used to relieve pain
- Antihypertensive medicines used to treat high blood pressure (e.g. propranolol, nifedipine, verapamil or ‘water tablets’)
- Medicines used to treat anxiety or insomnia (e.g. diazepam, temazepam)
- Combined oral contraceptive or hormone replacement therapy (HRT)
- Medicines to treat Parkinson’s disease such as levodopa, entacapone
- Linezolid (used to treat some infections)
- Lithium (used to treat depression and mental illness)
- MAOIs (monoamine oxidase inhibitors) used to treat depression (e.g. phenelzine)
- Medicines to treat mental illness (e.g. chlorpromazine and thioridazine)
- Moxisylyte used to treat Raynaud’s syndrome
- Muscle relaxants such as baclofen, tizanidine
- Nitrates (e.g. glycerol trinitrate “GTN”, isosorbide dinitrate/mononitrate)
- Steroids (e.g. prednisolone, hydrocortisone)
- Sympathomimetics medicines used mainly for coughs and colds (e.g. ephedrine or salbutamol)

- Medicines used to treat ulcers such as carbenoxolone
- Iron supplements.

Taking Aldomet® with food and alcohol

Drinking alcohol with Aldomet® may make you feel dizzy or light-headed. If you are concerned about how much you can drink while you are taking Aldomet®, discuss this with your doctor as medicines used to reduce blood pressure and alcohol can have additive effects. Aldomet® may be taken with or without food.

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or are breast-feeding ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

You may feel dizzy, while taking Aldomet®. This is more likely to happen when you start taking Aldomet® or start taking a higher dose. If this happens, do not drive or use any tools or machines.

3. HOW TO TAKE ALDOMET®

Always take Aldomet® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

Swallow the tablets with water.

How much to take

- Treatment of high blood pressure:
Your doctor will adjust the amount you take until your blood pressure is controlled.

- Adults and children over 12 years:
Initially 250 mg two or three times a day, for 2 days, then increased every 2 or more days until an adequate response is achieved up to a maximum of 3g daily.

- Children under 12 years:
Initially 10 mg per kg of bodyweight daily in 2-4 divided doses adjusted as required up to 65 mg/kg or 3g daily, whichever is less.

- Elderly:
Initially no more than 250 mg a day (e.g. 125 mg twice

daily), increasing up to a maximum of 2 g a day.

If you take more Aldomet® than you should

Tell a doctor or go to the nearest hospital casualty department straight away. Do not drive to the hospital, get somebody else to take you or call for an ambulance. Take the medicine pack with you. This is so the doctor knows what you have taken.

If you forget to take Aldomet®

If you miss a dose, take your normal dose as soon as you remember.

If it is almost time for your next dose, skip the missed dose and continue with the regular dosing schedule. Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Aldomet® can cause side effects, although not everybody gets them.

Please tell your doctor or pharmacist if you notice any of the following or any effect not listed in this leaflet:

- Allergic reactions: skin rash which may be red and/or scaly, fever, inflammation of heart muscle (myocarditis), inflammation of the sac surrounding the heart (pericarditis).
- Blood: your medicine may alter the numbers and types of your blood cells and cause a rise in urea in the blood. If you notice increased bruising, nosebleeds, sore throats, infections or fever, you should tell your doctor who may want to give you a blood test.
- Endocrine system: abnormal production of milk.
- Central nervous system: drowsiness (usually lasts a few days at start of treatment or after an increased dose), headache, loss of strength or weakness, tingling or pins and needles, trembling and shuffling walk, partial paralysis of the face, involuntary jerky movements, mental changes including nightmares, confusion, mild depression, dizziness, light-headedness, reduced blood flow to the brain.
- Heart: slow heart rate and low blood pressure, wors-

ening of existing angina, low blood pressure causing dizziness on standing, water retention causing swelling and weight gain.

- Respiratory system: blocked/stuffy nose.
- Stomach and intestines: feeling or being sick, bloated stomach, constipation, flatulence, diarrhea, colitis, mild dryness of the mouth, sore or “black” tongue, inflamed salivary glands and inflammation of the pancreas (pancreatitis). Tell your doctor immediately if you get very severe abdominal pains.
- Liver: abnormal liver function, hepatitis, jaundice (yellowing of the skin and/or whites of the eyes). These would be detected by a blood test.
- Skin: eczema, hard skin rash (lichenoid), severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis).
- Muscles and bones: mild joint pain with or without swelling, muscle pain or cramps.
- Reproductive system and breasts: absence of periods, swelling of breasts in men and women, production of breast milk, failure to ejaculate, decreased sex drive, failure to maintain an erection (impotence).

5. HOW TO STORE ALDOMET®

Keep out of the reach and sight of children.

Do not store above 30°C.

Store in the original package.

Do not use Aldomet® tablets after the expiry date stated on the carton and the blisters. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

What Aldomet® contains

Aldomet® 250 mg contains 250 mg anhydrous methylodopa

Aldomet® 500 mg contains 500 mg anhydrous methylodopa

Excipients: powdered cellulose, ethylcellulose, colloidal silicon dioxide, calcium disodium edetate, citric acid anhydrous, magnesium stearate, hydroxypropylmethylcellulose, propylene glycol, red ferric oxide, titanium dioxide, talc, carnauba wax, guar gum, D&C yellow #10 aluminum lake.

What Aldomet® looks like and contents of the pack

Aldomet® 250 mg tablets are yellow, round biconvex film-coated tablets, engraved “ALG A250” on one side, plain on the other.

Aldomet® 500 mg tablets are yellow, round biconvex film-coated tablets, engraved “ALG A500” on one side, plain on the other.

The pack contains 30 tablets.
Not all strengths may be marketed.

For more information about this medicinal product,

please contact:

Algorithm SAL

Tel: +961-9-222050

To report any side effect:

Lebanon and all MENA countries

Algorithm SAL

Fax: +961-9-222141

Email: pharmacovigilance@blgx.net

Website: www.algorithm-lb.com

Also contact the relevant competent authority.

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold you the medicament.

- The doctor and the pharmacist are experts in medicine, its benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed.

- Do not repeat the same prescription without consulting your doctor.

Manufactured by

ALGORITHM S.A.L., Zouk Mosbeh, Lebanon

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