

ALDOMET® 250 mg Film-coated Tablets
ALDOMET® 500 mg Film-coated Tablets
(Methyldopa)

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

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet:

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

1. What Aldomet is and what it is used for

Aldomet contains the active substance called methyldopa. This belongs to a group of medicines called ‘antihypertensives’.

Your doctor has prescribed Aldomet to treat high blood pressure (hypertension).

2. What you need to know before you take Aldomet

Do not take Aldomet if you have:

- ever had a bad reaction, such as an allergy to methyldopa, or to any of the other ingredients (listed in section 6)
- liver disease
- depression
- high blood pressure due to a tumour near your kidney called ‘phaeochromocytoma’ or ‘paraganglioma’.
- been taking a type of medicine called a ‘monoamine oxidase inhibitor’ (MAO inhibitor)
- porphyria (a rare, inherited blood disorder)

Do not take Aldomet if any of the above applies to you. If you are not sure talk to your doctor or pharmacist before taking Aldomet.

Warnings and precautions

Talk to your doctor or pharmacist before taking Aldomet if you have:

- a blood disorder called haemolytic anaemia
- liver problems
- jaundice (yellowing of the skin and eyes)
- fever
- any abnormal movements (involuntary)
- had a stroke
- had a heart attack (myocardial infarction)

Check with your doctor while taking this medicine if you are going to have:

- dialysis
- an operation
- a blood transfusion.

Tolerance

There is the possibility to develop a tolerance to this medicine. If you have any concerns you should talk to your doctor.

Tests you may have while taking Aldomet

Your doctor may do blood tests to check how your liver is working during the first 6 – 12 weeks. He or she may use similar tests if you have a fever at any time while you are taking Aldomet. Tell your doctor you are taking Aldomet if you have a laboratory test where a urine or blood sample is taken. This is because Aldomet may affect the results of some types of tests. Rarely, in patients taking Aldomet urine may darken when it is exposed to air after voiding, If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Aldomet.

Other medicines and Aldomet

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription as some drugs may affect each other's action. This includes herbal medicines.

Do not take Aldomet if you are taking a type of medicine called a 'monoamine oxidase inhibitor' (MAO inhibitor) used to treat depression.

It is particularly important that you tell your doctor or pharmacist if you are taking any of the following before taking Aldomet

- other medicines for high blood pressure (antihypertensives)
- lithium - used to treat some types of depression
- medicines called 'phenothiazines' such as chlorpromazine - used for mental illness and sometimes feeling and being sick
- medicines called 'tricyclic antidepressants' - used to treat depression
- cough and cold remedies that contain a decongestant
- haloperidol – used to treat psychiatric disorders
- iron and supplements containing iron, such as multivitamins with minerals

Surgery

If you have to have surgery, including dental, that requires an anaesthetic, you must inform the dentist or hospital that you are taking Aldomet tablets.

Aldomet with alcohol

You are advised not to drink alcohol while taking Aldomet tablets. Discuss this with your doctor if you have any questions.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

You may feel drowsy or light-headed while taking Aldomet. If this happens do not drive or use any tools or machines.

Aldomet contains sodium

This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Aldomet

Always take Aldomet exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

You should take this medicine by mouth and exactly as advised by your doctor or pharmacist. The amount you take each day will depend upon your condition. It is very important to continue taking Aldomet for as long as your doctor has prescribed. Do not take more or less than your doctor has prescribed.

The usual doses of Aldomet are:

Adults

- The usual starting dose for the first two days is 250 mg two or three times a day.
- Your doctor may then change your dose depending on how you respond.
- You should not take more than 3000 mg in a day.

Elderly

Your doctor will work out the number of tablets you should take. Follow this dosage.

- Your doctor may change the dosage after he has monitored your response to the initial dosage regimen.
- Side effects in the elderly such as fainting can be minimised by using the lowest effective dose possible.

Use in children

The doctor will work out the number of tablets. The dose is based on the weight of the child.

- The usual starting dose is 10 mg for each kg of body-weight each day.
- This dose is taken in two to four doses during the day.
- Your doctor may then change the dose, depending on how the child responds.
- A child will not usually take more than 65 mg for each kg (or 3000 mg a day), whichever is less.

If you take more Aldomet than you should

If you take too many tablets by mistake, contact your doctor immediately or seek medical attention.

If you forget to take Aldomet

- If you forget to take a dose, just carry on with the next dose as normal.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Aldomet

Do not stop taking Aldomet without talking to your doctor.

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.

Contact your doctor **IMMEDIATELY** if you have any of the following side effects as they are serious and require medical attention:

- an allergic reaction – symptoms such as shortness of breath, skin rash or itching, hives, swelling of your lips, face or tongue, chills or
- fever or painful joints
- chest pain, slow heart rate, existing angina made worse, problems with the electrical current in the heart (AV block)

- severe skin reactions (such as painful reddening, followed by blistering and peeling of layers of skin)
- liver problems, including jaundice and hepatitis - signs include yellowing of your skin and eyes, sometimes with a fever, pale stools and dark urine
- pain in the gut and diarrhoea caused by inflammation of the bowel (colitis)
- severe pain in the gut and back caused by inflammation of the pancreas (pancreatitis).

Other unwanted effects which may occur while taking Aldomet Tablets are:

Blood:

- reduction in red blood cells (anaemia) – this can make your skin pale and make you weak or breathless
- abnormal blood test causing symptoms such as pale skin, tiredness, fever and sore throat
- bruising and prolonged bleeding after injury
- your medicine may alter the numbers and types of your blood cells and cause a rise in urea in the blood.

Nervous system:

- feeling sleepy or tired - this may happen at the start of treatment or when the dose is increased, and usually goes away
- headache or feeling weak – this may happen at the start of treatment and usually goes away
- pins and needles
- being unable to move part of your face (paralysis)
- having movements you cannot control
- Parkinsonism – with symptoms such as tremor, a decrease in body movements with an inability to move your muscles
- confusion
- frequent dizziness or fainting
- dizziness due to low blood pressure and light-headedness (particularly when standing up quickly)

Nose and chest:

- nasal stuffiness

Stomach and gut:

- | | |
|-------------------|-----------------|
| • feeling sick | • excess wind |
| • being sick | • diarrhoea |
| • abdominal pain | • dry mouth |
| • feeling bloated | • sore or black |
| • constipation | tongue |

Skin and hair:

- skin rash or peeling skin

Joints and muscles:

- painful and/or swollen joints
- muscle pains

Infections:

- swelling of salivary glands

General:

- water retention causing swelling and weight gain
- fever

Allergic:

- inflammation of heart muscle or the sac surrounding the heart, skin rash which may be red and/or scaly, fever.

Sexual:

- breast enlargement
- breast development in men
- loss of periods in women
- abnormal production of milk
- changes in sexual function such as impotence and not being able to ejaculate
- decreased sex drive

Psychiatric:

- mental changes, including nightmares or depression
- delusions and paranoia - which will stop when you stop taking this medicine

Laboratory tests:

Your doctor may need to carry out simple blood tests during the first few months of therapy with Aldomet. Results could show:

- a decrease in blood cell production
- an increase in some white blood cells
- abnormal levels of prolactin
- a positive result for antinuclear antibodies, LE cells and rheumatoid factor

If you get any side effects, please tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Aldomet

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

Do not use the medicine after the expiry date which is stated on the carton or bottle after 'EXP'. For the blister strip refer to the expiry information on the side of the carton.

Do not store above 25°C.

Blisters: Store in the original package in order to protect from light.

Bottles: Keep the container tightly closed in order to protect from light.

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 protect the environment.

6. Contents of the pack and other information

What Aldomet contains

Active substances

The active substance in Aldomet tablets is methyldopa.

Aldomet tablets are available in two different strengths containing methyldopa equivalent to either 250 mg anhydrous methyldopa, or 500 mg anhydrous methyldopa.

Other ingredients

Cellulose powder, anhydrous citric acid, colloidal anhydrous silica, ethylcellulose, guar gum, magnesium stearate, sodium calcium edetate, hypromellose, propylene glycol, quinoline yellow aluminium lake E104, red iron oxide E172, talc, titanium dioxide, carnauba wax.

What Aldomet looks like and contents of the pack

Aldomet is available as film-coated tablets which come in two different strengths. They are yellow-coloured, round tablets containing methyldopa equivalent to either 250 mg anhydrous methyldopa, or 500 mg anhydrous methyldopa.

Aldomet Tablets 250 mg are available in packs of 60.

Aldomet Tablets 500 mg are available in packs of 30.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland

Manufacturer:

Aspen Bad Oldesloe GmbH Industriestrasse 32-36, 23843 Bad Oldesloe, Germany

The leaflet was last amended