

Aldomet® 250 mg Film-coated Tablets

(methyl dopa)

2226
16.11.20[15]

PATIENT INFORMATION LEAFLET

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, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

Your medicine is available using the above name but will be referred to as Aldomet throughout the leaflet. This medicine is also available as 500mg tablets.

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 methyl dopa. This belongs to a group of medicines called 'antihypertensives'.

Methyl dopa is changed inside your body to a natural substance that lowers blood pressure. 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 methyl dopa, or to any of the other ingredients (listed in section 6)
- ever had liver disease
- ever had 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.

Take special care with Aldomet

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)

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

- dialysis
- an operation
- a blood transfusion.

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
- iron and supplements containing iron, such as multivitamins with minerals

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

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

You should check with your doctor before taking Aldomet if you are or think you may be pregnant, if you are planning to become pregnant or if you are breast-feeding.

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.

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.

The elderly

- The usual starting dose will not be more than 250 mg each day.
- Your doctor may then slowly increase the dose.
- You should not usually take more than 2000 mg in a day.

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).

The following reactions have also been reported:

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

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

Aldomet may also interfere with the interpretation of certain blood and urine tests.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard 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 ALDOMET

Keep out of the sight and reach of children.

Do not use Aldomet after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from light.

If the medicines become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Aldomet Tablets contain

The active ingredient in 'Aldomet' Tablets is methyldopa.

Each Aldomet 250 mg film-coated tablet contains methyldopa equivalent to 250mg anhydrous methyldopa.

Aldomet also contains: 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 E171, citric acid monohydrate and carnauba wax.

What Aldomet looks like and the contents of the pack

Aldomet 250 mg Film-Coated Tablets are yellow, round biconvex film-coated tablets with 'ALDOMET' embossed on one side and '250' on the reverse.

Available in pack size of 60 tablets.

PRODUCT LICENCE HOLDER AND MANUFACTURER

Manufactured by H.A.C. Pharma, Pericentre IV, 8 avenue de la Cote de Nacre, 14052 CAEN Cedex, France.

Procured from within the EU by Product Licence holder:

Star Pharmaceuticals Ltd., 5, Sandridge Close, Harrow, Middlesex HA1 1XD. Repackaged by Servipharm Ltd.

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**Blind or partially sighted?
Is this leaflet hard to see or read?
Call 020 8423 2111 to obtain the
leaflet in a format suitable for you.**

Methyldopa 250 mg Film-coated Tablets

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- If you get any side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

Your medicine is available using the above name but will be referred to as Methyldopa throughout the leaflet. This medicine is also available as 500mg tablets.

What is in this leaflet:

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

1. WHAT METHYLDOPA IS AND WHAT IT IS USED FOR

Methyldopa contains the active substance called methyldopa. This belongs to a group of medicines called 'antihypertensives'.

Methyldopa is changed inside your body to a natural substance that lowers blood pressure. Your doctor has prescribed Methyldopa to treat high blood pressure (hypertension).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE METHYLDOPA

Do not take Methyldopa 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)
- ever had liver disease
- ever had 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 Methyldopa if any of the above applies to you. If you are not sure talk to your doctor or pharmacist before taking Methyldopa.

Take special care with Methyldopa

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

- a blood disorder called haemolytic anaemia
- liver problems
- jaundice (yellowing of the skin and eyes)
- fever
- any abnormal movements (involuntary)

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

- dialysis
- an operation
- a blood transfusion.

Tests you may have while taking Methyldopa

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 Methyldopa. Tell your doctor you are taking Methyldopa if you have a laboratory test where a urine or blood sample is taken. This is because Methyldopa may affect the results of some types of tests.

Rarely, in patients taking Methyldopa 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 Methyldopa.

Other medicines and Methyldopa

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 Methyldopa 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 Methyldopa

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- medicines called 'tricyclic antidepressants' - used to treat depression
- cough and cold remedies that contain a decongestant
- iron and supplements containing iron, such as multivitamins with minerals

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

Surgery

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

Methyldopa with alcohol

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

Pregnancy and breast-feeding

You should check with your doctor before taking Methyldopa if you are or think you may be pregnant, if you are planning to become pregnant or if you are breast-feeding.

Driving and using machines

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

3. HOW TO TAKE METHYLDOPA

Always take Methyldopa 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 Methyldopa for as long as your doctor has prescribed. Do not take more or less than your doctor has prescribed.

The usual doses of Methyldopa are:

Adults

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The elderly

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

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If you stop taking Methyldopa

Do not stop taking Methyldopa 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

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- 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).

The following reactions have also been reported:

Blood:

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- 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:

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- excess wind
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- dry mouth
- sore or black tongue

Skin and hair:

- skin rash or peeling skin

Joints and muscles:

- painful and/or swollen joints
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Infections:

- swelling of salivary glands

General:

- water retention causing swelling and weight gain
- 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 Methyldopa. Results could show:
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Methyldopa may also interfere with the interpretation of certain blood and urine tests.

Reporting of side effects

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www.mhra.gov.uk/yellowcard 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 METHYLDOPA

Keep out of the sight and reach of children.

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Do not store above 25°C. Store in the original package in order to protect from light.

If the medicines become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

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Methyldopa also contains: 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 E171, citric acid monohydrate and carnauba wax.

What Methyldopa looks like and the contents of the pack

Methyldopa 250 mg Film-Coated Tablets are yellow, round biconvex film-coated tablets with 'ALDOMET' embossed on one side and '250' on the reverse.

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