

Applicant: Aurogen South Africa (Pty) Ltd
Product Name: DAMLOVAN 5 mg/160 mg; DAMLOVAN 10 mg/160 mg
Dosage form and strength: Each tablet contains Amlodipine Besilate equivalent to Amlodipine 5 mg or 10 mg base and Valsartan 160 mg, 5 mg/160 mg and 10 mg/160 mg film coated tablets.

MODULE 1

1.5.5.2

Submission date: 05 April 2023

Approved Patient Information Leaflet

SCHEDULING STATUS S3

PATIENT INFORMATION LEAFLET

DAMLOVAN 5 mg/160 mg, film coated tablets (5 mg amlodipine besilate and 160 mg valsartan).

DAMLOVAN 10 mg/160 mg, film coated tablets (10 mg amlodipine besilate and 160 mg valsartan).

Sugar free

Read all of this leaflet carefully before you start taking DAMLOVAN

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- DAMLOVAN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

05. What DAMLOVAN is and what it is used for

You have been prescribed DAMLOVAN because:

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DAMLOVAN tablets contain two substances called amlodipine and valsartan. Both of these substances help to control high blood pressure.

Amlodipine belongs to a group of substances called “calcium channel blockers”. Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.

Valsartan belongs to a group of substances called “angiotensin-II receptor antagonists”. Angiotensin II is produced by the body and makes the blood vessels tighten, thus increasing the blood pressure. Valsartan works by blocking the effect of angiotensin II.

This means that both of these substances help to stop the blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.

DAMLOVAN is used to treat high blood pressure in adult patients whose blood pressure is not adequately controlled with a single blood pressure lowering medicines either amlodipine or valsartan.

2. What you need to know before you take DAMLOVAN

Do not take DAMLOVAN:

- If you have a history of allergies related to taking this type of medicine.
- If you have experienced swelling, particularly of the face and throat, while taking other medicines (including angiotensin converting enzyme inhibitors).
- If you have recurrent episodes of severe swelling without a known cause.
- If your doctor has diagnosed that you are suffering from a narrowing of valves in your heart (called aortic or mitral stenosis), or abnormally increased thickness of your heart muscle with narrowing (called obstructive hypertrophic cardiomyopathy).
- If you have received a kidney transplant or if you had been diagnosed to suffer from a narrowing of your kidney artery or if you are suffering from severe kidney problems.
- If you are taking other medicine or substances, which increase the potassium levels in your blood (such as certain types of diuretics, potassium supplements, etc.)
- If you are taking medicines that contain lithium (a medicine used to treat some type of depression).
- If you have porphyria

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- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- If you have severe liver impairment
- If you have severe low blood pressure (hypotension)
- If you have cardiogenic shock (a condition where your heart is unable to supply enough blood to the body)
- If you suffer from heart failure after a heart attack.
- If you are pregnant or breastfeeding.

If any of these apply to you, tell your doctor without taking DAMLOVAN.

Warnings and precautions

Take special care with DAMLOVAN

- If you are suffering from several episodes of vomiting or diarrhoea.
- If you suffer from liver or severe kidney problems.
- If you have a condition affecting the renal glands called “primary hyperaldosteronism”.
- If you have experienced swelling, particularly of the face and throat, while taking other medicines (including angiotensin converting enzyme inhibitors). If you get these symptoms, stop taking DAMLOVAN and contact your doctor straight away. You should never take DAMLOVAN again.
- If you have had heart failure or have experienced a heart attack. Follow your doctor’s instructions for the starting dose carefully. Your doctor may also check your kidney function.
- Contact your doctor to re-evaluate your treatment if you are treated with ACE Inhibitors/Angiotensin receptor blockers together with a fluoroquinolone antibiotic.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

Children and adolescents

- The use of DAMLOVAN in children and adolescents is not recommended (aged below 18 years old).

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Other medicines with DAMLOVAN:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

Concomitant use of DAMLOVAN with the following medicines may cause undesirable interactions.

- ACE inhibitors or aliskiren (medicines used to treat high blood pressure) (see also information under the headings “Do not take DAMLOVAN”);
- Diuretics (a type of medicine also called “water tablets” which increase the amount of urine you produce)
- Potassium-sparing medicines, potassium supplements, or salt substitutes containing potassium and other substances that may increase potassium levels.
- Nitroglycerin and other nitrates, or other substances called “vasodilators”;
- Medicines used for HIV/AIDS (e.g. ritonavir, indinavir, nelfinavir);
- Medicines used to treat fungal infections (e.g. ketoconazole, itraconazole);
- Clarithromycin (for infections caused by bacteria);
- Verapamil, diltiazem (heart medicines);
- Medicines used to treat bacterial infections (such as rifampicin, erythromycin, 5elithromycin;
- Anticonvulsant medicines like carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone, rifampicin, Hypericum perforatum:
- Non-steroidal anti-inflammatory medicines (NSAIDs), including selective COX-2 inhibitors, acetylsalicylic acid, and non-selective NSAIDs like pain killer medicines.
- St. John’s wort
- Simvastatin (a medicine used to control high cholesterol levels)
- Dantrolene (infusion for severe body temperature abnormalities)
- Tacrolimus (used to control your body’s immune response, enabling your body to accept the transplanted organ).
- Medicines used to protect against transplant rejection (ciclosporin)

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- Lithium (a medicine used to treat some types of depression) (see also information under the headings “Do not take DAMLOVAN”)

Taking DAMLOVAN with food and drink

- Grapefruit and grapefruit juice should not be consumed by people who are taking DAMLOVAN. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active substance amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of DAMLOVAN.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking DAMLOVAN.

Safety of DAMLOVAN in pregnant and breast feeding women has not been established.

You should not use DAMLOVAN if you are pregnant, trying to become pregnant or breastfeeding your baby.

If you are a woman of childbearing age, you should ensure that you use an effective contraception.

Driving and using machines

DAMLOVAN may cause dizziness and affect the ability to concentrate. So before you drive a vehicle, use machinery, or carry out other activities that require concentration, make sure you know how you react to the effects of DAMLOVAN.

3. How to take DAMLOVAN

Do not share medicines prescribed for you with any other person. Always take DAMLOVAN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

- The usual dose of DAMLOVAN is one tablet per day.
- It is preferable to take your medicine at the same time each day.
- Swallow the tablets with a glass of water.

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- You can take DAMLOVAN with or without food.
- Do not take DAMLOVAN with grapefruit or grapefruit juice.
- Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.
- Do not exceed the prescribed dose.

DAMLOVAN and older people (age 65 years or over)

Your doctor should exercise caution when increasing your dose.

If you take more DAMLOVAN than you should

If you have accidentally taken too many tablets of DAMLOVAN, consult your doctor immediately, If doctor is not available, contact the nearest hospital or poison centre.

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness. Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

If you forget to take DAMLOVAN

It is advisable to take your medicine at the same time each day, preferably in the morning. If you forget to take DAMLOVAN, take it as soon as you remember and then take your next dose at its usual time. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for the forgotten tablet.

If you stop taking DAMLOVAN

Stopping your treatment with DAMLOVAN may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

4. Possible side effects

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DAMLOVAN can have side effects.

Not all side effects reported for DAMLOVAN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DAMLOVAN, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following symptoms occur, stop taking DAMLOVAN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- sudden wheeziness, chest pain, shortness of breath or difficulty in breathing
- severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of the mucous membranes (Stevens-Johnson Syndrome, toxic epidermal necrolysis) or other allergic reactions
- inflamed pancreas, which may cause severe abdominal and back pain accompanied with feeling of being very unwell
- heart attack, abnormal heartbeat
- upper airway swelling.

These are all serious side effects. You may need urgent medical attention.

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Tell your doctor if you notice any of the following:

Frequent:

- Flu-like symptoms; nasal congestion;
- Sore throat and discomfort when swallowing;
- Low potassium levels in the body;
- Headache;
- Asthenia (weakness);
- Dizziness;
- Stomach pain;
- Feeling sick (nausea);
- Tiredness;
- Facial swelling;
- Redness and warm feeling of the face and/or the neck;
- Swelling in the body caused by excess fluid. It often affects the lower body, such as the legs, feet, and ankle but it can occur anywhere.

Less Frequent:

- Anorexia, loss of appetite;
- High Calcium levels in the body;
- High uric acid levels in the body;
- High lipid levels in the body;
- Low levels of sodium in the blood;
- Anxiety (feeling anxious);
- Abnormal coordination;
- Paraesthesia (Tingling or prickling sensation).
- Somnolence (sleepiness, feeling of drowsiness);
- Vision disturbance and impairment;
- Tinnitus (ringing in the ears);

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- Vertigo (head spinning);
- Fast heart beat including palpitations;
- Low blood pressure and light headedness when standing up;
- Cough, sneezing/runny nose caused by inflammation of the lining of the nose (rhinitis);
- Throat pain;
- Constipation, change of bowel habit;
- Diarrhoea, dry mouth;
- Nausea, vomiting, indigestion;
- Excessive sweating;
- Redness of the skin;
- Skin rash all over your body;
- Joint swelling;
- Back pain; pain in joints, muscle spasm, muscle cramps;
- Sensation of heaviness;
- Passing more urine than normal or feeling more of an urge to pass urine;
- Inability to get or maintain an erection;
- A low level of white blood cells in the blood;
- Low blood platelet count;
- Excess sugar in blood (hyperglycaemia);
- Mood changes, depression, confusion;
- Taste abnormalities, loss of pain sensation, abnormal sensation, typically tingling or pricking ('pins and needles'), high level of muscle tone;
- Trembling, sleeplessness, partial or total loss of sensation in a part of your body;
- An inflammation of the blood vessels that causes changes in the blood vessel walls;
- Swelling of the gums;
- Abdominal bloating (gastritis), increased liver enzyme which may have an effect on some medical tests;
- Abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice);
- Hair loss;

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- Skin discolouration;
- Skin sensitivity to light, purple spots under the skin, hives;
- Discomfort or enlargement of the breasts in men;
- Lack of energy;
- Chest pain, feeling unwell;
- Pain;
- Weight increase or decrease.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via the “6.04 Adverse Drug reaction Reporting Form” found online under 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 this medicine.

5. How to store DAMLOVAN

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C (room temperature).

Do not remove blisters from the original carton until required for use.

Keep HDPE containers tightly closed.

Keep all medicines out of the reach and sight of children.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DAMLOVAN contains

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Valsartan

Cellulose Microcrystalline

Silica, Colloidal Anhydrous

Sodium Starch Glycolate

Povidone Ph.Eur

Amlodipine besilate

Starch, Pregelatinised

Magnesium Stearate

Opadry 03F82429 Yellow HIS (for 5 mg/160mg only)

Opadry 03F82428 Yellow HIS (for 10 mg/160mg only)

Purified water

Blister pack: DAMLOVAN 5 mg/160 mg, 10 mg/160 mg, are proposed to be marketed in the Blister pack 30's (3X10's).

HDPE container: DAMLOVAN 5 mg/160 mg, 10 mg/160 mg, White opaque round 40 mL HDPE container 30's. Each HDPE container shall contain 1 no of 1 g silica gel sachet.

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

AUROGEN SA (Pty) Ltd

Woodhill Office Park, Building 1, First Floor

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South Africa

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