

PACKAGE LEAFLET: INFORMATION FOR THE USER
Daman 0.5 mg, 1 mg, 2 mg and 4 mg Capsules hard
(Trandolapril)

Read all of this leaflet carefully before you start using 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, please tell your doctor or pharmacist.

In this leaflet:

1. What **Daman** is and what it is used for
2. Before you use **Daman**
3. How to use **Daman**
4. Possible side effects
5. How to store **Daman**
6. Further information

1. What Daman is and what it is used for

Trandolapril, the active ingredient in **Daman** belongs to a group of medicines called angiotensin-converting enzyme inhibitors (sometimes called ACE inhibitors). ACE inhibitors work by relaxing the blood vessels which makes it easier for the heart to pump blood around the body. This helps to lower the blood pressure.

Daman is used to treat high blood pressure. It may also be used to protect the heart after a heart attack.

2. Before you use Daman

Do not use Daman if:

- You are allergic to trandolapril, other ACE inhibitors (e.g. perindopril or ramipril) or any of the other ingredients listed in section 6
- You have ever had the condition known as angioedema (an itchy rash such as nettle rash or hives) or Quinke's oedema (this is a severe allergic skin condition)
- You are more than 3 months pregnant. (It is also better to avoid Daman in early pregnancy – see pregnancy section.)

Take special care with Daman if:

It is possible that you may develop problems with low blood pressure and reduced kidney function if you are a patient at risk being treated with Daman. This may cause you to faint. You must be placed in a side position and someone in your surroundings must call an ambulance or the emergency services.

You must tell your doctor if:

- You have been taking diuretics (water tablets) for a long time or you have been on a low salt diet
- You recently had severe or prolonged vomiting or diarrhoea
- You ever had an allergic reaction (named Quinke's oedema or angioedeme) to any other ACE inhibitors (e.g. perindopril or ramipril – including swelling in the face, lips, tongue or throat with difficulty in swallowing or breathing)
- You suffer from a condition known as collagen vascular disease (this is sometimes called connective tissue disease, for example lupus or scleroderma)
- You suffer from diabetes mellitus
- You suffer from heart failure
- You are on kidney dialysis (some kinds of dialysis membrane may not be suitable)
- You have liver or kidney problems
- You are going to be anaesthetised before an operation

- You have a narrowing of one of the valves in the heart (aorta stenosis) or in the outflow from the left chamber of the heart
- You are being treated with medicine that lowers your immune response
- You develop a cough. Your doctor may choose another medicine for you
- You are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine)
- You are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings
- You think you are (or might become) pregnant. Daman is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Using other medicines

Other medication can affect the efficacy and safety of this medication. On the other hand, **Daman** can affect to the efficacy and safety of other medication. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, herbal products or natural products. Remember to tell your doctor about **Daman** if you receive another medication during your treatment or shortly after your treatment with **Daman**. It is especially important to inform your doctor if you use:

- Other medicines for high blood pressure including water tablets such as bendroflumethiazide
- Diuretics (water tablets) that retain potassium such as spironolactone, amiloride and triamterene or potassium supplements
- Anti-inflammatory pain killers (NSAIDs – e.g. ibuprofen, diclofenac, indometacin)
- Lithium or tricyclic antidepressant (e.g. amitriptyline, dosulepin)
- Medicines for diabetes (such as insulin, glibenclamide or gliclazide)
- Sympathomimetics – these include ephedrine, pseudoephedrine and salbutamol and may be found in some decongestants, cough/cold medicines and asthma medication
- Antacids
- Allopurinol (for gout) or procainamide (for abnormal heart rhythms)
- Immunosuppressants (e.g. ciclosporin), steroid medication (e.g. prednisolone, hydrocortisone) or anticancer medication
- Morphine and similar strong pain killers / antipsychotic drugs
- Antipsychotic drugs such as chlorpromazine, thioridazine, flupentixol

If you need to have an operation, it is important that you tell the surgeon or dentist that you are taking **Daman**. It may affect the anaesthetic or other treatments used.

Contact your doctor and inform him if you are taking any of the above medications. It may be necessary to adjust the dose.

Using Daman with food and drink

You may take **Daman** with or after food and with drink.

Drinking alcohol increases the blood pressure lowering effect of Daman.

Alcohol can also reduce your reactions, see 'Driving and using machines'.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy:

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Daman before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Daman. Daman is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast feeding:

Tell your doctor if you are breast-feeding or about to start breast-feeding. Daman is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Daman can make some people feel dizzy or faint especially when they first start to take the capsules. Do not drive, operate machinery or do anything that requires you to be alert for several hours after your first dose or any increase in the dose. Wait and see how the capsules affect you.

Important information about some of the ingredients of Daman

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine (in capsules of 0.5 mg, 1 mg and 2 mg) contains sunset yellow (E110). May cause allergic reactions.

3. How to use Daman

Always take **Daman** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Swallow your capsules whole without chewing them and take them with a glass of water. Always take them at the same time of day.

The number of capsules that you will need to take will depend on what you are treated for. If you are already taking diuretics your doctor may tell you to reduce the dose of the diuretic or even tell you to stop taking them, before you start to take **Daman**.

Adults:

High blood pressure (hypertension):

The usual starting dose is 0.5 mg once a day. Your doctor will probably increase this dose to 1-2 mg daily. The maximum dose is 4 mg a day.

Treatment following a heart attack:

Treatment will normally be started quite soon after a heart attack, usually at a low dose of 0.5 mg each day. Your doctor will probably increase this dose gradually to a maximum of 4 mg each day.

Dose for adults treated earlier with diuretics (water tablets):

The diuretic treatment (water tablets) should be discontinued at least 72 hours (3 days) before beginning treatment with Daman, and/or treatment may be started with 0.5 mg once daily. Afterwards the dose will be adjusted when your doctor sees the effect of the treatment.

The elderly:

It is not necessary to reduce the dose if you have normal kidney function. You must start with a low dose, and your doctor will watch your blood pressure and measure your kidney function during treatment. However, caution is needed if at the same time you are being treated with diuretics (water tablets) or you have reduced heart, liver or kidney function.

Children:

Daman is not recommended for use in children.

Patients with kidney problems:

Your doctor will adjust your dose depending on the results of your laboratory tests (0.5-1 mg daily). Patients in kidney dialysis: 0.5 mg daily.

Patients with liver problems: The initial dose is 0.5 mg daily. Afterwards your doctor may adjust your dose as needed.

If you take more Daman than you should

Contact your doctor, hospital or pharmacy, if you have taken too much of this medicine and you feel uncomfortable.

The symptoms of overdose are severely reduced blood pressure, shock (swelling in the mouth and throat which causes difficulty breathing - contact your doctor), slowing down of thought processes (lethargy), slow pulse, disturbances in the salt balance and reduced kidney function.

If you forget to take Daman

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

If you stop using Daman

It is important that you keep taking the capsules until your doctor tells you to stop. Do not stop just because you feel better. If you stop taking the capsules, your condition may get worse.

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

4. Possible side effects

Like all medicines, **Daman** can cause side effects, although not everybody gets them.

Very common side effects (*occur in more than 1 out of 10 treated*) **and common side effects** (*occur in between 1 and 10 out of 100 treated*):

Reduced blood pressure

Common side effects (*occur in between 1 and 10 out of 100 treated*): Dizziness, headache, weakness and cough.

Uncommon side effects (*occur in between 1 and 10 out of 1,000 treated*):

Noticeable heartbeats. Nausea. Itching and skin rash. feeling sick and/or being sick.

Rare side effects (*occur in between 1 and 10 out of 10,000 treated*) **and very rare side effects** (*occur in fewer than 1 out of 10,000 treated*):

Nervousness, difficulties sleeping, sleepiness moving towards loss of consciousness. Throat irritation, nosebleed. Vomiting, stomach pain, diarrhoea, constipation, indigestion. Fluid retention (oedema), tendency to sweat, nettle rash. Muscle pain. Hot flashes.

Side effects with unknown frequency:

Changes to blood test parameters such as liver enzyme, creatinine and urea. Allergic reaction such as itching and skin rash. Increased levels of potassium in the blood. Bleeding in the brain, muscular paralysis, temporary loss of consciousness. Shortness of breath, bronchitis. Dry mouth, inflammation in the pancreas. Hair loss. Severe skin diseases (including Erythema multiforme and Stevens-Johnson's syndrome). Fever. Blood disorders such as agranulocytosis (a condition in which there is an insufficient number of white blood cells and therefore infections can occur), leucopenia (reduction in the number of white blood cells), pancytopenia (a reduction of all types of blood cells, including red and white blood cells as well as platelets) and decreased amount of oxygen-carrying protein in the blood (haemoglobin) and haematocrit (the proportion of space red blood cells take up in the blood).

Other side effects that have been reported with ACE inhibitors include kidney problems, severe drops in blood pressure with symptoms such as fainting, chest pain or stroke.

Allergic reactions have been reported very rarely. If you experience any sudden wheeziness, tightness in the chest, difficulty swallowing, swelling of eyelids, face or lips, a skin rash such as red spots or hives (skin lumps) or itching, please talk to your doctor **immediately**.

If you suffer from any of these side effects or any other side effects not mentioned in this leaflet, please talk to your doctor or pharmacist.

5. How to store Daman

- Keep out of the reach and sight of children.
- Store in the original package.
- Store below 25°C
- Do not use after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- 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. Further information

What Daman contains

- The active substance in your medicine is trandolapril 0.5 mg, 1 mg, 2 mg or 4 mg
- The other ingredients are: lactose monohydrate, starch pregelatinised, microcrystalline cellulose, dimeticone, magnesium stearate, colloidal silicon dioxide, gelatin, titanium dioxide (E171) and erythrosine (E127). In addition, each strength also contains the following;

0.5 mg: sunset yellow (E110), quinoline yellow (E104)
 1 mg: sunset yellow (E110)
 2 mg: sunset yellow (E110)
 4 mg: red iron oxide (E172) and yellow iron oxide (E172)

What Daman looks like and contents of the pack

0.5 mg: light scarlet – rich yellow, size 2 capsules
 1 mg: light scarlet – light orange, size 2 capsules
 2 mg: light scarlet – light scarlet, size 2 capsules
 4 mg: swedish orange – swedish orange, size 2 capsules

Contents:

0.5 mg: 14, 20, 28, 30, 50, 56, 100
 1 mg: 28, 30, 98, 100
 2 mg: 14, 20, 28, 30, 50, 56, 100
 4 mg: 14, 20, 28, 30, 56, 84, 90

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Meditrina Pharmaceuticals Ltd.
 Irakleitou 117, 152 38, Halandri, Greece
 +30 210 6726260

Manufacturer

Pharmathen S.A., Athens, Greece

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Trandolapril Pharmathen 0.5mg, 1 mg, 2 mg, 4 mg hårde kapsler
Greece	DAMAN 0.5mg, 1 mg, 2 mg, 4 mg caps
Slovakia	Trandolapril Pliva 0.5mg, 1 mg, 2 mg, 4 mg tvrdá kapsula
United Kingdom	Trandolapril 0.5mg, 1 mg, 2 mg, 4 mg capsules hard