

Package leaflet: Information for the user

Corvaton 2 mg tablets

molsidomine

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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Corvaton 2 mg tablets (hereinafter Corvaton tablets) are and what they are used for
2. What you need to know before you take Corvaton tablets
3. How to take Corvaton tablets
4. Possible side effects
5. How to store Corvaton tablets
6. Contents of the pack and other information

1. What Corvaton tablets are and what they are used for

Molsidomine, the active substance of Corvaton tablets, dilates the coronary arteries, thereby improving oxygen supply to the heart muscle. In addition, molsidomine reduces cardiac effort by decreasing the heart's peripheral load, and decreases the heart's oxygen requirement. Molsidomine also simultaneously inhibits platelet aggregation.

Based on the above, this medicine is primarily used in case of insufficient oxygen supply to the heart muscle.

Corvaton tablets are used in the following conditions:

- Stable or unstable angina pectoris (pain around the heart caused by a circulation disorder of the coronary arteries), in case of concomitant left ventricular failure.
- Angina pectoris (chest pain caused by coronary artery disease) during the acute phase of myocardial infarction, after circulation has been restored.
- Cases of angina pectoris where other agents are not indicated, lack efficacy or are not well tolerated by the patient, and for the treatment of elderly patients.

2. What you need to know before you take Corvaton tablets

Do not take Corvaton tablets:

- if you are allergic to molsidomine or any of the other ingredients of this medicine (listed in section 6),
- in case of very low blood pressure,
- in case of acute peripheral circulatory failure,
- to alleviate chest pain caused by sudden-onset coronary artery spasm,
- while breast-feeding,
- concomitantly with tablets containing the active substances sildenafil, tadalafil or vardenafil due to the risk of potentiation of the blood pressure lowering effects,
- concomitantly with medicines called soluble guanylate cyclase (sGC) stimulators (such as

riociguat, a medicine used to treat high blood pressure in the blood vessels of the lungs/pulmonary arterial hypertension/) due to the risk of potentiation of the blood pressure lowering effects.

Warnings and precautions

Talk to your doctor or pharmacist before taking Corvaton tablets.

Corvaton tablets may be given based on the doctor's individual judgement, with increased caution:

If insufficient cardiac function occurs as a result of heart muscle disease, inflammation of the pericardium or heart valve stenosis.

More frequent medical monitoring and, if necessary, dose reduction is recommended in patients for whom an excessive drop in blood pressure may present a risk.

The doctor should monitor patients for whom an excessive drop in blood pressure represents a risk more frequently.

In case of recent myocardial infarction, Corvaton may only be used after circulation has been restored, under close medical supervision and constant monitoring of circulation.

Other medicines and Corvaton tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Corvaton tablets should not be taken concomitantly with medicines called soluble guanylate cyclase (sGC) stimulators (see “Do not take Corvaton tablets”).
- Concomitant administration of Corvaton tablets and blood pressure lowering medicines (such as vasodilator nitrates, calcium antagonists, beta receptor blockers) or other medicines with a blood pressure lowering effect (such as desipramine, nortriptyline, dothiepin, desipramine: antidepressants called tricyclic antidepressants or medicines used to treat schizophrenia called antipsychotic medicines, such as chlorpromazine, diethazine, haloperidol, olanzapine, risperidone, tiapride, domperidone) may lead to potentiation of the blood pressure lowering effect of Corvaton tablets.
- Concomitant administration of Corvaton tablets and medicines containing what are called phosphodiesterase-5 inhibitors (such as sildenafil, tadalafil, vardenafil) used to treat erectile dysfunction may result in a very significant potentiation of the blood pressure lowering effect (see “Do not take Corvaton tablets”).
- Concomitant administration of Corvaton tablets and ergot alkaloids with a vasoconstrictor effect (such as ergotamine, dihydroergotamine) should be avoided, as they may inhibit each other's effect.

Corvaton tablets with food, drink and alcohol

The tablets may be taken independently of meals.

Alcohol may potentiate the blood pressure lowering effect of Corvaton tablets.

Pregnancy, breast-feeding and fertility

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

There are no adequate data regarding the use of the active substance (molsidomine) in pregnant women. During pregnancy, the doctor may only prescribe this medicine in exceptional cases, after careful consideration of the benefit/risk, therefore you must tell your doctor about the pregnancy. Do not use during breast-feeding (molsidomine passes into breast milk).

Driving and using machines

Certain side effects of this medicine (such as dizziness) may impair concentration and reaction time, mainly at the start of treatment. If you experience the above symptoms, do not drive or perform that carries the risk of accident.

Corvaton tablets contain lactose

Corvaton tablets contain 130 mg lactose (lactose monohydrate) per tablet. If your doctor has previously warned you that you are sensitive to certain sugars, consult your doctor before you start using this medicine.

3. How to take Corvaton tablets

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

Unless instructed otherwise by your doctor, the recommended dose of this medicine is:
2× 1 Corvaton tablet daily (4 mg molsidomine).

In some cases, taking 2×½ Corvaton tablet (2 mg molsidomine) daily may be sufficient.

In more severe cases, however, administration of 3×1 Corvaton tablet (6 mg molsidomine), or even 3×2 tablets (12 mg molsidomine) or 4×2 tablets (16 mg molsidomine) daily may be necessary.

Tablets should be taken whole or broken in half, without chewing, with ample fluid (at least half a glass of water) at regular intervals. The tablet can be divided into equal doses.
The tablets may be taken before, during or after a meal.

If you take more Corvaton tablets than you should

If you have taken one tablet more than the prescribed dose on one occasion, it is sufficient to seek advice from your doctor only if side effects occur.

If you have accidentally taken a large quantity of this medicine and/or symptoms of overdose occur, see your doctor or go to the emergency department of the nearest hospital immediately.

Symptoms of overdose: drop in blood pressure, slower heartbeat, weakness, dizziness, wooziness, fainting or shock.

If you forget to take Corvaton tablets

Do not take a double dose to make up for a forgotten dose. By doing so you would not make up for the missed amount but would risk an overdose. Continue treatment with the dose prescribed by the doctor.

If you stop taking Corvaton tablets

Do not stop taking Corvaton tablets without telling and getting consent from your doctor, as your condition may worsen.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some of the side effects of this medicine may be life-threatening under certain conditions.

Therefore, stop taking Corvaton tablets and contact a doctor immediately if the following severe side effects occur, or if any other side effect listed below appears suddenly or to a serious degree:

- **Anaphylactic shock** (this is a condition that generally involves swelling of the face, tongue and/or larynx and shortness of breath, which may escalate to life-threatening shock) (*side effect of unknown frequency*),
- **Significant drop in blood pressure** that involves severe symptoms (such as circulatory collapse, fainting or shock) (*rare side effect*)

- **Hypersensitivity reactions** (such as allergic skin symptoms, difficulty breathing resulting from bronchospasm) (*rare side effect*).

Other side effects:**Very common side effects** (affect more than 1 in 10 patients):

- drop in blood pressure, dizziness (may require dose reduction or discontinuation of treatment)

Common side effects (affect 1-10 in 100 patients):

- headache (mostly resolves over the course of treatment)

Rare side effects (affect 1-10 in 10,000 patients):

- dizziness.
- nausea.

Frequency not known (frequency cannot be estimated from the available data):

- abnormal decrease in platelet count (thrombocytopenia).

Reporting of side effects

If you get any 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 directly via the national reporting system listed in Appendix V.

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

5. How to store Corvaton tablets

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

Do not store above 25°C.

Store in the original packaging in order to protect from light and moisture.

Do not use this medicine after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month.

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 Corvaton tablets contain

- The active substance is: each tablet contains 2 mg molsidomine.
- The other ingredients are: magnesium stearate, crospovidone, macrogol 6000, lactose monohydrate (130 mg)

What Corvaton tablets look like and contents of the pack

White or off-white, oblong, flat tablet marked "MFF" on one side and with the "HOECHST" company logo above and below the score line on the other side. The breakage surface is white.

The tablet can be divided into equal doses.

Packaging: 30 tablets in a clear green PVC/PVDC//Al blister and in a carton.

Marketing Authorisation Holder

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