

**Package leaflet: Information for the user**

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

**1. What Corvaton forte is and what it is used for**

Molsidomine, the active substance in Corvaton forte, is used for the treatment of coronary disorders. It dilates the coronary vessels and increases oxygen supply to the heart. It also reduces cardiac work and the heart's oxygen demand.

The product is used for the prevention and long-term treatment of angina pectoris (insufficient blood flow to the heart muscle associated with chest pain) in cases when other treatment with medicines called beta-blockers and/or calcium channel blockers is not indicated, not tolerated or not sufficiently effective, and for the treatment of elderly patients.

**2. What you need to know before you take Corvaton forte**

**Do not take Corvaton forte:**

- If you are allergic to molsidomine or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from acute circulatory failure (e.g. shock, left ventricular failure or acute myocardial infarction).
- If you have very low blood pressure.
- If you are taking erectile dysfunction medication containing substances such as sildenafil, tadalafil or vardenafil.
- if you are taking soluble guanylate cyclase stimulators at the same time (medicines that help to dilate the pulmonary arteries – blood vessels that connect the heart and lungs, thereby making it easier for the heart to pump blood to the lungs) because of an increased risk of low blood pressure
- If you are breast-feeding.

Corvaton forte is not suitable for treatment of an acute angina pectoris attack.

**Warnings and precautions**

**File no: sukls29817/2021**

Talk to your doctor or pharmacist before taking Corvaton forte.

Special caution is required in patients suffering from severe cardiac disorders (patients with 'hypertrophic obstructive cardiomyopathy', constrictive pericarditis, pericardial tamponade, patients with acute myocardial infarction and with left ventricular dysfunction, patients with aortic and/or mitral stenosis).

If you are at increased risk of a reaction associated with low blood pressure (a 'hypertensive reaction'), a doctor will monitor you carefully and may adjust your dose of the product.

In the event of heart attack, Corvaton forte should only be administered under strict medical supervision and with careful circulatory monitoring.

**Other medicines and Corvaton forte**

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

The effect of other blood pressure-lowering medicines (e.g. blood vessel dilating medicines such as nitrates, calcium channel blockers, etc.), and alcohol may be increased.

Concomitant use of Corvaton forte and ergot alkaloids (used to treat migraines, circulation problems, vascular diseases) is not recommended.

Concomitant use of Corvaton forte and products containing 'PDE5 inhibitors' (e.g. sildenafil in Viagra) carries a risk of a significant drop in blood pressure and must be avoided (see 'Do not take Corvaton forte').

**Corvaton forte with food, drink and alcohol**

The tablets are to be taken with sufficient amounts of liquid (approximately half a glass) with or without food.

You should not consume alcohol when taking Corvaton forte.

**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.

Due to insufficient data on safety, it is not recommended to administer Corvaton forte during pregnancy and it should not be used during breast-feeding.

**Driving and using machines**

Some adverse effects (e.g. dizziness) may impair patients' ability to concentrate and react and therefore constitute a risk in situations in which these abilities are of particular importance (e.g. using machines or driving cars). Do not perform such activities unless a doctor has expressly told you otherwise.

**Corvaton forte contains lactose monohydrate**

If your doctor has told you that you are allergic to certain sugars, you should check with your doctor before you start taking this medicinal product.

**3. How to take Corvaton forte**

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

The precise dosage and duration of treatment will be determined by your doctor.

The usual dose is ½ tablet of the product twice a day. If necessary, the doctor can increase the dose to ½ - 1 tablet three to four times a day.

The tablets should be taken at equal intervals.

The tablet can be divided into two equal doses.

**File no: sukls29817/2021**

### **If you take more Corvaton forte than you should**

The main symptoms of overdose are low blood pressure (hypotension) and decreased heart rate (bradycardia), weakness, dizziness and drowsiness, to collapse and shock. In the event of an overdose, seek medical attention immediately.

### **If you forget to take Corvaton forte**

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

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

## **4. Possible side effects**

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

The incidence of adverse effects reported is defined as follows:

Common (affecting 1 to 10 patients in 100)

- Headaches. These occur in particular at the start of treatment and usually disappear as treatment progresses. The dose may be individually adjusted, where applicable, by a doctor, to reduce or eliminate this adverse effect.

Rare (affecting 1 to 10 patients in 10,000):

- Allergic reactions (e.g. skin reactions, bronchospasm).
- Dizziness.
- Severe drop in blood pressure Corvaton forte usually reduces resting blood pressure. Adverse decreases in blood pressure (e.g. with dizziness) occur in 1 to 10% of patients, potentially requiring dose reduction or discontinuation of therapy. In rare cases, a severe drop in blood pressure may occur, with symptoms such as circulatory collapse and shock.
- Nausea.
- Allergic skin reactions.

Very rare (affecting less than 1 patient in 10,000):

- Anaphylactic shock (acute allergic reaction accompanied by a drop in blood pressure, tissue swelling, possibly asphyxiation).

Not known (cannot be estimated from the available data)

- Low platelet count (thrombocytopenia).

### 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 to the following address:

*Státní ústav pro kontrolu léčiv [Czech State Institute for Drug Control]*

*Šrobárova 48*

*100 41 Prague 10*

*Website: [www.sukl.cz/nahlasit-nezadouci-ucinek](http://www.sukl.cz/nahlasit-nezadouci-ucinek).*

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

**File no: sukls29817/2021**

## **5. How to store Corvaton forte**

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

Store below 25°C. Keep the blister in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton after "Use by:". The expiry date refers to the last day of that month.

Do not use this product if you notice visible signs of deterioration.

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 forte contains**

- The active substance is molsidomine. Each tablet contains 4 mg molsidomine.
- The other excipients are cospovidone, lactose monohydrate, macrogol 6000 and magnesium stearate.

### **What Corvaton forte looks like and contents of the pack**

Corvaton forte are white to off-white, oblong, biconvex tablets, marked with "MFG" above the score and the logo "HOECHST" below the score on one side, and the logo "HOECHST" above the score and "MFG" below the score on the other.

The tablet can be divided into two equal doses.

Pack size: 30 tablets.

### **Marketing Authorisation Holder and Manufacturer**

#### Marketing Authorisation Holder

#### Until 31 March 2021

sanofi-aventis, s.r.o., Evropská 846/176a, 160 00 Prague 6, Czech Republic

#### From 1 April 2021

CHEPLAPHARM Arzneimittel GmbH, Ziegelhof 24, 17489 Greifswald, Germany

#### Manufacturer

Sanofi Aventis S.A., Riells i Viabrea, Spain

**This leaflet was last revised on 9 March 2021.**