

CORVASAL® 2 mg

molsidomine

sanofi aventis

Scored tablet

Read all of the leaflet carefully before taking this medicine. It contains important information about your treatment.

- If you have any other questions or doubts, ask your doctor or pharmacist for further information.
- This medicine has been prescribed personally for you.
- Do not give it to anybody else, even if he/she has identical symptoms since it might cause harm to him/her.
- Keep this leaflet you may need to read it again.

IDENTIFICATION OF THE MEDICINE

Composition
molsidomine.....2 mg
for one scored tablet.
Excipients : lactose monohydrate, crospovidone, magnesium stearate, macrogol 6000.

Pharmaceutical form and presentation

Scored tablet. Boxes of 30 and 90.

Pharmacotherapeutic group

OTHER VASODILATOR IN CARDIOLOGY

Packed by

Benta S.A.L Dbayeh –Lebanon



under license from
Sanofi Aventis - France

WHEN SHOULD THIS MEDICINE BE USED

This medicine is an anti-anginal agent. This medicine is recommended for the preventive treatment of angina pectoris.

CORVASAL® is not suited to the treatment of the angina pectoris attack.

WARNING !

When should this medicine not be used

This medicine SHOULD NOT BE USED in the following Cases:

- Severe hypotension with shock,
- Concomitant treatment with VIAGRA (sildenafil) (medicinal product treating erectile dysfunction) :
.if you are currently treated with molsidomine, do not use sildenafil,
.if you are currently treated with sildenafil, do not use molsidomine.
- This medicine is usually not advisable in breast-feeding (cf. section Pregnancy and breast-feeding).

Special warnings

- The combination of molsidomine and VIAGRA (sildenafil) can induce a marked and sudden fall in blood pressure, possibly causing a lipothymia (*transient malaise*), fainting or a cardiac event.
- Due to its content in lactose, you should not take this medicine in case of galactosemia, of glucose and galactose malabsorption syndrome or in case of deficit in lactase (rare metabolic diseases).

Precautions for use

A slight fall in blood pressure is usually observed with molsidomine.

This medicinal product must be used cautiously in patients with low blood pressure and in elderly subjects, in patients with hypovolaemia (*decreased total blood volume*) and in subjects already treated with a vasodilator substance.

The dosage should be increased gradually in patients with impaired liver function.

It is not logical to combine molsidomine with delayed organic nitrates insofar as their way of action is similar.

Drug interactions and other interactions

IN ORDER TO AVOID CERTAIN DRUG INTERACTIONS, more especially with VIAGRA (sildenafil), YOU SHOULD INFORM YOUR PHYSICIAN OR YOUR PHARMACIST OF ANY OTHER TREATMENT WHICH YOU MAY BE TAKING.

Pregnancy - Breast-feeding

It is preferable not to use this medicinal product during pregnancy. If you discover that you are pregnant while taking treatment, consult your physician, as only he can decide whether or not treatment should be continued.

Breast-feeding is not advisable during the treatment.

AS A GENERAL RULE, IF YOU ARE PREGNANT OR BREAST-FEEDING, ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE BEFORE TAKING ANY MEDICINE

List of excipients which must be known to allow safe use in some patients

Lactose.

HOW TO USE THIS MEDICINE

Dosage

- Effort angina (usual dosage) : 1/2 to 1 tablet, 3 times a day, generally with breakfast, lunch and dinner (i.e. 3 to 6 mg of molsidomine).

- Unstable angina and severe effort angina : 1 tablet 4 times a day (i.e. 8 mg of molsidomine).

Method and route of administration

Oral use.

UNPLEASANT AND UNWANTED EFFECTS

LIKE ALL MEDICINE, THIS DRUG MAY, IN CERTAIN PERSONS, GIVE RISE TO VARYING DEGREES OF UNPLEASANT EFFECTS

- headache and slight fall in blood pressure at the beginning of treatment. These effects disappear spontaneously within a few days ;

- exceptionally : postural hypotension (*fall in blood pressure when standing up, possibly accompanied by dizziness*), gastrointestinal disorders, itching.

INFORM YOUR DOCTOR OR PHARMACIST OF ANY UNWANTED AND UNPLEASANT EFFECT WHICH MAY NOT BE MENTIONED IN THIS LEAFLET.

STORAGE

DO NOT EXCEED THE EXPIRY DATE CLEARLY INDICATED ON THE PACKAGING.

Special precautions for storage

Store below + 25°C and protect from light.

DATE OF LEAFLET REVISION

December 2009.

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Medicament: keep out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

Prepared by: Nisrine Wehbeh

Date: April 2014

Color Shade number:

Product Name: Corvasal 2mg

Type: Package insert



Black

Die Cut N°: N/A

Die Cut Dimension: 160*200

Version N°: 2

Market: Lebanon

Checked & Approved by:

Supplier: _____

Code: PIL090

RA : _____ Date: _____

Reason for Revision: Different Content

Production: _____ Date: _____

Delivered to Logistic Department:

Marketing: _____ Date: _____

Quality Assurance: _____ Date: _____

Name: _____ Date: _____