Please, read carefully this leaflet before taking this medicine.

If you have any questions, if you have any doubt, ask your physician or your pharmacist for more information.

Keep this leaflet, you shoud need to refer to it once more.

## CORVASAL 4 mg, tablets

molsidomine

### **FULL STATEMENT OF THE ACTIVE SUBSTANCE AND EXCIPIENTS**

Molsidomine ...... 4 mg

Excipients: lactose monohydrate, crospovidone, magnesium stearate, macrogol 6000

For one tablet of 320 mg.

## PHARMACEUTICAL FORM

Tablet

### PHARMACOTHERAPEUTIC GROUP

OTHER VASODILATOR IN CARDIOLOGY

(C01DX12 : cardiovascular system)

# NAME AND ADDRESS OF THE MARKETING AUTORISATION HOLDER

Laboratoires Hoechst Houdé

1, Terrasse Bellini

92910 Paris La Défense Cedex - France

# NAME AND ADDRESS OF THE MANUFACTURER

USIPHAR - L'Aigle

## THERAPEUTIC INDICATIONS

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

### WARNING!

#### CONTRAINDICATIONS

This medicine SHOULD NOT BE USED in case of:

- 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.

### **SPECIAL WARNING**

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.

# APPROPRIATE 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 vasodilatator substance.

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

# INTERACTIONS WITH OTHER MEDICINAL PRODUCTS

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.

#### **USE BY PREGNANT OR BREAST-FEEDING WOMEN**

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.

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

### EFFECTS ON THE ABILITY TO DRIVE OR TO USE MACHINES

The use of this medicine may cause dizziness.

LIST OF EXCIPIENTS WHICH MUST BE KNOWN TO ALLOW SAFE USE IN SOME PATIENTS Lactose, macrogol 6000.

# HOW TO USE THIS MEDICINE

#### DOSAGE

The recommended dosage is 1 tablet, 3 times daily; in certain cases of angina pectoris, the dosage may be increased to 4 tablets daily, i.e. 16 mg of molsidomine daily.

The daily dosage should be fractioned and adjusted to each individual.

### METHOD AND ROUTE OF ADMINISTRATION

Oral route

### POSSIBLE SIDE EFFECTS

LIKE ALL MEDICINE, THIS DRUG MAY, IN CERTAIN PEOPLE, HAVE MORE OR LESS UNPLEASANT EFFECTS:

- Headache and slight blood pressure at the beginning of treatment. These effects disappear spontaneously within a few days;
- Exceptionally: postural hypotension (fall in blood pressure on standing up, possibly accompanied by dizziness), gastrointestinal disorders, itching.

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

## STORAGE

DO NOT EXCEED THE EXPIRY DATE CLEARLY INDICATED ON THE PACKAGING. Store below + 25°C and protect from light.

**DATE OF LEAFLET REVISION**: April 1999