

# AMLODIPINE BESILATE

JOHNVASC

5 mg Tablet



CALCIUM CHANNEL BLOCKER

#### FORMULATION:

Each tablet contains:

Amlodipine besilate equivalent to 5 mg amlodipine.

#### DESCRIPTION:

A white or almost white powder. Slightly soluble in water and isopropyl alcohol; sparingly soluble in alcohol; freely soluble in methyl alcohol.

Johnvasc Tablet, white to off white, round, biconvex, one side scored tablet, 5 strips of 20's (box of 100's).

#### WHAT IS IN THE MEDICINE?

Johnvasc contains the active substance amlodipine which belongs to a group of medicines called calcium antagonists. In patients with high blood pressure this medicine works by relaxing blood vessels, so that blood passes through them more easily. In patients with angina Johnvasc works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. This medicine does not provide immediate relief of chest pain from angina.

**STRENGTH OF THE MEDICINE:** See Formulation

#### WHAT IS THIS MEDICINE USED FOR?

Johnvasc is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina, a rare form of which is Prinzmetal's or variant angina.

#### HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

##### Adults

The usual initial antihypertensive oral dose of JOHNVASC is 5 mg once daily, and the maximum dose is 10 mg once daily.

Small, fragile, or elderly patients, or patients with hepatic insufficiency may be started on 2.5 mg once daily and this dose may be used when adding JOHNVASC to other antihypertensive therapy.

Adjust dosage according to blood pressure goals. In general, wait 7 to 14 days between titration steps. Titrate more rapidly, however, if clinically warranted, provided the patient is assessed frequently.

**Coronary artery disease:** The recommended dose range for patients with coronary artery disease is 5-10 mg once daily. In clinical studies, the majority of patients required 10 mg.

##### Children

The effective antihypertensive oral dose in pediatric patients ages 6-17 years is 2.5 mg to 5 mg once daily. Doses in excess of 5 mg daily have not been studied in pediatric patients [see Clinical Pharmacology].

#### WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

If you are allergic (hypersensitive) to amlodipine, or any of the other ingredients of this medicine. To any other calcium antagonists. This may be itching, reddening of the skin or difficulty in breathing.

- \* If you have severe low blood pressure (hypotension).
- \* If you have narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- \* If you suffer from heart failure after a heart attack.

#### CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?

Talk to your doctor or pharmacist before taking Johnvasc.

You should inform your doctor if you have or have had any of the following conditions:

- \* Recent heart attack
- \* Heart failure
- \* Severe increase in blood pressure (Hypertensive crisis)
- \* Liver disease
- \* You are elderly and your dose needs to be increased

#### UNDESIRABLE EFFECT:

As for Dihydropyridine calcium - channel blocker

The most common adverse effects are associated with its vasodilator action often diminish on continued therapy, they include dizziness, flushing, headache, hypotension, peripheral edema, tachycardia and palpitations, nausea and other gastro-intestinal disturbances, increased micturition frequency, lethargy, eye pain, and mental depression have also occurred.

**WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Johnvasc may affect or be affected by other medicines, such as:

- \* ketoconazole, itraconazole (anti-fungal medicines)
- \* ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV)
- \* rifampicin, erythromycin, clarithromycin (antibiotics)
- \* hypericum perforatum (St. John's Wort)
- \* verapamil, diltiazem (heart medicines)
- \* dantrolene (infusion for severe body temperature abnormalities)
- \* tacrolimus, sirolimus, temsirolimus and everolimus (medicines used to alter the way your immune system works)
- \* simvastatin (cholesterol lowering medicine)
- \* cyclosporine (an immunosuppressant)

Johnvasc may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure.

Grapefruit juice and grapefruit should not be consumed by people who are taking Johnvasc. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Amlodipine.

**WHAT SHOULD YOU DO IF YOU MISS A DOSE?**

If you miss a dose, just take the next dose and subsequent doses at the usual recommended schedule. Do not double dose.

**SIGNS AND SYMPTOMS OF OVER DOSE**

swelling of your legs or ankles.  
tiredness or extreme sleepiness.  
stomach pain.  
nausea.

dizziness.  
hot or warm feeling in your face (flushing)  
irregular heart rate (arrhythmia)  
very fast heart rate (palpitations)

**WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?**

If you have taken more than the recommended dosage, consult a doctor or contact a Poison Control Center right away.

**STORAGE CONDITION:**

Store at temperatures not exceeding 30°C

**WHEN SHOULD YOU CONSULT YOUR DOCTOR?**

Visit your doctor immediately if you experience any of the following side effects after taking this medicine.

- \* Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing
- \* Swelling of eyelids, face or lips
- \* Swelling of the tongue and throat which causes great difficulty breathing
- \* Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome) or other allergic reactions
- \* Heart attack, abnormal heart beat
- \* Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell

**AVAILABILITY:**

Amlodipine Besilate (JOHNVASC) 5 mg Tablet-In blister pack of 20's (box of 100's)

**ADR REPORTING STATEMENT:**

For suspected adverse drug reaction, report to FDA: [www.fda.gov.ph](http://www.fda.gov.ph) Patient must seek medical attention immediately at the first sign of any adverse drug reactions.

FDA REGISTRATION NO. : DRP -8096

DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

November 19, 2013

Date of Revision of the Package Leaflet : April 17, 2020

Reference : Martindale 36th Edition

SHELF-LIFE : 36 Months

RETAIL PRICE NOT TO EXCEED P22.85  
UNDER DRUG PRICE REGULATION

Manufactured by:

**SAN MARINO LABORATORIES CORP.**  
#1 Crisanto delos Reyes Street  
Brgy. Javalera, Gen. Trias, Cavite



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