

**Applicant/PHCR:** Innovata Pharmaceuticals (Pty) Ltd

**Product Proprietary Name :** INNOVASC 5 and INNOVASC 10

**Dosage Form & Strength :** Tablets, Amlodipine 5 mg and 10 mg

Application name (number): INNOVASC 5/10 (490165/6)

Date:05/02/2021

## Proposed Patient Information Leaflet for INNOVASC

### PATIENT INFORMATION LEAFLET

#### SCHEDULING STATUS

S3

**INNOVASC 5 mg tablets**

**INNOVASC 10 mg tablets**

**Amlodipine (as besilate)**

**Sugar free**

#### Read all of this leaflet carefully before you start taking INNOVASC

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- **INNOVASC** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

#### What is in this leaflet

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

## Proposed Patient Information Leaflet for INNOVASC

### 1. What INNOVASC is and what it is used for

**INNOVASC** contains the active substance amlodipine which belongs to a group of medicines called selective calcium channel blockers.

**INNOVASC** is used to treat high blood pressure (hypertension) and to treat chest pain or discomfort, called angina pectoris. Your doctor may prescribe you **INNOVASC** together with other medicines used to lower your blood pressure.

### 2. What you need to know before you take INNOVASC

#### Do not take INNOVASC

- If you are hypersensitive (allergic) to amlodipine, other calcium channel blockers or any of the other ingredients of **INNOVASC** listed in section 6 of this leaflet.
- If you have severe low blood pressure
- If you have had shock or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- If you have aortic stenosis(narrowing of the heart valve of the aorta)
- If you recently suffered a heart attack (within the past 28 days).
- If you have been diagnosed with unstable angina (chest pain occurring while resting).
- If you are pregnant or breastfeeding.

#### Warnings and precautions

*Tell your doctor before taking INNOVASC :*

- If you suffer from heart failure.
- If you have been diagnosed with aortic stenosis (narrowing of the aortic heart valve).
- If you have severe liver problems. Your doctor may need to monitor your liver function and

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adjust your dose of **INNOVASC** accordingly.

- If you are 65 years or older.
- If you suffer from severe kidney problems
- If you suffer from diabetes
- If you have porphyria (a group of disorders that result in a buildup of natural chemicals called porphyrins in your body)
- If you experience chest pain while taking **INNOVASC**.
- If you have low blood pressure.

#### Children and adolescents

Do not give **INNOVASC** to children and adolescents as safety and efficacy have not been established.

#### Other medicines and INNOVASC

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

*Tell your doctor or pharmacist before you take **INNOVASC** if you are taking:*

- Protease inhibitors (used to treat human immunodeficiency virus (HIV)).
- Azole antifungals, such as itraconazole or ketoconazole (used to treat fungal infections).
- Macrolide antibacterials, such as erythromycin or clarithromycin (used to treat bacterial infections).
- Verapamil (used to treat high blood pressure and heart pain) or any medicine that may lower your blood pressure.
- Diltiazem (used to treat chest pain).

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- Rifampicin (used to treat tuberculosis (TB) or certain other bacterial infections).
- St. John's Wort (herbal medicine).
- Carbamazepine, phenobarbitone, phenytoin or valproate (used to treat seizures (fits)).
- Dantrolene (used to treat severe body temperature abnormalities).
- Medicines for treating angina (chest pains), such as nitro-glycerine or beta-blockers.
- Tacrolimus (used to treat eczema or during organ transplants).
- Mammalian target of rapamycin (mTOR) inhibitors, such as temsirolimus, everolimus and sirolimus (used to treat cancer).
- Simvastatin (used to lower fat in your blood).
- Quinidine or procainamide (used to treat heart rhythm disorders).
- Lithium (used to treat some types of depression).

Tell your doctor or pharmacist before you take **INNOVASC** if you have had a kidney transplant and are taking ciclosporin (used to treat cancer, rheumatoid arthritis or organ transplants). Your doctor may need to monitor your blood and adjust your dose of ciclosporin according to the test results.

#### **INNOVASC with food and drink**

While taking **INNOVASC**, you should avoid consuming grapefruit juice or grapefruits as it may increase the risk of your blood pressure lowering more than expected.

#### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking **INNOVASC**.

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You should not take **INNOVASC** if you are pregnant or breastfeeding.

#### Driving and using machines

**INNOVASC** may cause dizziness, tiredness, nausea (feeling sick) or headaches, which may affect your ability to drive or use machines. You may experience these effects more at the start of your treatment with **INNOVASC**. Do not drive or operate machinery until you know how **INNOVASC** affects you.

#### 3. How to take INNOVASC

Do not share medicines prescribed for you with any other person.

Always take **INNOVASC** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one tablet of **INNOVASC** 5 mg or one tablet of **INNOVASC** 10 mg once a day taken orally.

Your doctor will determine your dose based on your age, liver function or your response to **INNOVASC**.

**INNOVASC** can be taken with or without food.

Your doctor will tell you how long your treatment with **INNOVASC** will last.

If you have the impression that the effect of **INNOVASC** is too strong or too weak, tell your doctor or pharmacist.

Taking your tablets at the same time each day will have the best effect on your blood pressure. It will also help you remember when to take the tablets.

**If you take more INNOVASC than you should**

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Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24 – 48 hours after intake.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take along any tablets that are left, including the carton, so that the hospital staff can easily tell what you have taken.

#### **If you forget to take INNOVASC**

If you forget to take a dose, take it as soon as you remember unless it is nearly time to take your next dose. Do not take a double dose to make up for forgotten individual doses.

#### **4. Possible side effects**

**INNOVASC** can have side effects.

Not all side effects reported for **INNOVASC** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **INNOVASC**, please consult your health care provider for advice.

If any of the following happens, stop taking **INNOVASC** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **INNOVASC**. You may need urgent medical attention or hospitalisation.

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**Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:**

- changes in the way your heart beats (irregular heartbeats, beating slower or faster than usual) or heart attack;
- painful, blistering or peeling skin rash;
- bleeding or bruising more easily than normal or abnormal blood test results;
- frequent infections such as fever, severe chills, sore throat or mouth ulcers;
- yellowing of your skin and eyes, also called jaundice or hepatitis;
- pancreatitis (nausea, vomiting, fever, pain in your stomach area radiating to your back);
- erythema multiforme (red, often itchy spots, similar to the rash of measles which starts on the limbs and sometimes on the face and the rest of the body, the spots may blister or may progress to form raised, red, pale-centred marks, other symptoms include fever, sore throat, headache and/or diarrhoea);
- difficulty breathing or chest pain.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following

#### **Frequent side effects**

- water retention (causing swelling of your ankles, hands and feet);
- visual disturbance (seeing double);
- sleepiness, dizziness or headaches (especially when you first start taking **INNOVASC**);
- pain in your stomach area, nausea (feeling sick), feeling bloated (caused by excessive gas) and indigestion;
- changes in bowel movements, such as constipation or diarrhoea;

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- muscle cramps, physical weakness and lack of energy;
- flushing of your skin (blushing).

#### **Less frequent side effects**

- bleeding or small pin-sized purple spots on the skin;
- increased blood sugar levels;
- changes in test results when your doctor monitors your liver function;
- a decrease in blood pressure (causing light-headedness, clammy skin, nausea and dizziness);
- vasculitis (fever, headache, fatigue, weight loss, general aches and pains, night sweats, nerve problems such as numbness or weakness);
- changes in the frequency or control of urination, urinating more at night;
- feeling depressed or confused, changes in your mood, anxiousness and insomnia;
- shaking (tremor);
- ringing in the ears;
- numbness, a loss of sensation, tingling or numbness in your hands or feet, feeling of weakness or heaviness in your arms and legs;
- stiffness of your muscles and joint, muscle or back pain, pain in a joint and feeling unwell;
- vomiting (being sick), a dry mouth or gastritis (causing pain, nausea, vomiting, vomiting blood, blood in the stool);
- overgrowth of the gums (causing pain, swelling and bad breath);
- distortion of the sense of taste;
- coughing or a runny nose;
- breast enlargement in men;
- problems with sexual performance;
- hair loss or excessive sweating;

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- discolouration of the skin or sensitivity to the sun;
- gaining or losing weight.

#### *Side effects with an unknown frequency*

- muscle spasms, slow movement and irregular, jerky movements.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

#### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: [www.sahpra.org.za](http://www.sahpra.org.za). By reporting side effects, you can help provide more information on the safety of **INNOVASC**.

#### **5. How to store INNOVASC**

**INNOVASC** should be stored in the original packaging (keep blisters in the carton until required for use).

Store at or below 25 °C.

Protect from moisture and sunlight.

**STORE ALL MEDICINE OUT OF REACH OF CHILDREN.**

Do not use after the expiry date stated on the label and carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

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**6. Contents of the pack and other information**

**What INNOVASC contains**

The active substances in **INNOVASC** is amlodipine.

**INNOVASC 5 mg:** Each tablet contains 5 mg amlodipine (as amlodipine besilate).

**INNOVASC 10 mg:** Each tablet contains 10 mg amlodipine (as amlodipine besilate).

The other ingredients are colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose, pregelatinised starch, sodium starch glycolate.

**What INNOVASC looks like and contents of the pack**

**INNOVASC 5 mg:** White to off white round shaped, biconvex tablets debossed with 'J' on one side and '20' on the other side.

**INNOVASC 10 mg:** White to off white round shaped, biconvex tablets debossed with 'J' on one side and '21' on the other side.

**INNOVASC** tablets 5 mg and 10 mg are both available in aluminium-aluminium blister strips and aluminium- PVC/PVdC blister strips of 10 tablets per strip in unit cartons containing 30 tablets.

**Holder of certificate of registration**

Innovata Pharmaceuticals (Pty) LTD

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Johannesburg

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**This leaflet was last revised in**

21/07/2023

**Registration numbers**

**INNOVASC 5:** 49/7.1/0165

**INNOVASC 10:** 49/7.1/0166

**Access to the corresponding Professional information.**

A copy of the professional Information is contained in the packaging of **INNOVASC**