PATIENT INFORMATION LEAFLET: MONICOR 60 mg SR

Read all of this leaflet carefully before you start using MONICOR 60 mg SR:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **MONICOR 60 mg SR** 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.

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

MONICOR 60 mg SR slow release tablets.

1. WHAT MONICOR 60 mg SR CONTAINS:

The active ingredient is isosorbide-5-mononitrate. Each tablet contains 60 mg isosorbide-5-mononitrate.

In addition **MONICOR 60 mg SR** contains the following inactive ingredients: Carnauba wax, ferric oxide, hydroxypropylmethylcellulose, macrogol, magnesium stearate, silica anhydrous colloidal, stearic acid, titanium dioxide.

MONICOR 60 mg SR also contains the sugar lactose monohydrate. (See "**Important information about some of the ingredients of MONICOR 60 mg SR**")

2. WHAT MONICOR 60 mg SR IS USED FOR:

MONICOR 60 mg SR is prescribed by doctors for the preventative treatment of angina pectoris, a condition characterised by frequent and intense pain in the chest.

3. BEFORE YOU USE MONICOR 60 mg SR:

Do not take MONICOR 60 mg SR:

- If you are hypersensitive (allergic) to isosorbide-5-mononitrate, organic nitrate type medications or any of the other ingredients of **MONICOR 60 mg SR.**
- If you have very low blood pressure, a low amount of blood in the body, a clear reduction in the amount of red blood cells in the body, a weak heart due to blockage of your heart arteries or increased pressure in the skull due to head injury or bleeding in the brain.
- If you have angle closure glaucoma (increased pressure in the eye/eyes); **as MONICOR 60 mg SR** may increase the pressure in the eye further.

- If you are also taking sildenafil or other similarly acting medicines (see "**Using other medicines with MONICOR 60 mg SR**").
- For the relief of sudden attacks of angina pectoris. Your doctor will prescribe sublingual (under the tongue) nitroglycerin tablets to be used in these situations. (See "**HOW TO USE MONICOR 60 mg SR**").

Take special care with MONICOR 60 mg SR:

- If you have severe cerebral arteriosclerosis (hardening and/or thickening of the walls of the smaller arteries of the brain) or severe low blood pressure (see "**Do not take MONICOR 60 mg SR**")
- You are undernourished, have severely weakened kidney or liver function, decreased function of the thyroid gland or have a low body temperature.
- If you have angle closure glaucoma (increased pressure in the eye/eyes); as MONICOR 60 mg SR may increase the pressure in the eye further. (See "**Do not take MONICOR 60 mg SR**").

Taking MONICOR 60 mg SR with food or drink:

- **MONICOR 60 mg SR** can be taken with or without food.
- **MONICOR 60 mg SR** tablets can be broken in 2, but should not be chewed or crushed and should be taken with half a glass of water.

Pregnancy and breastfeeding:

- **DO NOT use MONICOR 60 mg SR** if you are pregnant, suspect that you are pregnant or are breastfeeding as the safety of **MONICOR 60 mg SR** in pregnancy and breastfeeding is not known.
- If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health professional for advice before taking this medicine.

Driving and using machinery:

- **MONICOR 60 mg SR** may impair your ability to drive and use machinery. Take care if you feel dizzy, tired or drowsy while using **MONICOR 60 mg SR**, especially if other blood-pressure lowering medications are taken at the same time.

Important information about some of the ingredients of MONICOR 60 mg SR:

- **MONICOR 60 mg SR** contains lactose. Please consult your doctor if you know or suspect that you are lactose intolerant before taking **MONICOR 60 mg SR**.

Using other medicines with MONICOR 60 mg SR:

- Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines).

- If you intend taking alcohol or other medicines that cause widening of the blood vessels, these may cause excessive lowering of blood pressure.

If you are taking:

- Sildenafil and other phosphodiesterase type 5 inhibitors (PDE5)
- Other antihypertensive agents (medicines used for high blood pressure)
- Alcohol

Please consult your doctor, pharmacist or other health professional for advice.

Not all medicines that may interact with **MONICOR 60 mg SR** are listed above.

4. HOW TO USE MONICOR 60 mg SR:

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

Always take **MONICOR 60 mg SR** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Take one **MONICOR 60 mg SR** tablet daily, in the morning. This dosage may be increased to two **MONICOR 60 mg SR** tablets once daily, in the morning. Treatment may be started with half a tablet of **MONICOR 60 mg SR** tablet daily, in the morning for the first two to four days to decrease the possibility of headache. **MONICOR 60 mg SR** tablets may be broken in half, but should not be chewed or crushed and should be taken with half a glass of water.

Your doctor will tell you how long your treatment with **MONICOR 60 mg SR** will last. Do not stop treatment early because your condition may worsen.

If you have the impression that the effect of **MONICOR 60 mg SR** is too strong or too weak, talk to your doctor or pharmacist.

MONICOR 60 mg SR may be used on its own or in combination with other medicines to control angina pectoris.

NOTE:

MONICOR 60 mg SR tablets are not to be used for the relief of sudden attacks of angina pectoris.

If you take more MONICOR 60 mg SR than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and the rest of the remaining tablets with you so the doctor will know what you have taken.

If you forget to take your MONICOR 60 mg SR:

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

5. POSSIBLE SIDE EFFECTS:

MONICOR 60 mg SR may have side effects. Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MONICOR 60 mg SR, please consult your doctor, pharmacist or other health care professional for advice.

Check with your doctor if any of the following side effects continue or are bothersome. If you experience any of these side effects accompanied by seizures and coma, seek help urgently.

- Frequently reported side effects: Rapid and irregular heartbeat, dizziness, restlessness, fainting spells, headache, low blood pressure, nausea, flushing of the face.
- Less frequently reported side effects: Vomiting, blurred vision, difficulty breathing, severe or prolonged headache; slowing of the heartbeat; a bluish discolouration of the skin; rash, itchiness, muscle pain, a runny tummy and a blood disorder that causes a bluish discolouration of the skin, headache, breathlessness, tiredness, dizziness, fainting and irregular heartbeat.

The following side effects may not need medical attention and may go away during treatment:

Frequently reported side effects: Headache or low blood pressure which is often experienced as dizziness and nausea.

6. STORING AND DISPOSING OF MONICOR 60 mg SR:

- Store at or below 25 ◦C.
- Store in the original container.
- Protect from light.
- Keep the container tightly closed.
- **STORE ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN**.
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF MONICOR 60 mg SR:

MONICOR 60 mg SR tablets are packed in a white plastic securitainer containing 30 tablets.

8. IDENTIFICATION OF MONICOR 60 mg SR:

MONICOR 60 mg SR tablets are cream coloured, oval tablets, half-scored on both sides, marked with "60" on one side.

9. REGISTRATION NUMBERS:

RSA | S3 | 37/ 7.1.4/ 0340 NAM | NS2 | 08/ 7.1.4/ 0181

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION:

PHARMA DYNAMICS (PTY) LTD

F02 Grapevine House

Steenberg Office Park

WESTLAKE, 7945

Cape Town

South Africa

11. DATE OF PUBLICATION:

To be allocated by council

Version: PD9041A