PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

PROPRIETARY NAMES AND DOSAGE FORM

Dafiro® 5/160 mg film-coated tablet

Dafiro® 10/160 mg film-coated tablet

Dafiro® 5/320 mg film-coated tablet

Dafiro® 10/320 mg film-coated tablet

Keep this leaflet. You may need to read it again.

DAFIRO 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.

If you have further questions, please ask your doctor or your pharmacist.

1. WHAT DAFIRO CONTAINS

The active substance of DAFIRO is amlodipine besylate (equivalent to 5 mg or 10 mg amlodipine base) and valsartan (160 mg or 320 mg).

The other ingredients are microcrystalline cellulose, sodium starch glycolate (5/320 mg and 10/320 mg), crospovidone, anhydrous colloidal silicon dioxide, magnesium stearate, hypromellose, polyethylene glycol 4000, talc, titanium dioxide (E171), iron oxide, yellow (E172), iron oxide, red (E172) (10/160 mg tablets and 5/320 mg).

Sugar free.

2. WHAT DAFIRO IS USED FOR

DAFIRO is used to treat high blood pressure in patients whose blood pressure is not adequately controlled with a single blood pressure lowering medicine.

3. BEFORE YOU TAKE DAFIRO

Do not take DAFIRO:

- If you have a history of allergies related to taking this type of medicine.
- If your doctor has diagnosed that you are suffering from a narrowing of valves in your heart (called aortic or mitral stenosis), or abnormally increased thickness of your heart muscle with narrowing (called obstructive hypertrophic cardiomyopathy).
- If you have received a kidney transplant or if you had been diagnosed to suffer from a narrowing of your kidney artery or if you are suffering from severe kidney problems.

- If you are taking other medicine or substances, which increase the potassium levels in your blood (such as certain types of diuretics, potassium supplements, etc.).
- If you are taking medicines that contain lithium (a medicine used to treat some type of depression)
- If you have ever had an unusual or allergic reaction to amlodipine besylate or valsartan or to any other ingredients of DAFIRO listed at the beginning of this leaflet. If you think you may be allergic, ask your doctor for advice.
- If you are pregnant or breastfeeding.

If any of these apply to you, tell your doctor without taking DAFIRO.

Take special care with DAFIRO:

- If you are suffering from several episodes of vomiting or diarrhoea or are taking a diuretic (a medicine increasing the amount of urine).
- If you are taking other medicines or substances, which increase the potassium levels in your blood (such as certain types of diuretics, potassium supplements, etc.).
- If you suffer from liver or severe kidney problems.

If any of these apply to you, tell your doctor before you take DAFIRO.

Taking DAFIRO with food and drink:
You can take DAFIRO with or without food.

Older people (age 65 years and over):
There are no special dose recommendations for patients aged 65 years or older.

Children and adolescents (below the age of 18 years):
Use of DAFIRO in children and adolescents is not recommended.

Pregnancy:
Do not take DAFIRO if you are pregnant. Use during pregnancy may cause serious damage to your unborn child. It is therefore important to check with your doctor immediately if you think you may have become pregnant or are planning to become pregnant.

Breastfeeding mothers:
Tell your doctor if you are breastfeeding. Treatment with DAFIRO is not recommended during breastfeeding.

Driving and using machines:
DAFIRO may cause dizziness and affect the ability to concentrate. So before you drive a vehicle, use

machinery, or carry out other activities that require concentration, make sure you know how you react to the effects of DAFIRO.

Taking other medicines with DAFIRO:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, concomitant use of DAFIRO may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice. It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This applies to medicines both prescribed and not prescribed by a doctor, especially:

- Potassium-sparing medicines, potassium supplements, or salt substitutes containing potassium.

4. HOW TO TAKE DAFIRO

It is very important that you take DAFIRO exactly as your doctor tells you in order to get the best results and reduce the risk of side effects. DAFIRO is for oral use only.

- Do not exceed the recommended dose.
- Do not share medicines prescribed for you with others.
- In the event of overdosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control center.

How much DAFIRO to take:

Your doctor will tell you exactly how many tablets of DAFIRO you should take.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

The recommended dose of DAFIRO is one film coated tablet per day.

When and how to take DAFIRO:

DAFIRO may be taken with or without food. Swallow the tablets with a glass of water.

How long to take DAFIRO:

Your doctor will tell you exactly how long you will need to take the tablets.

If you take more DAFIRO than you should:

If you have accidentally taken too many tablets of DAFIRO, **consult your doctor immediately**.

If you forget to take DAFIRO:

It is advisable to take your medicine at the same time each day, preferably in the morning. If you forget to take DAFIRO, take it as soon as you remember and the take your next dose at its usual

time. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for the forgotten tablet.

Effects when treatment with DAFIRO is stopped:
Stopping your treatment with DAFIRO may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

5. POSSIBLE SIDE EFFECTS

DAFIRO can cause unwanted side effects. Not all side effects reported for DAFIRO are included in this leaflet. Should your general health worsen while taking DAFIRO, please consult your doctor, pharmacist or other healthcare professional for advice.
DAFIRO can have side effects.

Some side effects can be serious.
Less frequent: Allergic reaction with symptoms such as rash, itching, swelling of face or lips or tongue, difficulty breathing, low blood pressure.
If you experience any of these, tell your doctor straight away.

Other possible side effects are:
Frequent: Flu-like symptoms; nasal congestion, sore throat and discomfort when swallowing; headache; swelling of arms, hands, legs, ankles or feet; tiredness; redness and warm feeling of the face and/or the neck.

Less Frequent: Dizziness; nausea and abdominal pain; dry mouth; drowsiness, tingling or numbness of the hands or feet; vertigo; fast heart beat including palpitations; dizziness on standing up; cough; diarrhoea; constipation; skin rash, redness of the skin; joint swelling, back pain; pain in joints.
Anxiety; tinnitus; fainting; passing more urine than normal or feeling an increased urge to pass urine; inability to get or maintain an erection; sensation of heaviness; low blood pressure with symptoms such as dizziness, light-headedness; excessive sweating; generalised skin rash; itching; muscle spasm.

If any of these affect you severely, tell your doctor.

Additional undesirable effects with amlodipine or valsartan alone, which can be serious, are:
Amlodipine
Stomach pain with nausea; thickening of gums; breast enlargement in men; decreased number of white blood cells which could increase the risk of infections; muscle pain; inflammation of the pancreas or liver which can cause symptoms such as vomiting, loss of appetite, nausea, yellow discolouration of the skin and eyes; decreased number of platelets in your blood which could cause bleeding or bruising more easily; inflammation of the blood vessel with skin rash as a symptom;

shortness of breath; swelling of the feet or legs due to

fluid build-up; easy tiredness after light physical activity (heart disorder); mood changes and depression; altered bowel movements; indigestion; hair loss; rhinitis; increase in blood sugar levels.

Valsartan

Decreased number of white blood cells which could increase the risk of infections; decreased number of platelets in your blood which could cause bleeding or bruising more easily; insomnia; rhinitis; inflammation of the blood vessel with skin rash as a symptom; decreased sex drive; decrease in neutrophils; increase in potassium levels.

If you experience any of these, tell your doctor straight away.

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

6. STORING AND DISPOSING OF DAFIRO

- Store at or below 30 °C. Protect from moisture.
- Store your tablets in the original package.
- Do not use DAFIRO after the expiry date which is stated on the pack.
- Do not use any DAFIRO pack that is damaged or shows signs of tampering.
- Store all medicines out of the reach of children.

7. PRESENTATION OF DAFIRO

- DAFIRO comes in packs of 7, 14, 28, 56, 90, or 98 film-coated tablets in PA/Al/PVC (polyamide/aluminum/polyvinylchloride) blisters with an aluminum foil backing.
- Not all pack sizes may be available.

8. IDENTIFICATION OF DAFIRO

DAFIRO 5/160 mg: Dark yellow, ovaloid, film-coated tablets with bevelled edges. Debossed with "NVR" on one side and “ECE” on the other.

DAFIRO 10/160 mg: Light yellow, ovaloid, film-coated tablets with bevelled edges. Debossed with "NVR” on one side and “UIC” on the other.

DAFIRO 5/320 mg: Very dark yellow, ovaloid, film-coated tablets with bevelled edges. Debossed with "NVR” on one side and “CSF” on the other.

DAFIRO 10/320 mg: Dark yellow, ovaloid, film-coated tablets with bevelled edges. Debossed with "NVR” on one side and “LUF” on the other.

9. REGISTRATION NUMBERS

DAFIRO 5/160 mg tablet: 45/7.1.3/0706

DAFIRO 10/160 mg tablet: 45/7.1.3/0707

DAFIRO 5/320 mg tablet: 45/7.1.3/1011

DAFIRO 10/320 mg tablet: 45/7.1.3/1012

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Sandoz SA (Pty) Ltd[1]
Waterfall 5-Ir
Magwa Crescent West
Waterfall City
Jukskei view
2090

11. DATE OF PUBLICATION

26 October 2012

[1]Company Reg. No.: 1990/001979/07