APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking VANICON.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine 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.

S3

VANICON 1,25 mg (Capsule)

VANICON 2,5 mg (Capsule)

VANICON 5 mg (Capsule)

VANICON 10 mg (Capsule)

Ramipril

1. WHAT VANICON CONTAINS

The active ingredient is ramipril.

VANICON 1,25 mg: Each hard gelatin capsule contains ramipril 1,25 mg. Sugar free.

VANICON 2,5 mg: Each hard gelatin capsule contains ramipril 2,5 mg. Sugar free.

VANICON 5 mg: Each hard gelatin capsule contains ramipril 5 mg. Sugar free.

VANICON 10 mg: Each hard gelatin capsule contains ramipril 10 mg. Sugar free.

The other ingredients of **VANICON** are silica hydrophobic colloidal anhydrous and starch pregelatinised. The capsule shells contain gelatin, iron oxide yellow (C.I. No: 77492), sodium lauryl sulphate, titanium dioxide (C.I. No: 77891) and water. **VANICON 2,5 mg** shells contain ponceau 4R (C.I. No.: 16255). **VANICON 5 mg** and **VANICON 10 mg** contain patent blue V (C.I. No.: 42051) and ponceau 4R (C.I. No.: 16255). The black ink contains black iron oxide (C.I. No: 77499), butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, shellac and strong ammonia solution.

2. WHAT VANICON ARE USED FOR

VANICON are used to treat high blood pressure and to reduce the risk of heart attack, stroke and heart-related death in patients at risk for these problems. **VANICON** are also used to improve survival in patients with heart failure after a heart attack. **VANICON** belongs to a class of medications called angiotensin-converting enzyme (ACE) inhibitors. It works by decreasing certain chemicals that tighten the blood vessels, so blood flows more smoothly and the heart can pump blood more efficiently.

3. BEFORE YOU TAKE VANICON

Do not take VANICON:

- If you have ever had an unusual or allergic reaction to ramipril or any ingredient of **VANICON**.
- If you have or have ever had angioedema (a condition that causes difficulty in swallowing or breathing and painful swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs) whilst taking previous angiotensin-converting enzyme (ACE) inhibitor medication or angiotensin receptor blockers (ARBs). You must never again take these medicines.
- If you have abnormal narrowing of the valve between the left part of your heart to the major blood vessel of the heart (the aorta).
- If you have abnormal thickening of the heart muscle.
- If you have moderate to severe kidney disease.
- If you have narrowing of the blood vessel of kidney with a single kidney.
- If you have narrowing of the blood vessels to both kidneys.
- If you suffer from porphyria which could result in symptoms such as severe abdominal pain, restlessness, excessive sweating, dehydration, painful skin redness, and red urine.
- If you are currently taking diuretics (water tablets) that increase potassium in the blood such as triamterene, amiloride or spironolactone.
- If you are taking lithium, a medicine used to treat mental illness. **VANICON** may increase the lithium levels in your blood.
- If you are pregnant or breast-feeding your baby.
- **VANICON** should not be given to children.

Take special care with VANICON:

- Vomiting, diarrhoea, heavy sweating or not drinking enough fluids can cause you to become dehydrated. This can lead to very low blood pressure, electrolyte disorders, or kidney failure while you are taking **VANICON**.
- If you develop swelling of the face around your lips, tongue, or throat or difficulty swallowing, you should stop taking **VANICON** and contact your doctor immediately.
- If you are having surgery, tell you doctor that you are taking **VANICON**.
- Do not use salt substitutes or potassium supplements while taking **VANICON**.
- To be sure **VANICON** is helping your condition, your blood pressure will need to be checked on a regular basis. Your kidney or liver function may also need to be tested. Do not miss any scheduled visits to your doctor.

Tell your doctor:

- if you have heart or blood vessel disease.
- if you have an autoimmune disease (such as lupus) or scleroderma or if you are taking immunosuppressive medication.
- if you have kidney disease.
- if you have liver disease.
- if you have bone marrow disease.
- if you have diabetes.
- if you are on a special diet, such as a low-salt diet.

Pregnancy and Breast-feeding:

VANICON can cause birth defects in the baby if taken during pregnancy. Use an effective form of birth control. Stop using **VANICON** and tell your doctor right away if you become pregnant during treatment. Do not use **VANICON** if you are breast-feeding your baby.

If you are pregnant or breast-feeding your baby while taking **VANICON**, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:

VANICON may impair your ability to drive and use machines, especially during the first days of therapy, and if you are taking alcohol. Avoid drinking alcohol. Do not drive or operate machinery until you know how **VANICON** affects you.

Taking other medicines with VANICON:

Before taking **VANICON**, tell your doctor if you are using any of the following medicines:

- Diuretics (water tablets)
- Potassium supplements
- Lithium – a medicine used to treat mental illness as it may lead to toxic blood concentrations of lithium.
- Non-steroidal anti-inflammatory medications such as indomethacin and ibuprofen which are used for pain relief, fever and inflammation.
- Medicines for high blood pressure
- Alcohol

If you are using any of these medicines, you may not be able to take **VANICON**, or you may need dosage adjustments. Your doctor may need to monitor you carefully for side-effects.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **VANICON** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE VANICON

- Take **VANICON** only as directed by your doctor.
- Do not take more or less of **VANICON** or take **VANICON** more often than prescribed by your doctor.
- **VANICON** should be taken during or after meals with half a glass of liquid.
- The usual dose of **VANICON** is 2,5 – 10 mg a day. Your doctor may start you on a lower dose of **VANICON** (1,25 mg per day) and gradually increase your dose.

Always take **VANICON** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **VANICON** is too strong or too weak, talk to your doctor or pharmacist.

If you take more VANICON than you should:

Symptoms of overdose may include lightheadedness and fainting.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take VANICON:

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

5. POSSIBLE SIDE-EFFECTS

VANICON can have side-effects.

Get emergency medical help if you have any of these signs of an allergic reaction:

- Hives (skin rash)
- Difficulty breathing
- Swelling of your face, lips, tongue, or throat

Call your doctor at once if you have any of these serious side-effects:

- Feeling light-headed; fainting
- Yellowing of the skin or eyes
- Blood disorders which may manifest with fever, sore throat, chills, and other signs of infection
- Urinating less than usual, or not at all
- Fast or uneven heart beat, fast or irregular heart beat or chest pain
- Pale skin, easy bruising or bleeding

Other side-effects include: Headache, excessive tiredness, confusion, dizziness, nausea, diarrhoea, vomiting, indigestion, sleep problems, sexual dysfunction, weakness, dry cough, rash,

itching, hair loss, loss of appetite, dry mouth, visual disturbance, runny nose, abdominal pain, taste disturbance.

Not all side-effects reported for **VANICON** are included in this leaflet. Should your general health worsen while taking **VANICON**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF VANICON

Store at or below 25 °C. Do not remove the blisters from the carton until required.

Keep all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF VANICON

VANICON 1,25 mg / VANICON 2,5 mg / VANICON 5 mg / VANICON 10 mg:

1. **Blister Packs:**

Capsules are packed in blister packs composed of cold form laminate: 60 micron PVC/ 25 µm OPA/ 60 micron aluminium foil/ 60 micron PVC film as the forming material and 25 micron aluminum foil as the lidding material. One blister contains 10 capsules.

Pack size: 30's – Each carton contains 3 blisters of 10 capsules each.

Capsules are packed in blister packs composed of clear 250 µm PVC/ 25 µm PE/90 g/m^2 PVdC as the forming material and 25 µm aluminum foil as the lidding material. One blister contains 10 capsules.

Pack size: 30's – Each carton contains 3 blisters of 10 capsules each.

2. **HDPE Container Pack:**

Capsules are packed in 40 ml HDPE containers with polypropylene closures with induction sealing wad, containing 1 silica gel sachet. Each container contains 30 capsules.

Pack size: 30's - One HDPE container contains 30 capsules.

8. IDENTIFICATION OF VANICON

VANICON 1,25 mg:

Yellow/White size ‘4’ hard gelatin capsules imprinted with ‘D’ on yellow cap and ‘40’ on white body with black edible ink filled with white to almost white powder.

VANICON 2,5 mg:

Orange/White size ‘4’ hard gelatin capsules imprinted with ‘D’ on orange cap and ‘41’ on white body with black edible ink filled with white to almost white powder.

VANICON 5 mg:

Red/White size ‘4’ hard gelatin capsules imprinted with ‘D’ on red cap and ‘42’ on white body with black edible ink filled with white to almost white powder.

VANICON 10 mg:

Blue/White size ‘4’ hard gelatin capsules imprinted with ‘D’ on blue cap and ‘43’ on white body with black edible ink filled with white to almost white powder.

9. REGISTRATION NUMBER/REFERENCE NUMBER

VANICON 1,25 mg CAPSULES: 44/7.1.3/1069

VANICON 2,5 mg CAPSULES: 44/7.1.3/1070

VANICON 5 mg CAPSULES: 44/7.1.3/1071

VANICON 10 mg CAPSULES: 44/7.1.3/1072

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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1448

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11. DATE OF PUBLICATION

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