NOVARTIS

MIGROBEN®

80, 160 mg

Film-coated Tablets

(Valsartan)

Document type:	Professional Information
Document status:	Final
Approval date:	09 October 2023

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

MIGROBEN 80 mg, 160 mg Film-coated tablets

Valsartan

Sugar free

Read all of this leaflet carefully before you start taking MIGROBEN

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- MIGROBEN 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 MIGROBEN is and what it is used for
2. What you need to know before you take MIGROBEN
3. How to take MIGROBEN
4. Possible side effects
5. How to store MIGROBEN
6. Contents of the pack and other information

1. What MIGROBEN is and what it is used for

MIGROBEN belongs to a class of medicines known as angiotensin-II receptor antagonists, which help to control high blood pressure.

MIGROBEN is used to treat high blood pressure. Due to narrowed arteries blood pressure increases your heart's workload. If it continues for a long time, it can damage the blood vessels of the brain, heart, and kidneys, and may result in a stroke, heart failure, or kidney failure. High blood pressure increases the risk of heart attacks. Lowering your blood pressure to normal reduces the risk of developing these disorders.

Angiotensin II is a natural substance in the body that causes blood vessels to tighten, thus causing your blood pressure to increase. MIGROBEN works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

If you have any question about how MIGROBEN works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take MIGROBEN

Follow your doctor's instructions carefully. They may differ from the general instructions contained in this leaflet.

Do not take MIGROBEN

- If you have ever had an unusual or allergic reaction to valsartan or to any other ingredients of MIGROBEN (listed in section 6)
- If you are pregnant or planning to become pregnant
- If you have poor kidney function
- If you have high level of sugar in the blood and you are suffering from type 2 diabetes mellitus while you are taking a blood pressure lowering medicine called aliskiren
- If you have moderate to severe liver disease
- If you have a single kidney and have narrowing or constriction of the renal artery
- If you have too low level of potassium or sodium in your blood, or if you have too high a level of calcium in your blood despite treatment
- If you have gout

- if you have porphyria
- If you have a heart condition where you have an abnormal narrowing of the aortic valve or the mitral valve
- If you have heart condition called “hypertrophic obstructive cardiomyopathy” where the cardiac muscle is abnormally thickened and, during the contraction, it obstructs the blood flow in the left lower cavity of the heart
- If you have a history of angioedema
- If you use lithium (medicine used to treat psychiatric disorders)
- If you use potassium sparing diuretics (water pills) such as spironolactone, triamterene, amiloride.

If either of these apply to you, tell your doctor without taking MIGROBEN.

If you think you may be allergic, ask your doctor for advice.

Warnings and precautions

Special care should be taken with MIGROBEN:

- If you have a liver disease
- If you have a severe kidney disease or are undergoing dialysis
- If you are vomiting or have diarrhoea or are taking high doses of a diuretic (water pill)
- If you ever had a swelling mainly of the face and throat while taking other drugs (including an ACE-inhibitor [hypertension pills]). **If you get those symptoms, stop taking MIGROBEN and contact your doctor immediately. You should never take MIGROBEN again.**
- If you are a Type 2 diabetic and are treated with aliskiren (hypertension pill)

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

Children and adolescents

The safety and efficacy of MIGROBEN have not been established in children below the age of 6 years.

Other medicines and MIGROBEN

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

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 both prescription and non-prescription medicines, especially:

- Medicines used to lower blood pressure, especially diuretics (water pills), ACE-inhibitors or aliskiren (hypertension pill);
- Potassium-sparing medicines, potassium supplements, salt substitutes containing potassium or other drugs that may increase potassium levels. Your doctor may check the amount of potassium in your blood periodically;
- Certain type of painkillers called non-steroidal anti-inflammatory medicines (NSAIDs) or Selective Cyclooxygenase-2 Inhibitors (Cox-2 Inhibitors). Your doctor may also check your kidney function;
- Lithium, a medicine used to treat some types of psychiatric illness;
- Some antibiotics (rifamycin group), a drug used to protect against transplant rejection (ciclosporin) or a drug used to treat HIV/AIDS infection (ritonavir). These drugs may increase the effect of MIGROBEN.

MIGROBEN with food and drink

You can take MIGROBEN with or without food.

Pregnancy and breastfeeding

Do not take MIGROBEN if you are pregnant or planning to become pregnant. Use of similar medicines has been associated with serious harm to the unborn child.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor for advice before taking this medicine.

Your doctor will discuss with you the potential risk of taking MIGROBEN during pregnancy.

Do not take MIGROBEN while breastfeeding. Tell your doctor if you are breastfeeding.

Driving and using machines

It is not always possible to predict to what extent MIGROBEN may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which MIGROBEN affects you.

3. How to take MIGROBEN

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

Always take MIGROBEN exactly as your doctor or pharmacist has told you. Check with your doctor if you are not sure.

Patients who have high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it all the more important for you to keep your appointments with the doctor even if you are feeling well. It is very important that you take this medicine exactly as your doctor and your pharmacist tells you in order to get the best results and reduce the risk of side effects.

MIGROBEN is for oral use only.

How much MIGROBEN to take

Your doctor and your pharmacist will tell you exactly how many tablets of MIGROBEN to take.

- For adults with high blood pressure, the usual dosage is one 80 mg tablet once a day. In some cases, your doctor may prescribe a higher dose (e.g. 160 mg tablet) or an additional medicine (e.g. a diuretic).

When to take MIGROBEN

Taking MIGROBEN at the same time each day will help you remember when to take your medicine.

How long to take MIGROBEN

Continue to take MIGROBEN as your doctor tells you.

If you have questions about how long to take MIGROBEN, talk to your doctor or your pharmacist.

If you take more MIGROBEN than you should

If you have accidentally taken too many tablets of MIGROBEN, talk to your doctor.

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

If you experience severe dizziness and/or fainting, tell your doctor as quickly as possible.

If you forget to take MIGROBEN

It is advisable to take your medicine at the same time each day, preferably in the morning. However, if you forget to take a dose of MIGROBEN, carry on with the next one at the usual time. Do not take a double dose to make up for the forgotten dose.

If you stop taking MIGROBEN

Stopping your treatment with MIGROBEN may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

4. Possible side effects

MIGROBEN can have side effects.

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

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

Some side effects could be serious (frequency unknown: frequency cannot be estimated from the available data)

- You may experience symptoms of angioedema (an allergic reaction), such as

- swollen face, tongue, or throat
- difficulty in swallowing
- hives and difficulties in breathing

If you get any of these, tell your doctor immediately.

Frequent side effects:

- dizziness
- low blood pressure with symptoms such as dizziness
- decreased kidney function (signs of renal impairment)

Less frequent side effects:

- allergic reaction with symptoms such as rash, itching, dizziness, swelling of face or lips or tongue or throat, difficulty breathing or swallowing (signs of angioedema) - (see also “Some side effects could be serious” listed before)
- sudden loss of consciousness
- spinning sensation
- severely decreased kidney function (signs of acute renal failure)
- muscle spasms, abnormal heart rhythm (signs of hyperkalaemia)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- headache
- cough
- abdominal pain
- nausea
- diarrhoea
- tiredness
- weakness

Frequency not known

- blistering skin (sign of dermatitis bullous)
- rash, itching, together with some of the following signs or symptoms: fever, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms (signs of serum sickness)
- purplish-red spots, fever, itching (signs of inflammation of blood vessels also called vasculitis)
- unusual bleeding or bruising (signs of thrombocytopenia)
- muscle pain (myalgia)
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells also called neutropenia)
- decrease of level of haemoglobin and decrease of the percentage of red blood cells in the blood (which can, in severe cases, lead to anaemia)
- increase of level of potassium in the blood (which can, in severe cases, trigger muscle spasms, abnormal heart rhythm)
- elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can, in severe cases, trigger yellow skin and eyes)
- increase of level of serum urea and increase level of serum creatinine (which can indicate abnormal kidney function)
- increased level of potassium in the blood (which can trigger muscle spasms and abnormal heart rhythm in severe cases) has been observed in children and adolescents 6 to 18 years of age.

The following effects have also been observed during clinical trials with MIGROBEN without possibility to determine if they are caused by the drug or have other causes: Back pain, change in libido, inflammation of the sinuses, insomnia, joint pain, pharyngitis, runny or stuffy nose, swollen hands, ankles or feet, upper respiratory tract infections, viral infections.

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, pharmacist, or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of MIGROBEN.

5. How to store MIGROBEN

KEEP OUT OF THE REACH OF CHILDREN

Store below 30 °C.

Store your tablets in the original package.

Protect from moisture.

Do not use MIGROBEN after the expiry date shown on the pack.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What MIGROBEN contains

- The active substance of MIGROBEN is valsartan. The active substance of MIGROBEN is available as film-coated tablets which contain 80 mg or 160 mg valsartan.
- The other ingredients are microcrystalline cellulose, crospovidone, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide (E171) Macrogol 8000, red iron oxide (E172), yellow iron oxide (E172), black iron oxide (E172) (160 mg only).

What MIGROBEN looks like and contents of the pack

MIGROBEN is supplied as film-coated tablets in two strengths.

MIGROBEN 80 mg film-coated tablets are pale red, round, with bevelled edges, scored on one side with debossing “D” on one side of the score and “V” on the other side of the score and NVR on the reverse side of the tablet.

MIGROBEN 160 mg film-coated tablets are grey-orange, ovaloid, slightly convex, scored on one side with debossing “DX” on one side of the score and “DX” on the other side of the score and NVR on the reverse side of the tablet.

The score line on one side of MIGROBEN 80 mg or 160 mg FCT is only to facilitate breaking for ease of swallowing and not to divide into equal dose.

MIGROBEN FCT is available in packs of 28 tablets in polyvinyl chloride/polyethylene/polyvinyldichloride (PVC/PE/PVDC)/ aluminium foil blisters or polyamide/aluminium/polyvinylchloride (PA/AL/PVC)/ aluminium foil blisters.
The outer container is a printed cardboard box.

Holder of Certificate of Registration

Novartis South Africa (Pty) Ltd.
Magwa Crescent West
Waterfall City
Jukskei view
Johannesburg
2090

This leaflet was last revised in

09 October 2023

Registration number

MIGROBEN® 80 Tablet: 43/7.1.3/0032

MIGROBEN® 160 Tablet: 43/7.1.3/0033