NOVARTIS

EXFORGE®

5/160, 10/160, 5/320, 10/320 mg

Film-coated Tablets

(amlodipine/valsartan)

Patient Information Leaflet

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PATIENT INFORMATION LEAFLET

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EXFORGE® 5/160 mg, 10/160 mg, 5/320 mg, 10/320 mg

Film-coated tablets

Amlodipine/Valsartan

Read all of this leaflet carefully before you start taking EXFORGE

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

1. What EXFORGE is and what it is used for

What EXFORGE is

Your medicine is called EXFORGE and is available as a film-coated tablet.

EXFORGE contains amlodipine, a medicine that belongs to the class of calcium channel antagonists and valsartan, which belongs to the class of so-called angiotensin-II receptor antagonists. They both help to control high blood pressure.

What EXFORGE is used for

EXFORGE is used to treat high blood pressure in patients ≥ 18 years old whose blood pressure is not adequately controlled with a single blood pressure lowering medicine. EXFORGE is used in patients whose blood pressure is normalised with the individual components in the same doses as the proposed fixed dose combination of EXFORGE.

How EXFORGE works

Amlodipine blocks calcium channels at the blood vessels. Angiotensin II is a natural substance produced by the body that causes blood vessels to tighten, thus increasing the blood pressure. Valsartan works by blocking the effect of angiotensin II. As a result of both mechanisms, blood vessels relax and blood pressure is lowered.

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

2. What you need to know before you take EXFORGE

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

Do not take EXFORGE

- If you have a history of allergies related to taking valsartan, amlodipine and/or other similar types of medicines.
- If you have an unusual sudden onset allergic reaction involving swelling and accumulation of water due to a hereditary or unknown cause.
- If your doctor has diagnosed that you suffer from a narrowing of valves in your heart (called aortic or mitral valve stenosis), or abnormally increased thickness of your heart muscle with narrowing of the left ventricular cavity (called obstructive hypertrophic cardiomyopathy).

- If you suffer from severe liver problems.
- If you have received a kidney transplant or if you had been diagnosed as suffering from a narrowing of your kidney artery or if you are suffering from severe kidney problems.
- 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 have porphyria.
- If you are taking lithium (a medicine used to treat some types of depression).
- If you have ever had an unusual or allergic reaction to amlodipine besylate or valsartan or to any other ingredients of EXFORGE 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 your baby.
- If you are taking a blood pressure lowering medicine called aliskiren.

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

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

Warnings and precautions

- If you suffer from several episodes of vomiting or diarrhoea or are taking a diuretic (a medicine increasing the amount of urine).
- If you suffer from liver problems.
- If you suffer from mild to moderate kidney problems.
- If you ever had a swelling mainly of the face and throat while taking other medicines (including an ACE-inhibitor). If you get those symptoms**, stop taking EXFORGE and contact your doctor immediately. You should never take EXFORGE again**.
- If you suffer from heart failure or have experienced a heart attack. Follow your doctor’s instruction for the starting dose carefully. Your doctor may also check your kidney function.
- If you are on treatment with an ACE-inhibitor or aliskiren.

- Use of fluoroquinolones and ACE inhibitors/Renin-Angiotensin receptor blockers may precipitate acute kidney injury in patients, especially those with moderate to severe renal impairment and elderly patients.

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

Also tell your doctor if you have received a kidney transplant or if you had been diagnosed to suffer from a narrowing of your kidney artery.

Children and adolescents

The safety and efficacy of EXFORGE has not been established in children.

Other medicines and EXFORGE

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

If you are taking other medicines on a regular basis, including complementary or traditional medicines, concomitant use of EXFORGE 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.

Contact your doctor to re-evaluate your treatment if you are treated with ACE inhibitors/Angiotensin receptor blockers together with a fluoroquinolone antibiotic.

This applies to medicines both prescribed and not prescribed by a doctor, especially:

- medicines used to lower blood pressure, especially diuretics (water pills), ACE inhibitors or aliskiren.
- potassium-sparing medicines, potassium supplements, or salt substitutes containing potassium or other medicines that may increase potassium levels.

- certain types of pain killers 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 depression.
- nitroglycerin and other nitrates, or other substances called “vasodilators”.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines that can change the amount of amlodipine in your body, especially:

- medicines used to prevent and treat fungal skin infections (such as ketoconazole, itraconazole, voriconazole).
- medicines used to treat AIDS or HIV infections (such as ritonavir, indinavir).
- medicines used to treat bacterial infections (such as clarithromycin, talithromycin).
- simvastatin, (a medicine used to control elevated cholesterol).

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines that can change the amount of valsartan in your body, especially:

- some antibiotics (rifamycin group, erythromycin, clarithromycin),
- medicines used to protect against transplant rejection (ciclosporin) or
- an antiretroviral medicine used to treat HIV/AIDS infection (ritonavir).

These medicines may increase the effect of valsartan.

EXFORGE with food and drink

You can take EXFORGE with or without food.

You should not consume grapefruit and grapefruit juice if you are taking EXFORGE. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active substance amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of EXFORGE.

Older people (age 65 and over)

There are no special dose recommendations for patients aged 65 years or older. Your doctor will decide if EXFORGE is right for you.

Children and adolescents (below the age of 18 years)

The use of EXFORGE in children and adolescents is not recommended.

Pregnancy and breastfeeding

Do not take EXFORGE 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 a woman and old enough to be able to become pregnant, you should ensure that you use effective contraception.

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 EXFORGE during pregnancy.

EXFORGE crosses into breastmilk.

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

Driving and using machines

It is not always possible to predict to what extent EXFORGE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which EXFORGE affects them.

3. How to take EXFORGE

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

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

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

Do not take more than the recommended dose.

How much EXFORGE to take

Your doctor will tell you exactly how many tablets of EXFORGE to take.

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

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

When to take EXFORGE

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

EXFORGE may be taken with or without food.

How long to take EXFORGE

Continue to take EXFORGE as your doctor tells you.

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

If you take more EXFORGE than you should

If you have accidentally taken too many tablets of EXFORGE, 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.

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

If you forget to take EXFORGE

Take your medicine at the same time each day, preferably in the morning.

If you forget to take EXFORGE, take it as soon as you remember and then 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 a forgotten tablet.

If you stop taking EXFORGE

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

4. Possible side effects

EXFORGE can have side effects.

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

If any of the following happens, stop taking EXFORGE 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)

- swelling of the face, lips, mouth or tongue, which may cause difficulty in swallowing or breathing,
- rash or itching,
- difficulty breathing,
- low blood pressure,
- Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea.

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

Other possible side effects are:

Frequent:

- Nasal congestion
- Flu-like symptoms
- Sore throat and discomfort when swallowing; swelling of arms, hands, legs, ankles or feet; redness and warm feeling of the face and/or the neck
- Headache
- Tiredness

Less Frequent:

- Anxiety
- Dizziness, tingling or numbness of the hands or feet, vertigo
- Dizziness on standing up
- Tinnitus
- Fast heartbeat including palpitations
- Fainting, low blood pressure with symptoms such as dizziness, light-headedness
- Cough
- Nausea and abdominal pain, dry mouth, diarrhoea; constipation
- Excessive sweating, generalised skin rash, itching, redness of the skin,
- Joint swelling, back pain, pain in joints, muscle spasm, sensation of heaviness
- Passing more urine than normal or feeling an increased urge to pass urine
- Inability to get or maintain an erection
- Drowsiness

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

Additional undesirable effects with amlodipine or valsartan alone, which can be serious, are:

Amlodipine

- 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
- Increase in blood sugar levels
- Inflammation of the blood vessel with skin rash as a symptom
- Shortness of breath, rhinitis
- Stomach pain with nausea, thickening of gums, loss of appetite, nausea, altered bowel movements, indigestion
- Inflammation of the pancreas or liver which can cause symptoms such as vomiting, yellow discolouration of the skin and eyes
- Hair loss
- Muscle pain
- Breast enlargement in men
- Swelling of the feet or legs due to fluid build-up, easy tiredness after light physical activity (heart disorder), mood changes and depression

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, decrease in neutrophils
- Increase in potassium levels
- Insomnia
- Inflammation of the blood vessel with skin rash as a symptom
- Rhinitis
- Decreased sex drive

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

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of EXFORGE.

5. How to store EXFORGE

KEEP OUT OF THE REACH OF CHILDREN

Do not store above 30 °C.

Store your tablets in the original package.

Protect from moisture.

Do not use EXFORGE 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 EXFORGE contains

- The active substance of EXFORGE 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, colloidal silica anhydrous, magnesium stearate, hypromellose, polyethylene glycol 4000, talc, titanium dioxide (E171), iron oxide, yellow (E172), iron oxide, red (E172) (10/160 mg tablets, 5/320 mg and 10/320 mg).

What EXFORGE looks like and contents of the pack

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

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

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

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

7, 14, 28, 56, 90 or 98 film-coated tablets in PA/Al/PVC (polyamide/aluminium/polyvinylchloride) blisters with an aluminium foil backing. Not all pack sizes may be marketed.
The blister foil is imprinted with the proprietary name, company name, batch number and expiry date.

Holder of Certificate of Registration

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	Namibia	**Botswana**
Exforge 5/160	10/7.1.3/0035 NS2	BOT1101905 S2
Exforge 10/160	10/7.1.3/0036 NS2	BOT1101906 S2
Exforge 5/320	12/7.1.3/0126 NS2	BOT1302302 S2
Exforge 10/320	12/7.1.3/0127 NS2	BOT1302303 S2

Manufacturer

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