

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

EXFORGE has been prescribed for you personally and you should not pass it on to others. 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.

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

EXFORGE® 5/80 mg film-coated tablet

EXFORGE® 5/160 mg film-coated tablet

EXFORGE® 10/160 mg film-coated tablet

EXFORGE® 5/320 mg film-coated tablet

EXFORGE® 10/320 mg film-coated tablet

1. WHAT EXFORGE CONTAINS

The active substance of EXFORGE is amlodipine besylate (equivalent to 5 mg or 10 mg amlodipine base) and valsartan (80 mg, 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).

2. WHAT EXFORGE IS USED FOR

EXFORGE 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 EXFORGE

Do not take EXFORGE:

- **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 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.
If any of these apply to you, tell your doctor without taking EXFORGE.

Take special care with EXFORGE:

- **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 EXFORGE.

Taking EXFORGE with food and drink:

You can take EXFORGE 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 EXFORGE in children and adolescents is not recommended.

Pregnancy:

Do not take EXFORGE 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 EXFORGE is not recommended during breastfeeding.

Driving and using machines:

EXFORGE 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 EXFORGE.

Taking other medicines with EXFORGE:

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. 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 EXFORGE

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 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 EXFORGE to take:

Your doctor will tell you exactly how many tablets of EXFORGE you should 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 and how to take EXFORGE:

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

How long to take EXFORGE:

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

If you take more EXFORGE than you should:

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

If you forget to take EXFORGE:

It is advisable to 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 the forgotten tablet.

Effects when treatment with EXFORGE is stopped:

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

5. POSSIBLE SIDE EFFECTS

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

EXFORGE 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 EXFORGE

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

7. PRESENTATION OF EXFORGE

- EXFORGE 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 EXFORGE

EXFORGE 5/80 mg: Dark yellow, round, film-coated tablets with beveled edges. Debossed with "NVR" on one side and "NV" on the other.

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: 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.

9. REGISTRATION NUMBERS / REFERENCE NUMBERS

EXFORGE 5/80 mg tablet: 41/7.1.3/0290
EXFORGE 5/160 mg tablet: 41/7.1.3/0291
EXFORGE 10/160 mg tablet: 41/7.1.3/0292
EXFORGE 5/320 mg tablet: 41/7.1.3/0770
EXFORGE 10/320 mg tablet: 41/7.1.3/0771

10. NAME AND ADDRESS OF REGISTRATION HOLDER

NOVARTIS SOUTH AFRICA (PTY) LTD
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Spartan
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1619

11. DATE OF PUBLICATION

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