

NEAFORGE® 5mg/160mg, Film-coated tablets
NEAFORGE® 5mg/160mg, Film-coated tablets
NEAFORGE® 10mg/160mg, Film-coated tablets
Amlodipine besylate / Valsartan

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

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

If you have any further questions, if you have any doubt, ask your doctor or pharmacist for further information.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.

Even if your signs of illness are the same as yours.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects even if listed in this leaflet. See section 4

What is in this leaflet:

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

1. What NEAFORGE, Film-coated tablets, is and what it is used for

Pharmacotherapeutic class

Agents acting on the renin-angiotensin system; calcium channel blockers and angiotensin-II receptor antagonists

Therapeutic indications

This medicine is used to treat high blood pressure (hypertension).

Patients who are already taking amlodipine and valsartan tablets separately may instead receive one NEAFORGE tablet that contains the two active substances at the same doses.

NEAFORGE is a combination of two substances called amlodipine and valsartan that help control blood pressure when it is too high.

- Amlodipine belongs to a group of substances called "calcium channel blockers". Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.

- Valsartan belongs to a group of substances called "angiotensin-II-receptor antagonists". Angiotensin II is produced by the body and makes the blood vessels tighter, thus increasing the blood pressure. Valsartan works by blocking the effect of angiotensin II.

This means that both of these substances help to stop the blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.

2. What you need to know before you take NEAFORGE, Film-coated tablets

Do not take NEAFORGE, Film-coated tablets:

- if you are allergic to amlodipine or to any other calcium channel blockers. This may involve itching, reddening of the skin or difficulty in breathing.

- if you are allergic to valsartan or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, talk to your doctor before taking NEAFORGE.

- if you have severe liver problems or bile problems such as biliary cirrhosis or cholestasis.

- if you are more than 3 months pregnant. (It is also better to avoid NEAFORGE in early pregnancy, see Pregnancy section).

- if you have severe low blood pressure (hypotension).

- if you have narrowing of the aortic valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).

- if you suffer from heart failure after a heart attack.

- if you have high blood sugar or type 2 diabetes (also known as non-insulin-dependent diabetes) and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of the above applies to you, do not take NEAFORGE and talk to your doctor.

Take special care with NEAFORGE, Film-coated tablets:

- if you have been sick (vomiting or diarrhoea).

- if you have liver or kidney problems.

- if you have had a kidney transplant or if you have had a narrowing of your kidney arteries.

- if you have a condition affecting the renal glands called "primary hyperaldosteronism".

- if you have had heart failure or have experienced a heart attack. Follow your doctor's instructions for the starting dose carefully. Your doctor may also check your kidney function.

- if your doctor has told you that you have a narrowing of the valves in your heart (called "aortic or mitral stenosis") or that the thickness of your heart muscle is abnormally increased (called "obstructive hypertrophic cardiomyopathy").

- if you have experienced swelling, particularly of the face and throat, while taking other medicines (including angiotensin converting enzyme inhibitors). If you get these symptoms, stop taking NEAFORGE and contact your doctor straight away. You should never take NEAFORGE again.

- if you are taking any of the following medicines used to treat high blood pressure: an angiotensin-converting enzyme (ACE) inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.

- oestrogens.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals. See also information under the heading "Do not take NEAFORGE". If any of these apply to you, tell your doctor before taking NEAFORGE.

Children and adolescents

The use of NEAFORGE in children and adolescents is not recommended (aged below 18 years old).

Other medicines and NEAFORGE

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may need to change your dose and/or to take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below:

- Angiotensin converting enzyme (ACE) inhibitors or aliskiren (see also information under the headings "Do not take NEAFORGE" and "Warnings and precautions")

- diuretics (a type of medicine also called "water tablets" which increases the amount of urine you produce);

- lithium (a medicine used to treat some types of depression);

- potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium and other substances that may increase potassium levels;

- certain types of painkillers called non-steroidal anti-inflammatory medicines (NSAID) or selective cyclooxygenase-2 inhibitors (COX-2 inhibitors). Your doctor may also check your kidney function;

- anticonvulsant agents (e.g. carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone);

- St. John's wort;

- nitroglycerin and other nitrates, or other substances called "vasodilators";

- medicines used for HIV/AIDS (e.g. ritonavir, indinavir, nelfinavir);

- medicines used to treat fungal infections (e.g. ketoconazole, itraconazole);

- medicines used to treat bacterial infections (such as rifampicin, erythromycin, clarithromycin, talfithromycin);

- verapamil, diltiazem (heart medicines);

- simvastatin (a medicine used to control high cholesterol levels);

- dantrolene (injection for severe body temperature abnormalities);

- medicines used to protect against transplant rejection (cyclosporin);

- Taking NEAFORGE with food and drinks (including alcohol)

NEAFORGE with food and drinks

Grapefruit and grapefruit juice should not be consumed by people who are taking NEAFORGE. 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 NEAFORGE.

Interactions with herbal products or alternative therapies

Not applicable.

Use during pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking NEAFORGE before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of NEAFORGE. NEAFORGE is not recommended in early pregnancy (first 3 months) and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Amlodipine has been shown to pass into breast milk in small amounts. NEAFORGE is not recommended for mothers who are breastfeeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Ask your doctor or pharmacist for advice before taking any medicine.

Athletes

Not applicable.

Driving and using machines

This medicine may make you feel dizzy. This can affect how well you can concentrate. So, if you are not sure how this medicine will affect you do not drive, use machinery, or do other activities that you need to concentrate on.

List of excipients with known effect

Not applicable.

3. How to take NEAFORGE, Film-coated tablets

Instructions for good use

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. This will help you get the best results and lower the risk of side effects.

Posology, Method and/or Route (s) of Administration, Frequency of Administration and Duration of Treatment

Posology

The usual dose of NEAFORGE is one tablet per day.

- It is preferable to take your medicine at the same time each day.

- Swallow the tablets with a glass of water.

- You can take NEAFORGE with or without food. Do not take NEAFORGE with grapefruit or grapefruit juice.

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

Do not exceed the prescribed dose.

NEAFORGE and older patients (age 65 years or over)

Your doctor should exercise caution when increasing your dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Symptoms and instructions in case of overdose

If you take more NEAFORGE than you should:

If you have taken too many tablets of NEAFORGE, or if someone else has taken your tablets, consult a doctor immediately.

Instructions in case of omission of one or more doses

If you forget to take NEAFORGE:

If you forget to take this medicine, take it as soon as you remember. Do not take your next dose to make up for a forgotten tablet. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose. Then take up for a forgotten tablet.

Risk of withdrawal syndrome

If you stop taking NEAFORGE:

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

If you have any further questions about the use of this medicine, ask your doctor or pharmacist for more information.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects can be serious and need immediate medical attention:

A few patients have experienced these serious side effects (may affect up to 1 in 1,000 people). If any of the following happen, tell your doctor straight away:

Allergic reaction with symptoms such as rash, itching, swelling of face or lips or throat, difficulty breathing, low blood pressure (feeling of faintness, light-headedness).

Other possible side effects of NEAFORGE:

Common (may affect up to 1 in 10 people): influenza (flu); blocked nose, sore throat and discomfort when swallowing; headache; swelling of arms, hands, legs, ankles or feet; tiredness; asthma (wheezes); redness and warm feeling of the face and/or neck.

Uncommon (may affect up to 1 in 100 people): 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.

Rare (may affect up to 1 in 1,000 people): feeling anxious; rigidity in the toes (finitims); itching; passing more urine than normal or feeling more of an 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; skin rash all over your body; itching; muscle spasm.

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

Side effects reported with amlodipine or valsartan alone and either not observed with NEAFORGE or observed with a higher frequency than with NEAFORGE:

Amlodipine

Consult a doctor immediately if you experience any of the following very rare, severe side effects after taking this medicine:

- Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing.

- Swelling of eyelids, face or lips.

- Swelling of the tongue and throat which causes great difficulty breathing.

- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of the mucous membranes (Stevens-Johnson Syndrome, toxic epidermal necrolysis) or other allergic reactions.

- Heart attack, abnormal heart beat.

- Inflamed pancreas, which may cause severe abdominal and back pain accompanied with feeling of being very unwell.

The following side effects have been reported. If any of these cause you problems or if they last for more than one week, you should contact your doctor.

Common (may affect up to 1 in 10 people): Dizziness; sleepiness; palpitations (awareness of your heart beat); flushing; ankle swelling

(oedema); abdominal pain, feeling sick (nausea).

Uncommon (may affect up to 1 in 100 people): Mood changes, anxiety, depression, sleeplessness, trembling, taste abnormalities, fainting, loss of pain sensation; visual disturbances, visual impairment, ringing in the ears; low blood pressure; sneezing/nycturia nose caused by inflammation of the lining of the nose (rhinitis); dry mouth; increased sweating, itching, skin, skin discoloration; disorder in passing urine, increased need to urinate at night, increased number of times of passing urine; inability to obtain an erection, discomfort or enlargement of the breasts in men, pain, feeling unwell, muscle pain, muscle cramps, weight increase or decrease.

Rare (may affect up to 1 in 1,000 people): Confusion.

Very rare (may affect up to 1 in 10,000 people): Decreased number of white blood cells, decrease in blood platelets which may result in unusual bruising or easy bleeding (red blood cell damage); excess sugar in blood (hyperglycaemia); swelling of the gums, abdominal bloating (gastritis); abnormal liver function, inflammation of the liver (hepatitis); yellowing of the skin (jaundice); liver enzyme increase which may have an effect on some medical tests; increased muscle tension; inflammation of blood vessels often with skin rash, sensitivity to light; disorders combining rigidity, tremor and/or movement disorders.

Valsartan

Not known (frequency cannot be estimated from the available data): Decrease in red blood cells, fever, sore throat or mouth sores due to infections; spontaneous bleeding or bruising; high level of potassium in the blood; abnormal liver test results; decreased renal functions and severely decreased renal functions; swelling mainly of the face and the throat, muscle pain, rash, purplish-red spots, fever, itching; allergic reaction; blistering skin (sign of a condition called dermatitis bullous).

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet. You may also report side effects directly via the national reporting system: Centre National de Pharmacovigilance (CNPV) - web site: www.pharmacovigilance.rns.mt

5. How to store NEAFORGE, Film-coated tablets

Store at a temperature not exceeding 30 °C in the original packaging, protected from moisture.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and the packaging after (EXP). The expiry date refers to the last day of the month.

Do not dispose of any medication in the sewage system or garbage. Ask your pharmacist to discard medications you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

The active ingredients are:

NEAFORGE 5 mg / 80 mg

- Amlodipine 5 mg of amlodipine as amlodipine besylate

- Valsartan: 80 mg

NEAFORGE 5 mg / 160 mg

- Amlodipine 5 mg of amlodipine as amlodipine besylate

- Valsartan: 160 mg

NEAFORGE 10 mg / 160 mg

- Amlodipine 10 mg of amlodipine as amlodipine besylate

- Valsartan: 160 mg

The other components are:

Tablet core: cellulose microcrystalline PH12, croscopollose XL, colloidal silica, magnesium stearate

Film-coating: Opasol II white for NEAFORGE 5 mg / 80 mg and NEAFORGE 5 mg / 160 mg products) and opasol II orange

What NEAFORGE looks like and contents of the pack

- NEAFORGE 5 mg / 80 mg Box of 30 orange film-coated tablets contained in aluminium / aluminium blister packs put in cardboard boxes

- NEAFORGE 5 mg / 80 mg Box of 90 orange film-coated tablets contained in aluminium / aluminium blister packs put in cardboard boxes

- NEAFORGE 5 mg / 160 mg Box of 30 orange film-coated tablets contained in aluminium / aluminium blister packs put in cardboard boxes

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- NEAFORGE 10 mg / 160 mg Box of 90 orange film-coated tablets contained in aluminium / aluminium blister packs put in cardboard boxes

Prescription and dispensing conditions: List I

Marketing Authorization Holder:

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Manufacturers:

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FAX : +216 72.235.016

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M.A. N°:

- NEAFORGE 5mg/80mg Box of 30: ST9393041

- NEAFORGE 5mg/80mg Box of 90: ST9393042

- NEAFORGE 5mg/160mg Box of 30: ST9393043

- NEAFORGE 5mg/160mg Box of 90: ST9393044

- NEAFORGE 10mg/160mg Box of 30: ST9393045

- NEAFORGE 10mg/160mg Box of 90: ST9393046

This leaflet was last revised in: May 2019

This is a Medicine

A medicine is a product that has a very good effect.

A medicine is a product that affects your health. If it is not used properly, it can be harmful to your health.

Should you desire to use the prescription of your Doctor and the use instructions prescribed, follow your pharmaceutical advice.

Your doctor and your pharmacist know the medicine. It is safe and its use is effective.

Do not stop the use of the treatment on your own without the prescribed time.

Do not drink, do not increase the dose without doctor's advice.

Keep all medicines out of reach of children.