

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only.

Exforge® 5 mg/80 mg Film-Coated Tablets

Composition:

Each film-coated tablet contains:
Amlodipine (as besylate) 5 mg
Valsartan 80 mg

Exforge® 5 mg/160 mg Film-Coated Tablets

Composition:

Each film-coated tablet contains:
Amlodipine (as besylate) 5 mg
Valsartan 160 mg

Exforge® 10 mg/160 mg Film-Coated Tablets

Composition:

Each film-coated tablet contains:
Amlodipine (as besylate) 10 mg
Valsartan 160 mg

Inactive Ingredients: see section 6
“Additional information”.

Read this leaflet carefully and in its entirety before using this medicine. This leaflet contains summary information regarding the medicine. If you have further questions, contact the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of high blood pressure. Amlodipine blocks calcium channels in the blood vessels and as a result they are relaxed.

Angiotensin II is a substance produced by the body that causes blood vessels to constrict, 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.

Exforge is used to treat high blood pressure in patients in whom the high blood pressure was not decreased following the use of amlodipine or valsartan alone.

If high blood pressure persists for a long time, it can damage the blood vessels of the brain, heart and kidneys, and may result in stroke, heart failure, or kidney failure. Lowering the blood pressure to normal levels reduces the risk of developing these disorders.

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

Therapeutic group:

Amlodipine - calcium channels blocker.
Valsartan - angiotensin-II receptor antagonist.

2. BEFORE USING THE MEDICINE

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

There are no special dose recommendations for patients aged 65 years or older. Your doctor will decide whether **Exforge** is appropriate for you.

This medicine is not recommended for use in infants, children and adolescents under 18 years of age.

⚠ Do not use the medicine if:

You are sensitive (allergic) to the active ingredients, to a medicine of the dihydropyridine type, or to any of the other ingredients contained in the medicine, detailed in section 6. If you think you may be allergic, ask your doctor for advice.

You have severe liver problems, such as cholestasis.

You have severe kidney problems or if you are having dialysis.

You are pregnant or planning to become pregnant.

You have a high level of sugar in the blood and you are suffering from diabetes and you are taking a blood pressure lowering medicine containing aliskiren (such as: Rasilez) at the same time.

You are suffering from a kidney function impairment and you are taking a blood pressure lowering medicine containing aliskiren (such as: Rasilez) at the same time. If any of these apply to you, tell your doctor without taking **Exforge**.

Special warnings regarding use of the medicine:

⚠ Before treatment with Exforge, tell the doctor if:

- You are breastfeeding. Treatment with **Exforge** is not recommended during breastfeeding.
- You are suffering from several episodes of vomiting or diarrhea or are taking a diuretic (a medicine that increases the amount of urine).
- You are taking other drugs or substances, which increase the potassium levels in your blood (such as certain types of diuretics, salt substitutes containing potassium, potassium supplements, etc.).
- You suffer from liver or kidney problems. If you have a problem with adrenal gland function.
- 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).
- You have received a kidney transplant or if you had been diagnosed to suffer from a narrowing of the kidney artery.
- 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. In such a situation, you should never take Exforge again.**
- You are suffering from 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.
- You are taking an ACE-inhibitor or aliskiren.

If any of these apply to you, inform your doctor before taking **Exforge**.

⚠ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutrition supplements, inform the doctor or pharmacist. It may

be necessary to change the dose or in some cases, to stop taking one of the medicines. Especially inform the doctor or pharmacist if you are taking medicines from the following groups:

medicines used to lower blood pressure, especially diuretics, ACE-inhibitors or aliskiren; potassium-sparing medicines, potassium supplements, salt substitutes containing potassium or any other medicines that may increase potassium levels. Your doctor may check the amount of potassium in your blood periodically; certain types of pain killers called non-steroidal anti-inflammatory drugs (NSAIDs) or selective cyclooxygenase 2 inhibitors (Cox-2 inhibitors). The doctor may also check your kidney function; lithium, a medicine used to treat some types of psychiatric illness; anticonvulsant agents (e.g., carbamazepine, phenobarbital, phenytoin, primidone, fosphenytoin); nitroglycerin and other nitrates, or other medicines that belong to a group called “vasodilators”, *Hypericum perforatum*.

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, this is especially important for medicines belonging to the following groups: medicines used to prevent and treat fungal skin infections (such as ketoconazole, itraconazole); diltiazem (a medicine used to treat hypertension and angina). Medicines used to treat AIDS or HIV infections (such as ritonavir, indinavir); medicines used to treat bacterial infections (such as clarithromycin, telithromycin); simvastatin (a medicine used to lower 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, this is especially important for medicines belonging to the following groups: some antibiotics (rifampicin group), medicines used to protect against transplant rejection (ciclosporin) or an antiviral medicine used to treat HIV/AIDS infection (ritonavir). These medicines may increase the effect of valsartan.

⚠ Using the medicine and food:

Exforge may be taken with or without food.

⚠ Pregnancy and breastfeeding:

Do not take **Exforge** if you are pregnant or planning to become pregnant. Using **Exforge** during pregnancy has been

associated with 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. Your doctor will discuss with you the potential risk of taking **Exforge** during pregnancy. Treatment with **Exforge** is not recommended during breastfeeding.

⚠ Driving and using machines:

Like many other medicines used to treat high blood pressure, **Exforge** may in rare cases 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 **Exforge**.

3. HOW TO USE THE MEDICINE?

Always use according to the doctor's instructions. Follow them carefully. They may differ from the general instructions in this leaflet. You should check with the doctor or pharmacist if you are not sure.

It is very important that you take this medicine exactly as your doctor tells you in order to get the best results and reduce the risk of side effects.

Your doctor will tell you exactly how many tablets of **Exforge** you should take and for how long. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

Continue taking **Exforge** as your doctor tells you.

The dosage and manner of treatment will be determined by the doctor only. The usual dosage is generally one film-coated tablet per day.

Do not exceed the recommended dose.

There are no special dose recommendations for patients aged 65 years or older.

This medicine is not recommended for use in infants, children and adolescents under 18 years of age.

Exforge is for oral use only.

Swallow the tablets with a glass of water.

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

It is advisable to take the medicine at the same time each day, preferably in the morning. If you forget to take the

medicine at the specified time, do not take a double dose. Take the next dose at the regular time and consult the doctor.

Persist with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not discontinue use of the medicine without consulting the doctor or pharmacist. If you discontinue taking the medicine, your disease may get worse.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions about the use of the medicine or about how long to take **Exforge**, talk to your doctor or your pharmacist.

4. SIDE EFFECTS

Like with any medicine, using **Exforge** may lead to side effects in some of the users. Do not be alarmed following reading the list of side effects. You may experience none of them.

Refer to the doctor immediately if you have an allergic reaction with symptoms such as rash, itching, swelling of the face or lips or tongue, difficulty breathing, low blood pressure (rare side effects, affecting less than 1 in 1000 patients).

Additional side effects:

Occurring frequently (affecting less than 1 in 10 patients): flu; 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; weakness.

Occurring infrequently (affecting less than 1 in 100 patients): 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; diarrhea; constipation; skin rash; redness of the skin; joint swelling, back pain; pain in joints.

Occurring rarely (affecting less than 1 in 1000 patients): 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; generalized skin rash; itching; muscle spasm; vision disturbances.

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

Additional side effects with Amlodipine or Valsartan alone, which can be serious are:

Amlodipine: Spontaneous bleeding or bruising (possible symptoms of thrombocytopenia), fever, sore throat or mouth ulcers due to infections (possible symptoms of leucocytopenia), sensation of numbness or tingling in the fingers and toes (possible symptoms of peripheral neuropathy), irregular heart beat (possible symptoms of atrial fibrillation), slow heart beat (possible symptoms of bradycardia), sudden and oppressive chest pain (possible symptoms of myocardial infarction), rash, fever, itching (possible symptoms of vasculitis), severe upper stomach pain (possible symptoms of pancreatitis), yellowing of the skin and eyes, nausea, loss of appetite, dark colored urine (possible symptoms of hepatitis), swelling mainly of the face and throat (possible symptoms of angioedema), rash, skin reddening, blistering of the lips, eyes or mouth, skin peeling (possible symptoms of erythema multiforme), rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible symptoms of Steven-Johnson Syndrome).

Valsartan: decreased number of white blood cells which could increase the risk of infections, blistering skin (sign of dermatitis bullous).

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

If a side effect gets worse, or when you suffer from a side effect not mentioned in the leaflet, consult the doctor.

5. HOW TO STORE THE MEDICINE?

• Avoid poisoning! This medicine and all other medicines should be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

• Do not use this medicine after the expiry date (exp. date) stated on the package. The expiry date relates to the last day of that month.

Do not store above 30°C. Store in the original package in order to protect from moisture.

Do not store different medications in the same package. Do not use if the package is damaged.

6. ADDITIONAL INFORMATION

In addition to the active ingredients, the medicine also contains:

Cellulose microcrystalline; crospovidone; silica, colloidal anhydrous; magnesium stearate; hypromellose, macrogol 4000, talc, titanium dioxide (E171), iron oxide, yellow (E172), iron oxide, red (E172) (10 mg/160 mg tablets).

How does the medicine look and what is the content of the package:

Exforge 5 mg/80 mg: dark yellow, round film-coated tablet with bevelled edges, imprinted with “NVR” on one side and “NV” on the other side. The package contains 28 tablets.

Exforge 5 mg/160 mg: dark yellow, oval film-coated tablet with bevelled edges, imprinted with “NVR” on one side and “ECE” on the other side. The package contains 28 tablets.

Exforge 10 mg/160 mg: light yellow, oval film-coated tablet with bevelled edges, imprinted with “NVR” on one side and “UIC” on the other side. The package contains 28 tablets.

Registration holder and address:

Novartis Israel Ltd., 36 Shacham St., Petach-Tikva.

Name and address of the manufacturer:

Novartis Pharmaceutica S.A., Barcelona, Spain for Novartis Pharma AG, Basel, Switzerland.

This leaflet was checked and approved by the Ministry of Health in June 2015.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Exforge 5 mg/80 mg:

138 40 31566

Exforge 5 mg/160 mg:

138 41 31567

Exforge 10 mg/160 mg:

138 42 31568