

Package leaflet: information for the user

Exforge® 5 mg/80 mg film-coated tablets

Exforge® 5 mg/160 mg film-coated tablets

Exforge® 10 mg/160 mg film-coated tablets

amlodipine/valsartan

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their 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 not listed in this leaflet.

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

Exforge tablets contain two substances called amlodipine and valsartan. Both of these substances help to control high blood pressure.

- 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 tighten, 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.

Exforge is used to treat high blood pressure in adults whose blood pressure is not controlled enough with either amlodipine or valsartan on its own.

2. What you need to know before you take Exforge Do not take Exforge

- 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 Exforge.
- 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 Exforge 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 diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

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

Warnings and precautions

Talk to your doctor before taking Exforge:

- 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 had been told that you have 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 Exforge and contact your doctor straight away. You should never take Exforge again.
- if you are taking any of the following medicines used to treat high blood pressure:
 - an ACE inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
 - aliskiren.

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 Exforge”.

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

Children and adolescents

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

Other medicines and Exforge

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:

- ACE inhibitors or aliskiren (see also information under the headings “Do not take Exforge” 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 (NSAIDs) 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, talithromycin);
- verapamil, diltiazem (heart medicines);
- simvastatin (a medicine used to control high cholesterol levels);

- dantrolene (infusion for severe body temperature abnormalities);
- medicines used to protect against transplant rejection (ciclosporin).

Exforge with food and drink

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

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 Exforge before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Exforge. Exforge 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. Exforge is not recommended for mothers who are breast-feeding, 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.

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.

3. How to take Exforge

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.

The usual dose of Exforge 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 Exforge with or without food. Do not take Exforge 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.

Exforge and older people (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.

If you take more Exforge than you should

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

If you forget to take Exforge

If you forget to take this medicine, take it as soon as you remember. 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

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 tongue, difficulty breathing, low blood pressure (feeling of faintness, light-headedness).

Other possible side effects of Exforge:

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; asthenia (weakness); 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; ringing in the ears (tinnitus); fainting; 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 Exforge or observed with a higher frequency than with Exforge:

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/runny nose caused by inflammation of the lining of the nose (rhinitis); indigestion, vomiting (being sick); hair loss, increased sweating, itchy 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 effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

HPRa Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

5. How to store Exforge

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 carton and blister.

Do not store above 30°C.

Store in the original package in order to protect from moisture.

Do not use any Exforge pack that is damaged or shows signs of tampering.

6. Contents of the pack and other information

What Exforge contains

Exforge 5 mg/80 mg film-coated tablets

The active substances of Exforge are amlodipine (as amlodipine besylate) and valsartan. Each tablet contains 5 mg amlodipine and 80 mg valsartan.

The other ingredients are cellulose microcrystalline; crospovidone type A; silica, colloidal anhydrous; magnesium stearate; hypromellose; macrogol 4000; talc, titanium dioxide (E171); iron oxide, yellow (E172).

Exforge 5 mg/160 mg film-coated tablets

The active substances of Exforge are amlodipine (as amlodipine besylate) and valsartan. Each tablet contains 5 mg amlodipine and 160 mg valsartan.

The other ingredients are cellulose microcrystalline; crospovidone type A; silica, colloidal anhydrous; magnesium stearate; hypromellose; macrogol 4000; talc, titanium dioxide (E171); iron oxide, yellow (E172).

Exforge 10 mg/160 mg film-coated tablets

The active substances of Exforge are amlodipine (as amlodipine besylate) and valsartan. Each tablet contains 10 mg amlodipine and 160 mg valsartan.

The other ingredients are cellulose microcrystalline; crospovidone type A; silica, colloidal anhydrous; magnesium stearate; hypromellose; macrogol 4000; talc, titanium dioxide (E171); iron oxide, yellow (E172), iron oxide, red (E172).

What Exforge looks like and contents of the pack

Exforge 5 mg/80 mg tablets are round and dark yellow with “NVR” on one side and “NV” on the other side.

Exforge 5 mg/160 mg tablets are oval and dark yellow “NVR” on one side and “ECE” on the other side.

Exforge 10 mg/160 mg tablets are oval and light yellow with “NVR” on one side and “UIC” on the other side.

Exforge is available in packs containing 7, 14, 28, 30, 56, 90, 98 or 280 tablets and in multipacks comprising 4 cartons, each containing 70 tablets, or 20 cartons, each containing 14 tablets. All packs are available with standard blisters; the 56, 98 and 280 tablet packs are additionally available with perforated unit dose blisters. Not all pack sizes may be available in your country.

Marketing Authorisation Holder

Novartis Europharm Limited

Vista Building

Elm Park, Merriem Road

Dublin 4

Ireland

Manufacturer

Novartis Pharma GmbH

Roonstraße 25

D-90429 Nuremberg

Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien

Novartis Pharma N.V.

Tél/Tel: +32 2 246 16 11

България

Novartis Pharma Services Inc.

Тел.: +359 2 976 98 28

Česká republika

Novartis s.r.o.

Tel: +420 225 775 111

Danmark

Novartis Healthcare A/S

Tlf: +45 39 16 84 00

Deutschland

Novartis Pharma GmbH

Tel: +49 911 273 0

Eesti

Novartis Pharma Services Inc.

Tel: +372 66 30 810

Ελλάδα

Novartis (Hellas) A.E.B.E.

Τηλ: +30 210 281 17 12

España

Novartis Farmacéutica, S.A.

Tel: +34 93 306 42 00

France

Novartis Pharma S.A.S.

Tél: +33 1 55 47 66 00

Hrvatska

Novartis Hrvatska d.o.o.

Tel. +385 1 6274 220

Ireland

Novartis Ireland Limited

Tel: +353 1 260 12 55

Ísland

Vistor hf.

Sími: +354 535 7000

Italia

Novartis Farma S.p.A.

Tel: +39 02 96 54 1

Κύπρος

Novartis Pharma Services Inc.

Τηλ: +357 22 690 690

Latvija

Novartis Pharma Services Inc.

Tel: +371 67 887 070

Lietuva

Novartis Pharma Services Inc.

Tel: +370 5 269 16 50

Luxembourg/Luxemburg

Novartis Pharma N.V.

Tél/Tel: +32 2 246 16 11

Magyarország

Novartis Hungária Kft. Pharma

Tel.: +36 1 457 65 00

Malta

Novartis Pharma Services Inc.

Tel: +356 2122 2872

Nederland

Novartis Pharma B.V.

Tel: +31 26 37 82 111

Norge

Novartis Norge AS

Tlf: +47 23 05 20 00

Österreich

Novartis Pharma GmbH

Tel: +43 1 86 6570

Polska

Novartis Poland Sp. z o.o.

Tel.: +48 22 375 4888

Portugal

Novartis Farma - Produtos Farmacêuticos, S.A.

Tel: +351 21 000 8600

România

Novartis Pharma Services Romania SRL

Tel: +40 21 31299 01

Slovenija

Novartis Pharma Services Inc.

Tel: +386 1 300 75 50

Slovenská republika

Novartis Slovakia s.r.o.

Tel: +421 2 5542 5439

Suomi/Finland

Novartis Finland Oy

Puh/Tel: +358 (0)10 6133 200

Sverige

Novartis Sverige AB

Tel: +46 8 732 32 00

United Kingdom

Novartis Pharmaceuticals UK Ltd.

Tel: +44 1276 698370

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>