

EXFORGE[®] FILM-COATED TABLET

amlodipine besylate/valsartan 5/80 mg,
5/160mg, 10/160mg, 5/320mg and 10/320mg

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What Exforge is used for

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 antagonists and valsartan, which belongs to angiotensin-II receptor antagonists. They both help to control high blood pressure.

Exforge is indicated to treat high blood pressure which is not adequately controlled by a single drug.

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.

Before you use Exforge

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

When you must not use it

- If you have ever had an unusual or allergic reaction to amlodipine besylate or valsartan or to any other ingredients of this product listed at the end of this leaflet. If you think

you may be allergic, ask your doctor for advice.

- If you are pregnant or planning to become pregnant.
- If you have high level of sugar in the blood and you are suffering from type 2 diabetes (also called non-insulin dependent diabetes mellitus) while you are taking a blood pressure lowering medicine called aliskiren
- If you have severe liver impairment; biliary cirrhosis (blocking of bile ducts in the liver) and cholestasis (bile cannot flow from liver to intestine).

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

Pregnancy and breast-feeding

Do not take Exforge if you are pregnant or planning to become pregnant. Use 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.

Tell your doctor if you are breast-feeding. Treatment with Exforge is not recommended during breast-feeding.

Before you start to use it

Take special care with Exforge

- If you are suffering from several episodes of vomiting or diarrhea or are taking a diuretic (a drug increasing the amount of urine).
- If you are taking other drugs 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 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 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 are suffering 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 treated with an ACE-inhibitor or aliskiren

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.

Older people (aged 65 years and over)

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

Children and adolescents

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

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. 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:

- medicines used to lower blood pressure, especially diuretics (water pills), ACE-inhibitors or aliskiren;
- Potassium-sparing medicines, potassium supplements, or salt substitutes containing potassium. Your doctor may check the amount of potassium in your blood periodically.
- Certain type 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 psychiatric illness.

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)
- 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 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), 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

How to take Exforge

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. Exforge is for oral use only.

Do not exceed the recommended dose.

Swallow the tablets with a glass of water.

How much to use

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 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 taking 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 forget to take Exforge

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

If you take more Exforge than you should (overdose)

Symptoms of overdose include low blood pressure; dizziness and tachycardia (a rapid heart rate). If you have accidentally taken too many tablets of Exforge, consult your doctor immediately.

While using Exforge

Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Exforge.

Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

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

Things to be careful of

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 the effects of Exforge.

Side effects

As with all medicines, patients taking Exforge can experience side effects, although not everybody gets them.

Some side effects can be serious

Rare (affecting less than 1 in 1000 patients): 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 immediately.

Other possible side effects are:

Common (affecting less than 1 in 10 patients): 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.

Uncommon (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.

Rare (affecting less than 1 in 1000 patients): Anxiety; tinnitus (ringing of the ears); 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

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 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), yellow 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 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 immediately.

If you notice any other effects not mentioned in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Exforge

Storage

- Do not store above 30°C
- Store your tablets in the original package. Protect from moisture
- Do not use Exforge after the expiry date which is stated on the pack.
- Keep out of the reach and sight of children.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Exforge® 5/80 mg: Dark yellow, round shaped film-coated tablet with bevelled edge, debossed with “NVR” on one side and “NV” on the reverse side.

Exforge® 5/160 mg: Dark yellow, ovaloid shaped film-coated tablet with bevelled edge, debossed with “NVR” on one side and “ECE” on the reverse side.

Exforge® 10/160 mg: Light yellow, ovaloid shaped film-coated tablet with bevelled edge, debossed with “NVR” on one side and “UIC” on the reverse side.

Exforge® 5/320 mg: Very dark yellow, ovaloid shaped film-coated tablet with a bevelled edge, debossed with “NVR” on one side and “CSF” on the reverse side.

Exforge® 10/320 mg: Dark yellow, ovaloid shaped, film-coated tablet with a bevelled edge debossed with “NVR” on one side and “LUF” on the reverse side.

Ingredients

- *Active ingredient*

The active substances of Exforge are amlodipine besylate (5 mg or 10 mg) and valsartan (80 mg, 160 mg or 320 mg).

- *Inactive ingredients*

The **other ingredients** are cellulose microcrystalline; sodium starch glycolate (5/320 mg and 10/320 mg tablets); crospovidone; silica, colloidal anhydrous; magnesium stearate; hypromellose, macrogol 4000, talc, titanium dioxide (E171), iron oxide, yellow (E172), red (E172) (10/160 mg, 5/320mg and 10/320mg tablets).

MAL Number

Exforge 5/80mg film-coated tablet: MAL20081727A

Exforge 5/160mg film-coated tablet: MAL20081728A

Exforge 10/160mg film-coated tablet: MAL20081729A

Exforge 5/320mg film-coated tablet: MAL11040002A

Exforge 10/320mg film-coated tablet: MAL11040003A

Manufacturer

Exforge® 5/80 mg, 5/160mg and 10/160mg:

Novartis Farmaceutica S.A.,
Barbera, Del Valles, Spain.

Exforge® 5/320 mg and 10/320mg:

Novartis Pharma Stein AG,
Schaffhauserstrasse, CH-4332,
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Product Registration Holder

Novartis Corporation (Malaysia) Sdn. Bhd.

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Date of revision

18/08/2014