

EXFORGE HCT[®]

amlodipine besylate/valsartan/hydrochlorothiazide

5/160/12.5 mg, 10/160/12.5 mg, and 10/160/25 mg, Film-coated tablets

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What Exforge HCT is used for

Your medicine is called Exforge HCT and is available as a film-coated tablet. Exforge HCT contains three medicines: Amlodipine, a medicine that belongs to the class of calcium antagonists, valsartan, which belongs to the class of so-called angiotensin-II receptor antagonists and hydrochlorothiazide, a diuretic which belongs to the sulfonamides. All three medicines help in different ways to control high blood pressure. Exforge HCT is used to treat high blood pressure in patients whose blood pressure is not adequately controlled with a dual combination of blood pressure lowering drugs, or for patients on separate antihypertensive drugs who wish to take one tablet with all three components. 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 a stroke, heart failure, kidney failure or damage to the retina of the eye. High blood pressure increases the risk of heart attacks. Lowering your blood pressure to normal levels reduces the risk of developing these disorders.

How Exforge HCT works

Exforge HCT contains three medicines: Amlodipine blocks calcium channels at the blood vessels level. This has a relaxant effect on the blood vessels. Valsartan works by blocking the effect of angiotensin II. Angiotensin II is a substance produced by the body that causes blood vessels to tighten, thus increasing the blood pressure. Hydrochlorothiazide reduces the amount of salt and water in the

body by increasing the flow of urine. As a result of all three mechanisms, blood vessels relax and blood pressure is lowered. If you have any question about how Exforge HCT works or why this medicine has been prescribed for you, ask your doctor.

Before you use Exforge HCT

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

Your doctor may wish to have your blood tested before and at regular intervals during your treatment to check the values of potassium, magnesium, calcium, sodium, sugar, cholesterol, uric acid and the amounts of red and white cells as well as platelets. Your doctor may also monitor your kidney function.

When you must not use it

- If you are allergic (hypersensitive) to amlodipine, valsartan, hydrochlorothiazide or sulfonamides or any of the other ingredients of Exforge HCT listed at the end of this leaflet.
- If you are pregnant or planning to become pregnant
- If you have inability to produce urine (anuria)
- 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 any of these apply to you, tell your doctor without taking Exforge HCT. If you think you may be allergic, ask your doctor for advice.

Pregnancy and breast-feeding

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

Your doctor will discuss with you the potential risk of taking Exforge HCT during pregnancy. Tell your doctor if you are breast-feeding. Treatment with Exforge HCT is not recommended during breast-feeding.

Before you start to use it

Warnings and precautions

- If you suffer from kidney or liver disorders,
- If you are taking already a diuretic (a medicine to increase the amount of urine you produce),
- If you have fever, facial rash, and joint pain, which may be possible signs of lupus erythematosus (or a history of this disease),
- If you have diabetes (high levels of sugar in your blood),
- If you have been told you have high levels of cholesterol or triglycerides in your blood,
- If you have been told you have low levels of potassium or magnesium in your blood (with or without symptoms such as muscle weakness, muscle spasms, abnormal heart rhythm),
- If your doctor has told you that you have low levels of sodium in your blood (with or without symptoms such as tiredness, confusion, muscle twitching, convulsions).
- If you have been told you have high level of calcium in your blood (with or without symptoms such as nausea, vomiting, constipation, stomach pain, frequent urination, thirst, muscle weakness and twitching).
- If your doctor has told you that you have high levels of uric acid in the blood.
- If you are suffering from allergy or asthma.
- If you suffer from an impaired kidney function or a narrowing or blockage of the arteries that supply blood to your kidney,
- If you are suffering from several episodes of vomiting or diarrhea
- 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 are breast feeding.
- 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 HCT and contact your doctor straight away. You should never take Exforge HCT 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 you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Exforge HCT. Regularly check your skin for any new lesions and promptly report any suspicious skin lesions to your doctor.
- If you experience breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Exforge HCT, seek medical attention immediately.

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

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 HCT in children and adolescents is not recommended.

Taking other medicines

Tell your doctor or a pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes in particular:

- potassium-sparing medicines, potassium supplements, or salt substitutes containing potassium. Your doctor may check the amount of potassium in your blood periodically,
- amphotericin, penicillin G (medicines used to treat infections),
- carbenoxolone (medicine used for oesophageal ulceration and inflammation),
- other medicines used to lower blood pressure especially ACE-inhibitors or aliskiren;
- lithium, antidepressants, antipsychotics, medicines used to treat some psychological conditions;
- antiepileptics, such as carbamazepine (medicines used to treat convulsions)
- medicines used to relieve pain or inflammation, especially non-steroidal anti-inflammatory agents (NSAIDs), including Selective Cyclooxygenase-2 Inhibitors (Cox-2 inhibitors); Your doctor may also check your kidney function;
- cortisone-like medicines, steroids;
- antiarrhythmics (medicines used to treat heart problems);
- digoxin or other digitalis glycosides (medicines used to treat heart problems);
- muscle relaxant drugs (medicines used during operations);
- allopurinol (medicine used to treat gout);
- amantadine (anti-Parkinson therapy, also used to treat or prevent certain illnesses caused by viruses);
- certain cancer medicines;
- anticholinergic agents (medicines used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms,

Parkinson's disease and as an aid to anesthesia);

- ciclosporin (a medicine used in transplantation to prevent organ rejection or for other conditions, e.g.: rheumatoid arthritis or atopic dermatitis);
- insulin or antidiabetic medicines taken by mouth (medicines used to treat high levels of sugar in your blood);
- cholestyramine, colestipol or other resins (medicines used mainly to treat high levels of lipids in the blood);
- vitamin D and calcium salts;
- pressor amines, such as noradrenaline (substances that raise blood pressure);
- barbiturates, narcotics (medicines with sleep-inducing properties) and alcohol.

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, rifampicin)
- Simvastatin, (a medicine used to control elevated cholesterol)
- Medicines used to treat depression (such as St. John's Wort, hypericum perforatum)

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), a medicine 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 use Exforge HCT

Follow your doctor's instructions carefully. Do not exceed the recommended dose.

Exforge HCT is for oral use only.

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

How much to use

Your doctor will tell you exactly how many tablets of Exforge HCT 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 HCT is one film coated tablet per day.

When to take Exforge HCT

Taking Exforge HCT at the same time each day will help you remember when to take your medicine.

How long to take Exforge HCT

Continue taking Exforge HCT as your doctor tells you.

If you have questions about how long to take Exforge HCT, talk to your doctor or your pharmacist.

If you forget to take Exforge HCT

It is advisable to take your medicine at the same time each day, preferably in the morning. If you forget to take Exforge HCT, 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 use too much (overdose)

If you have accidentally taken too many tablets of Exforge HCT, consult your doctor immediately.

While using Exforge HCT

Things you must do

- If you experience dizziness and/or faintness during treatment with Exforge HCT
- If you experience a decrease in vision or eye pain. These could be symptoms of an increase of pressure in your eye and can happen within hours to weeks of taking Exforge HCT. This can lead to permanent vision impairment, if not treated.

If you get any of these symptoms, tell your doctor as soon as possible.

Things you must not do

Stopping your treatment with Exforge HCT 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 HCT 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 HCT.

Side effects

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

Amlodipine

Some side effects could be serious
If you experience: skin rash with or without difficulties in breathing (possible signs of allergic reactions); 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, purplish red spots, fever, itching (possible symptoms of vasculitis); severe upper stomach pain (possible symptoms of pancreatitis); yellow skin and eyes, nausea, loss of appetite, light 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)
If you get any of these, tell your doctor straight away.

Some side effects are common:
Palpitations; hot flushes (flushing);

abdominal pain; nausea; swelling (edema); tiredness (fatigue)

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

Valsartan

Some side effects could be serious (frequency unknown: frequency cannot be estimated from the available data)

You may experience symptoms of angioedema (an allergic reaction), such as: swollen face, tongue or throat; difficulty in swallowing; hives and difficulties in breathing.

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

Hydrochlorothiazide

Some side effects could be serious
If you experience: skin rash with or without difficulties in breathing (possible signs of hypersensitivity reactions); facial rash, joint pain, muscle disorder, fever (possible signs of Systemic Lupus Erythematosus); rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of Toxic Epidermal Necrolysis, erythema multiforme); rash, purplish-red spots, fever, itching (possible signs of necrotising vasculitis); unusual tiredness or weakness, muscle spasms, abnormal heart rhythm (possible signs of hypokalemia); unusual tiredness, confusion, muscle twitching or convulsions (possible signs of hyponatremia); confusion, tiredness, muscle twitching and spasm, rapid breathing (possible signs of hypochloremic alkalosis); gastrointestinal disturbances, such as nausea, vomiting, constipation, stomach pain, frequent urination, thirst, muscle weakness and twitching (possible signs of hypercalcemia); severe upper stomach pain (possible signs of pancreatitis); severe or persistent vomiting or diarrhea; irregular heart beat (possible signs of arrhythmia); purple skin patches (possible signs of thrombocytopenia, purpura); fever, sore throat, more frequent infections (possible signs of agranulocytosis); fever, sore throat or mouth ulcers due to infections (possible signs of leucopenia); weakness, bruising and frequent infections (possible signs of pancytopenia, bone marrow depression); pale skin, tiredness, breathlessness, dark urine (possible

signs of hemolytic anaemia); severely decreased urine output (possible signs of renal disorder or renal failure); an abnormal building of liquid in your eye that may result in vision changes (choroidal effusion), sudden nearsightedness, blurred vision (acute myopia), a rapid increased pressure in your eyes, eye pain, if left untreated, it may lead to permanent vision loss (acute angle-closure glaucoma) and skin and lip cancer (non-melanoma skin cancer -appearance of a lump of discoloured patch on the skin that continues to persist after a few weeks, and slowly progresses over months or sometimes years or cancerous lumps that are red/pink and firm and sometimes turn into ulcers, while cancerous patches are usually flat and scaly; often develops on areas of skin regularly exposed to the sun, such as the face, ears, hands, shoulders, upper chest and back)
If you get any of these, tell your doctor straight away.

Some side effects are very common

- High levels of lipids in your blood (hyperlipidaemia)

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

Some side effects are common

Low levels of magnesium in your blood (hypomagnesaemia); high levels of uric acid in your blood (hyperuricaemia); itchy rash or other forms of rash (urticaria); decreased appetite, mild nausea and vomiting; dizziness, fainting on standing up (orthostatic hypotension); inability to achieve or maintain an erection (impotence)

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

Some side effects are very rare

Acute respiratory distress (signs include severe shortness of breath, fever, weakness and confusion).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers →Reporting Side Effects to Medicines (ConSERF)).

Storage and Disposal of Exforge HCT

Storage

- Do not use after the expiry date shown on the box.
- Store in the original package.
- Keep out of the reach and sight of children.
- Information might differ in some countries.
- Do not store above 30°C

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 HCT is supplied as film-coated tablets in three strengths:
5/160/12.5 mg - 5 mg of amlodipine (as amlodipine besylate), 160 mg of valsartan and 12.5 mg hydrochlorothiazide, White film-coated tablet, ovaloid, biconvex with beveled edge with debossing “NVR” on one side and “VCL” on the other side.
10/160/12.5 mg - 10 mg of amlodipine (as amlodipine besylate), 160 mg of valsartan and 12.5 mg hydrochlorothiazide, Pale yellow film-coated tablet, ovaloid, biconvex with beveled edge with debossing “NVR” on one side and “VDL” on the other side.
10/160/25 mg - 10 mg of amlodipine (as amlodipine besylate) and 160 mg of valsartan and 25 mg hydrochlorothiazide, Brown-yellow film-coated tablet, ovaloid, biconvex with beveled edge with debossing “NVR” on one side and “VHL” on the other side

Ingredients

- *Active ingredient*
 - The active substances of Exforge HCT are amlodipine besylate, valsartan and hydrochlorothiazide.
- *Inactive ingredients*
 - The other ingredients are cellulose microcrystalline; crospovidone; silica, colloidal anhydrous; magnesium stearate; hypromellose, macrogol 4000, talc.

Exforge HCT 5/160/12.5 mg contains in addition titanium dioxide (E171).
Exforge HCT 10/160/12.5 mg contains in addition titanium dioxide (E171), iron oxide, yellow (E172), iron oxide, red (E 172).
Exforge HCT 10/160/25 mg contains in addition iron oxide, yellow (E172).

MAL Number

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Exforge HCT 10/160/25mg film-coated tablet: MAL15015058ARZ

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