

17.1 Information for Patients

Patient Information

Exforge HCT (X-phorj HCT)
(amlodipine and valsartan and hydrochlorothiazide) Tablets

Read the Patient Information that comes with EXFORGE HCT before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or treatment.

What is the most important information I should know about EXFORGE HCT?

If you become pregnant while taking EXFORGE HCT, stop taking EXFORGE HCT and call your doctor right away. EXFORGE HCT can harm an unborn baby causing injury or death. Talk to your doctor about other treatment options to lower your blood pressure before taking EXFORGE HCT if you plan to become pregnant.

What is EXFORGE HCT?

EXFORGE HCT contains three prescription medicines:

1. amlodipine, a calcium channel blocker
2. valsartan, an angiotensin receptor blocker, and
3. hydrochlorothiazide, a diuretic (water pill)

EXFORGE HCT may be used to lower blood pressure in adults when two medicines to lower your high blood pressure are not enough.

EXFORGE HCT has not been studied in children under 18 years of age.

Who should not take EXFORGE HCT?

Do not take EXFORGE HCT if you have low or no urine output (anuria).

What should I tell my doctor before taking EXFORGE HCT?

Tell your doctor about all of your medical conditions, including if you:

- **are pregnant or plan to become pregnant.** See “What is the most important information I should know about EXFORGE HCT?”
- **are breast-feeding or plan to breast-feed.** EXFORGE HCT may pass into your milk. Do not breast-feed while you are taking EXFORGE HCT.
- are allergic to any of the ingredients in EXFORGE HCT. See the end of this leaflet for a list of the ingredients in EXFORGE HCT.
- have heart problems
- have liver problems
- have kidney problems
- are vomiting or having a lot of diarrhea
- have or had gallstones
- have Lupus

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Some of your other medicines and EXFORGE HCT could affect each other, causing serious side effects.

Especially tell your doctor if you take:

- other medicines for high blood pressure or a heart problem
- water pills (“diuretics”)
- potassium supplements or using a salt substitute containing potassium

- diabetes medicine including insulin
- narcotic pain medicines
- sleeping pills and anti-seizure medicines called barbiturates
- lithium, a medicine used to treat some types of depression
- aspirin or other medicines called non-steroidal anti-inflammatory drugs (NSAIDs)
- steroids
- cholesterol lowering medicine
- alcohol

Know the medicines you take. Keep a list of your medicines and show it to your doctor or pharmacist when you get a new medicine.

How should I take EXFORGE HCT?

- Take EXFORGE HCT exactly as your doctor tells you.
- Take EXFORGE HCT one time each day.
- EXFORGE HCT can be taken with or without food.
- If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take the missed dose. Just take the next dose at the regular time.
- If you take too much EXFORGE HCT, call your doctor or Poison Control Center, or go to the emergency room.
- Tell all your doctors and dentist you are taking EXFORGE HCT. This is especially important if you:
 - are going to have surgery
 - go for kidney dialysis

What are the possible side effects of EXFORGE HCT?

EXFORGE HCT may cause **serious side effects** including:

- **harm to an unborn baby causing injury or death.** See “**What is the most important information I should know about EXFORGE HCT?**”
- **low blood pressure** (hypotension). Low blood pressure is most likely to happen if you:
 - take water pills
 - are on a low salt diet
 - have heart problems
 - get dialysis treatments
 - get sick with vomiting or diarrhea
 - drink alcohol.

Lie down if you feel faint or dizzy. If you faint (lose consciousness), stop taking EXFORGE HCT. Call your doctor right away.

- Get emergency help if you get worse chest pain or chest pain that does not go away.
- **kidney problems.** Kidney problems may become worse in people that already have kidney disease. Some people will have changes in blood tests for kidney function and may need a lower dose of EXFORGE HCT. Call your doctor if you have swelling in your feet, ankles, or hands, or unexplained weight gain. If you have heart failure, your doctor should check your kidney function before prescribing EXFORGE HCT.
- **laboratory blood test changes in people with congestive heart failure.** Some people with congestive heart failure who take valsartan, one of the medicines in EXFORGE HCT, have changes in blood tests including increased potassium and decreased kidney function.
- **allergic reactions**

- **skin rash.** Call your doctor right away if you get an unusual skin rash.

The **most common** side effects of EXFORGE HCT include:

- dizziness
- swelling (edema) of the hands, ankles, or feet
- headache
- indigestion
- tiredness
- muscle spasms
- back pain
- nausea.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of EXFORGE HCT. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store EXFORGE HCT?

- Store EXFORGE HCT at room temperature between 59°F to 86°F (15°C to 30°C).
- Keep EXFORGE HCT dry (protect it from moisture).

Keep EXFORGE HCT and all medicines out of the reach of children.

General Information about EXFORGE HCT

Medicines are sometimes prescribed for conditions that are not mentioned in the patient information leaflet. Do not use EXFORGE HCT for a condition for which it was not prescribed. Do not give EXFORGE HCT to other people, even if they have the same symptoms that you have. It may harm them.

This patient information leaflet summarizes the most important information about EXFORGE HCT. If you would like more information about EXFORGE HCT, talk with your doctor. You can ask your doctor or pharmacist for information about EXFORGE HCT that is written for health professionals. For more information go to www.EXFORGE.com or call 1-888-839-3674.

What are the ingredients in EXFORGE HCT?

Active ingredients: amlodipine besylate, valsartan and hydrochlorothiazide

The inactive ingredients of all strengths of the tablets are crospovidone, magnesium stearate, microcrystalline cellulose, and colloidal anhydrous silica. The film coating contains hypromellose, talc, macrogol 4000 and may contain titanium dioxide or yellow and red iron oxides.

What is high blood pressure (hypertension)?

Blood pressure is the force of blood in your blood vessels when your heart beats and when your heart rests. You have high blood pressure when the force is too much. EXFORGE HCT can help your blood vessels relax so your blood pressure is lower. Drugs that lower blood pressure lower your chance of having a stroke or heart attack.

High blood pressure makes the heart work harder to pump blood throughout the body and causes damage to blood vessels. If high blood pressure is not treated, it can lead to stroke, heart attack, heart failure, kidney failure and vision problems.

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