

30 Day Notice to Prior Authorize Exforge HCT

Oklahoma Health Care Authority
May 2009

Manufacturer Novartis Pharmaceuticals Corp.
Classification Combination Antihypertensive
Status Prescription Only

Summary

Exforge HCT is a fixed-dose combination drug containing amlodipine, valsartan, and hydrochlorothiazide indicated for the treatment of hypertension. This medication offers the convenience of once daily dosing. Exforge HCT is not indicated for the initial therapy of hypertension. It may be used as add-on/switch therapy for patients not adequately controlled on any two of the following antihypertensive classes: calcium channel blockers, angiotensin receptor blockers, and diuretics. The following are the available fixed dosed combinations:

Amlodipine	Valsartan	HCTZ
5 mg	160 mg	12.5 mg
10 mg	160 mg	12.5 mg
5 mg	160 mg	25 mg
10 mg	160 mg	25 mg
10 mg	320 mg	25 mg

Recommendations

The College of Pharmacy recommends placement of Exforge HCT in Tier-3 of the ARB Combination Antihypertensives. The existing prior authorization criteria for this category will apply.

ARBs (Angiotensin Receptor Blockers) and ARB Combination Products

Tier-1	Tier-2	Tier-3
<i>Any Tier-1 ACE Inhibitor:</i>	amlodopine/valsartan (Exforge®)	amlodopine/valsartan/ HCTZ (Exforge® HCT)
benazepril (Lotensin®)	irbesartan (Avapro®)	amlodopine/olmesartan (Azor™)
captopril (Capoten®)	irbesartan/HCTZ (Avalide®)	candesartan (Atacand®)
enalapril (Vasotec®)	telmisartan (Micardis®)	candesartan/HCTZ (Atacand® HCT)
enalaprilat (Vasotec® IV)	telmisartan/HCTZ (Micardis® HCT)	olmesartan (Benicar®)
fosinopril (Monopril®)	valsartan (Diovan®)	olmesartan/HCTZ (Benicar HCT®)
lisinopril (Prinivil®, Zestril®)	valsartan/HCTZ (Diovan HCT®)	losartan (Cozaar®)
moexipril (Univasc®)		losartan/HCTZ (Hyzaar®)
quinapril (Accupril®)		eprosartan (Teveten®)
trandolapril (Mavik®)		eprosartan/HCTZ (Teveten® HCT)

Blue Color indicates Supplemental Rebate Participation.

Product Details

Indication

- Exforge[®] HCT is indicated for the treatment of hypertension
- Exforge[®] HCT is not indicated for initial therapy

Contraindications

- Anuria
- Hypersensitivity to sulfonamide-derived drugs

Precautions

- Avoid fetal or neonatal exposure-risk of injury and even death to the developing fetus
- Symptomatic hypotension with volume or salt depletion-correct volume depletion prior to administration
- Increased angina and/or myocardial infarction
- Avoid in patients with severely impaired hepatic or renal function (creatinine clearance ≤ 30 mL/min)
- Observe for signs of fluid or electrolyte imbalance
- Thiazide diuretics may cause an exacerbation or activation of systemic lupus erythematosus

Common Adverse Effect

- dizziness
- peripheral edema
- headache
- dyspepsia
- fatigue
- muscle spasms
- back pain
- nausea
- nasopharyngitis

Drug Interactions

- **Alcohol, barbiturates, narcotics** - Potentiation of orthostatic hypotension
- **Antidiabetic drugs** - Dosage adjustment of antidiabetic may be required
- **Cholestyramine and colestipol** - Reduced absorption of thiazides
- **Corticosteroids, ACTH** - Hypokalemia, electrolyte depletion
- **Lithium** - Reduced renal clearance and high risk of lithium toxicity when used with diuretics. Should not be given with diuretics.
- **NSAIDs** - Can reduce diuretic, natriuretic and antihypertensive effects of diuretics.

Patient Information

- **If you become pregnant** while taking Exforge[®] HCT, stop taking Exforge[®] HCT and call your doctor right away.
- Exforge[®] HCT can be taken with or without food.
- **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.

REFERENCE

Exforge[®] HCT Product Information. Novartis Pharmaceuticals. April 2009.