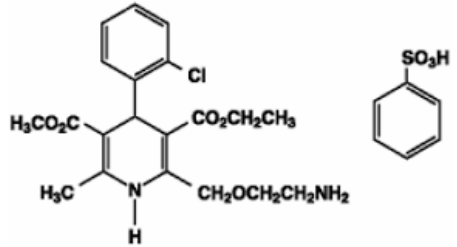


Address HCT Tablets ایڈریس ایچ سی ٹی ٹیبلیٹس

WARNING: FETAL TOXICITY

See full prescribing information for complete boxed warning.

- When pregnancy is detected, discontinue Address HCT as soon as possible.
- Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.



COMPOSITION:

Each Film Coated Tablet Contains

Amlodipine (as Amlodipine besylate) BP/USP: 5mg

Valsartan BP/USP: 160mg

Hydrochlorothiazide BP/USP: 25 mg

Each Film Coated Tablet Contains

Amlodipine (as Amlodipine besylate) BP/USP: 10mg

Valsartan BP/USP: 160mg

Hydrochlorothiazide BP/USP: 12.5 mg

Each Film Coated Tablet Contains

Amlodipine (as Amlodipine besylate) BP/USP: 10mg

Valsartan BP/USP: 160mg

Hydrochlorothiazide BP/USP: 25 mg

Each Film Coated Tablet Contains

Amlodipine (as Amlodipine besylate) BP/USP: 10mg

Valsartan BP/USP: 320mg

Hydrochlorothiazide BP/USP: 25 mg

DESCRIPTION:

Address HCT is a fixed combination of amlodipine, valsartan, and hydrochlorothiazide. Address HCT contains the besylate salt of amlodipine, a dihydropyridine calcium channel blocker (CCB). Amlodipine besylate, is a white to pale yellow crystalline powder, slightly soluble in water and sparingly soluble in ethanol. Amlodipine besylate's chemical name is 3-Ethyl 5-methyl (±)-2-[(2-aminoethoxy) methyl]-4- (o-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate, monobenzenesulfonate; its structural formula is:

CLINICAL PHARMACOLOGY:

Mechanism of Action: The active ingredients of Address HCT target 3 separate mechanisms involved in blood pressure regulation. Specifically, amlodipine blocks the contractile effects of calcium on cardiac and vascular smooth muscle cells; valsartan blocks the vasoconstriction and sodium retaining effects of angiotensin II on cardiac, vascular smooth muscle, adrenal and renal cells; and hydrochlorothiazide directly promotes the excretion of sodium and chloride in the kidney leading to reductions in intravascular volume. A more detailed description of the mechanism of action of each individual component follows.

Pharmacodynamics:

Address HCT has been shown to be effective in lowering blood pressure. The 3 components of Address HCT (amlodipine, valsartan, hydrochlorothiazide) lower the blood pressure through complementary mechanisms, each working at a separate site and blocking different effector pathways.

Pharmacokinetics:

Following oral administration of Address HCT in normal healthy adults, peak plasma concentrations of amlodipine, valsartan and HCTZ are reached in about 6 hours, 3 hours, and 2 hours, respectively. The rate and extent of absorption of amlodipine, valsartan and HCTZ from Address HCT are the same as when administered as individual dosage forms.

The Bioavailability of Amlodipine valsartan and HCTZ were not altered when Address HCT was administered with food. Address HCT may be administered with or without food.

INDICATIONS AND USAGE:

Address HCT is a combination tablet of amlodipine, a dihydropyridine calcium channel blocker (DHP CCB), valsartan, an angiotensin II receptor blocker (ARB), and hydrochlorothiazide, a thiazide diuretic. Address HCT is indicated for the treatment of hypertension to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes, and myocardial infarctions.

Limitation Of Use: Address HCT is not indicated for initial treatment of hypertension.

DRUG INTERACTIONS:

- If **simvastatin** is co-administered with amlodipine, do not exceed doses greater than 20 mg daily of simvastatin.
- **Antidiabetic drugs:** Dosage adjustment of antidiabetic may be required.
- **Cholestyramine and colestipol:** Reduced absorption of thiazides.
- **Lithium:** Increased risk of lithium toxicity. Monitor serum lithium concentrations during concurrent use.
- **Non-Steroidal Anti-Inflammatory Drug (NSAID)** use may lead to increased risk of renal impairment and loss of anti-hypertensive effect.
- **Dual inhibition of the renin-angiotensin system:** Increased risk of renal impairment, hypotension, and hyperkalemia.

CONTRAINDICATIONS:

- Anuria
- Hypersensitivity to sulfonamide-derived drugs
- Known hypersensitivity to any component

WARNINGS AND PRECAUTIONS:

- **Hypotension:** Correct volume depletion prior to initiation
- Increased angina and/or myocardial infarction.
- Monitor renal function and potassium in susceptible patients.

- Exacerbation or activation of systemic lupus erythematosus.
- Observe for signs of fluid or electrolyte imbalance.
- Acute angle-closure glaucoma.

ADVERSE REACTIONS:

Most common adverse events ($\geq 2\%$ incidence) are dizziness, peripheral edema, headache, dyspepsia, fatigue, muscle spasms, back pain, nausea, and nasopharyngitis.

USE IN SPECIFIC POPULATIONS:

Lactation: Breastfeeding is not recommended.

Geriatric Patients: Not recommended for initial therapy.

Hepatic Impairment: Not recommended for initial therapy.

DOSAGE AND ADMINISTRATION:

Dose once-daily. Titrate up to a maximum dose of 10/320/25 mg. Address HCT 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. Address HCT may be substituted for its individually titrated components.

STORAGE & PRECAUTIONS:

Avoid direct sunlight and protect from moisture and heat. Store below 25°C. Keep all medicines out of reach of children. To be sold and used on the prescription of Registered Medical Practitioners only.

PRESENTATION:

Address HCT 5/160/25mg, 10/160/12.5 mg, 10/160/25 mg and 10/320/25mg tablets are available in packing containing 28 film coated tablets.

عمومی خوردا ک: ڈا کٹر کی ہدایت کے مطابق۔

احتیاط: دوا صرف مستند ڈاکٹر کے زیر ہدایت استعمال کریں۔ دھوپ، نمی اور گرمی سے بچائیں۔ 25 ڈگری سینٹی گریڈ سے کم اور چہ حرارت پر محفوظ کریں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

Complete Medical Information available only for doctors on request.



Manufactured by: **SCOTMANN PHARMACEUTICALS**
5-D, I-10/3 Industrial Area, Islamabad-Pakistan.
www.scotmann.com