NOVARTIS

Exforge® HCT

(amlodipine besylate /valsartan/hydrochlorothiazide)

5 /160/12.5 mg, 10/160/12.5 mg, 5/160/25 mg, 10/160/25 mg and 10/320/25 mg Film-coated tablets

Basic Succinct Statement

CODE: BSS RD 10 SEP 18; APPR 03 JUL 20

This material is only meant for Healthcare Professionals

Exforge HCT®

Important note: Before prescribing, consult full prescribing information.

Presentation:

Film coated tablets containing 5 mg amlodipine as amlodipine besylate (a calcium antagonist), 160 mg valsartan (an angiotensin II antagonists) and 12.5 mg hydrochlorothiazide (a thiazide diuretic), or 10 mg amlodipine as amlodipine besylate, 160 mg valsartan and 12.5 mg hydrochlorothiazide or 5 mg amlodipine as amlodipine besylate, 160 mg valsartan and 25 mg hydrochlorothiazide or 10 mg amlodipine as amlodipine besylate, 160 mg valsartan and 25 mg hydrochlorothiazide or 10 mg amlodipine as amlodipine besylate, 320 mg valsartan and 25 mg hydrochlorothiazide.

Indications:

Treatment of essential hypertension. This fixed combination drug is not indicated for the initial therapy of hypertension.

Dosage and administration:

♦Adults: One tablet of Exforge HCT 5/160/12.5 mg or 10/160/12.5 mg or 5/160/25 mg or 10/160/25 mg or 10/320/25 mg daily. ♦Hepatic impairment: consider starting with the lowest available dose of amlodipine ♦Elderly: consider starting with the lowest available dose of amlodipine. The lowest strength of Exforge contains 5 mg of amlodipine

Contraindications:

♦ known hypersensitivity to the components of this product or to sulfonamides♦ pregnancy ♦ severe hepatic impairment ♦ biliary cirrhosis ♦ cholestasis ♦ severe renal impairment (creatinine clearance < 30 mL/min) ♦ anuria ♦ patients undergoing dialysis♦ refractory hypokalemia ♦ hyponatremia ♦ hypercalcemia ♦ symptomatic hyperuricemia ♦concomitant use with aliskiren in diabetic type II patients.

Warnings/Precautions:

♦Avoid use in women planning to become pregnant and while breast-feeding ♦Risk of hypotension in sodium- and/or volume-depleted patients. ♦Caution is advised when administering Exforge HCT to patients with renal impairment or systemic lupus erythematosus. ♦Like other thiazide diuretics, HCTZ can cause hypokalemia, which may favor the onset of digitalis-induced cardiac arrhythmias. Caution in patients with hypokalemia, hyponatremia, hypercalcemia or symptomatic hyperuricemia ♦No data available in patients with unilateral or bilateral renal artery stenosis, stenosis to a solitary kidney or after recent kidney transplantation ♦Disturbance of serum electrolyte balance (monitoring recommended), glucose tolerance and serum levels of cholesterol, triglycerides and uric acid. ♦Not recommended in patients below 18 years of age.♦Not recommended in patients with hepatic impairment or biliary obstructive disorders. ♦Caution in patients experiencing angioedema with Exforge HCT or having history of angioedema with other drugs. Discontinue Exforge HCT immediately and do not re-administer ♦Caution in patients with heart failure, severe chronic heart failure or other conditions with stimulation of the renin angiotensin-aldosterone-system. Impairment of renal function may occur. ♦Caution in patients with acute myocardial infarction. Worsening angina and acute myocardial infarction

can develop after starting or increasing dose of amlodipine, particularly in patients with severe obstructive coronary artery disease ♦As with all other vasodilators, special caution in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy. ♦Acute angle-closure glaucoma. ♦Caution in patients with allergy or asthma. ♦Avoid concomitant use with aliskiren in patients with severe renal impairment (GFR < 30 mL/min). ♦Caution is required while co-administering Exforge HCT with other agents blocking the RAS such as ACEIs or aliskiren. ♦Increased risk of non-melanoma skin cancer (NMSC) [basal cell carcinoma (BCC) and squamous cell carcinoma (SCC)] with increasing cumulative dose of hydrochlorothiazide. Patients should protect their skin from excessive sun exposure, regularly check their skin for new lesions and promptly report any suspicious skin lesions while taking Exforge HCT.

Adverse reactions:

Amlodipine

Common and uncommon adverse reactions: Headache, somnolence, dizziness, palpitations, flushing, abdominal pain, nausea, edema, fatigue, insomnia, mood changes including anxiety, tremor, hypoaesthesia, dysgeusia, paresthesia, syncope, visual impairment, diplopia, tinnitus, hypotension, dyspnea, rhinitis, vomiting, dyspepsia, dry mouth, constipation, diarrhoea, alopecia, hyperhidrosis, pruritus, rash, purpura, skin discoloration, photosensitivity, back pain, muscle spasm, myalgia, arthralgia, micturion disorders, nocturia, pollakiura, gynecomastia, erectile dysfunction, asthenia, pain, malaise, chest pain, weight decreased, weight increased. **Very rare adverse reactions**: hyperglycemia, hypertonia, ventricular tachycardia, cough, gastritis, gingival hyperplasia, jaundice, urticaria. **Very rare adverse reactions but potentially serious:** Thrombocytopenia, leucocytopenia, allergic reactions, peripheral neuropathy, arrhythmia, bradycardia, atrial fibrillation, myocardial infarction, vasculitis, pancreatic, hepatitis, angioedema, erythema multiforme, Steven-Johnson-Syndrome, Hepatic enzyme increased *(mostly consistent with cholestasis).*

Valsartan

Uncommon adverse reactions: Vertigo, cough, abdominal pain, fatigue **Frequency not known:** dermatitis bullous, rash, pruritus, haemoglobin decreased, haematocrit decreased, blood potassium increased, liver function abnormal including bilirubin increased, myalgia, blood creatinine increased. ♦**Frequency not known but Potentially serious:** Hypersensitivity including serum sickness, vasculitis, angioedema, renal failure and impairment, thrombocytopenia, neutropenia. ♦**Events** also observed during clinical trials irrespective of their causal association with the study drug: Arthralgia, asthenia, back pain, diarrhea, dizziness, headache, insomnia, libido decrease, nausea, edema, pharyngitis, rhinitis, sinusitis, upper respiratory tract infection, viral infections.

Hydrochlorothiazide

Very common and common adverse reactions: Hypokalaemia and blood lipids increased, hypomagnesemia, hyperuricemia, hyponatremia, urticaria and other forms of rash, decreased appetite, mild nausea and vomiting, orthostatic hypotension, erectile dysfunction. ♦**Additional potential serious adverse reactions are**: non-melanoma skin cancer (Basal cell carcinoma and Squamous cell carcinoma), jaundice or cholestasis, abdominal discomfort, photosensitivity reaction, hyperglycemia, glycosuria and worsening of diabetic metabolic state, sleep disorders, depression, visual impairment, arrhythmias, vasculitis necrotizing, lupus erythematosus, toxic epidermal necrolysis, erythema multiforme, pancreatitis, pneumonitis, pulmonary edema, skin rash with or without difficulties in breathing

(hypersensitivity reactions), alkalosis hypochloremic, hypercalcemia, thrombocytopenia with or without purpura, agranulocytosis, leucopenia, bone marrow depression, hemolytic or aplastic anemia, acute renal failure, renal disorder, angle-closure glaucoma. ♦**Additional adverse reactions are:** pyrexia, abdominal discomfort, constipation and diarrhea, headache, dizziness, paresthesia, muscle spasms, asthenia