NOVARTIS

EXFORGE® (amlodipine/valsartan)

5 mg/80 mg, 5 mg/160 mg, 10 mg/160 mg, 5 mg/320 mg and
10 mg/320 mg Film-coated tablets

Basic Succinct Statement

Version 3.0

CODE: BSS RD 10 SEP 2018; APPR 08 FEB 2019

This material is only meant for Healthcare Professionals

Exforge® Film-coated tablets

Important note: Before prescribing, consult full prescribing information.

Presentation: Exforge: Amlodipine (as amlodipine besylate) and valsartan 5 mg/80 mg, 5 mg/160 mg and 10 mg/160 mg film-coated tablets.

Indications: Treatment of essential hypertension. Exforge is indicated in patients whose blood pressure is not adequately controlled by monotherapy. Exforge is indicated for the initial treatment of hypertension. The choice of Exforge for initial treatment should be based on an assessment of the potential benefits and risks.

Dosage and administration:

♦Adults: Recommended dose is one film-coated tablet per day (5 mg amlodipine and 80 mg valsartan, or 5 mg amlodipine and 160 mg valsartan, or 10 mg amlodipine and 160 mg valsartan).
For initial therapy the usual starting dose is Exforge 5/80 mg once daily. The dosage can be increased after 1 to 2 weeks of therapy to a maximum of 10 mg/320 mg per day as needed to control blood pressure. Exforge is not recommended as initial therapy in patients with intravascular volume depletion (see "Warnings and precautions"). The maximum dose is 10/320 mg per day.
♦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: ♦Hypersensitivity to any component of Exforge. ♦Pregnancy. ♦Severe hepatic impairment; biliary cirrhosis and cholestasis. ♦Concomitant use with aliskiren in diabetic type II patients.

Warnings/Precautions: ♦Risk of hypotension in sodium- and/or volume-depleted patients. ♦Severe renal impairment (creatinine cleareance < 10 mL/min) and dialysis. ♦No data available in patients with unilateral or bilateral renal artery stenosis, stenosis to a solitary kidney or after recent kidney transplantation.♦ Patients with severe hepatic impairment, biliary cirrhosis or cholestasis should not take Exforge. ♦Caution in patients experiencing angioedema with Exforge or having history of angioedema with other drugs. Discontinue Exforge 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. ♦Not recommended in patients below 18 years of age. ♦Avoid concomitant use with aliskiren in patients with severe renal impairment (GFR < 30 mL/min). ♦Caution is required while co-administering Exforge with other agents blocking the RAS such as ACEIs or aliskiren.

Adverse reactions: ♦The most common and uncommon adverse reactions are: Nasopharyngitis, influenza, headache, oedema peripheral, oedema, pitting edema, facial edema, hot flush, fatigue, flushing, asthenia, dizziness, somnolence, dizziness postural, paraesthesia, vertigo, tachycardia, palpitations, orthostatic hypotension, cough, pharyngolaryngeal pain, diarrhea, nausea, abdominal pain, constipation, dry mouth, rash, erythema, joint swelling, back pain, arthralgia. ♦Rare adverse reactions are: visual disturbance, anxiety, tinnitus, syncope, hypotension, hyperhidrosis, exanthema, pruritus, muscle spasm, sensation of heaviness, pollakiuria, polyuria, erectile dysfunction ♦Rare adverse reactions but potentially serious are: Hypersensitivity.

♦Additional potentially serious adverse experiences reported with amlodipine monotherapy are: 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)*. ♦Other adverse experiences reported with amlodipine monotherapy are: diplopia, hyperglycemia, insomnia, mood changes, tremor, hypoesthesia, dysgeusia, hypertonia, dyspnea, rhinitis, vomiting, dyspepsia, gastritis, gingival hyperplasia, jaundice, alopecia, purpura, skin discoloration, photosensitivity, urticaria, myalgia, micturition disorder, nocturia, gynecomastia, pain, malaise, chest pain, weight decreased, weight increased

♦Additional potentially serious adverse experiences reported with valsartan monotherapy are: Neurtropenia, thrombocytopenia, hypersensitivity including serum sickness, vasculitis, angioedema, dermatitis bullous, renal failure and impairment.♦Other adverse experiences reported with valsartan monotherapy are: liver function test abnormal including blood bilirubin increase, myalgia, haemoglobin decreased, hematocrit decreased, blood potassium increased, blood creatinine increased.