



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 September 2015
EMA/CHMP/616915/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Entresto

sacubitril/valsartan

On 24 September 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Entresto, intended for the treatment of symptomatic chronic heart failure with reduced ejection fraction. The applicant for this medicinal product is Novartis Europharm Ltd.

Entresto will be available as 24 mg/26 mg, 49 mg/51 mg and 97 mg/103 mg film-coated tablets. The active substances of Entresto are sacubitril and valsartan, (ATC code: C09DX04) and the medicine works in two complementary ways: valsartan blocks the angiotensin II type-1 receptor, suppressing the harmful effects of angiotensin II on the cardiovascular system, while sacubitril blocks an enzyme known as neprilysin to enhance the protective neurohormonal systems of the heart.

The benefit with Entresto is its ability to reduce the risk of cardiovascular death or need for heart failure hospitalisations as compared to enalapril in patients with symptomatic chronic heart failure with reduced ejection fraction. The most common side effects are hypotension, hyperkalaemia and renal impairment. Angioedema occurs uncommonly.

The full indication is: "Entresto is indicated in adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction (see section 5.1)."

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

