

Summary Public Assessment Report

Sacubitril/Valsartan Reddy (sacubitril sodium, valsartan disodium)

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Sacubitril/Valsartan Reddy
sacubitril, sacubitril sodium, valsartan disodium, valsartan

Film-coated tablet, 24 mg/26 mg, 49 mg/51mg, 97 mg/103 mg

This is a summary of the public assessment report (PAR) for Sacubitril/Valsartan Reddy. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Sacubitril/Valsartan Reddy and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Entresto.

The product is a heart medicine containing an angiotensin receptor neprilysin inhibitor. It delivers two active substances, sacubitril and valsartan.

It is used to treat a type of long-term heart failure in adults, children and adolescents (one year and older).

This type of heart failure occurs when the heart is weak and cannot pump enough blood to the lungs and the rest of the body. The most common symptoms of heart failure are breathlessness, fatigue, tiredness and ankle swelling.

How is Sacubitril/Valsartan Reddy used?

The pharmaceutical form is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Sacubitril/Valsartan Reddy have been shown in studies?

Because the product is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicine, Entresto. Two medicines are bioequivalent when they produce the same levels of the active substance in the body. Based on the submitted bioequivalence studies, Sacubitril/Valsartan Reddy is considered bioequivalent with Entresto.

What are the possible side effects from Sacubitril/Valsartan Reddy?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

Why is Sacubitril/Valsartan Reddy approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Entresto, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Sacubitril/Valsartan Reddy?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Sacubitril/Valsartan Reddy

The full PAR for Sacubitril/Valsartan Reddy can be found on the following website: [MRI - Home](#). For more information about treatment with Sacubitril/Valsartan Reddy, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in YYYY-MM.