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EPAR summary for the public

Neparvis

sacubitril / valsartan

This is a summary of the European public assessment report (EPAR) for Neparvis. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Neparvis.

For practical information about using Neparvis, patients should read the package leaflet or contact their doctor or pharmacist.

What is Neparvis and what is it used for?

Neparvis is a heart medicine that contains the active substances sacubitril and valsartan. It is used in adults with long-term heart failure who have symptoms of the disease. Heart failure is the inability of the heart to pump enough blood around the body.

This medicine is the same as Entresto, which is already authorised in the European Union (EU). The company that makes Entresto has agreed that its scientific data can be used for Neparvis ('informed consent').

How is Neparvis used?

Neparvis is available as tablets (24 mg sacubitril / 26 mg valsartan, 49 mg sacubitril / 51 mg valsartan, and 97 mg sacubitril / 103 mg valsartan). Neparvis can only be obtained with a prescription.

Neparvis tablets are taken twice a day. The recommended starting dose is one tablet of Neparvis 49 mg / 51 mg twice a day and the dose is then doubled after 2 to 4 weeks to 97 mg / 103 mg twice a day. The doctor may choose lower doses for certain patients. For further information, see the summary of product characteristics (also part of the EPAR).

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How does Neparvis work?

The two active substances in Neparvis, sacubitril and valsartan, work in different ways. Sacubitril blocks the breakdown of natriuretic peptides produced in the body. Natriuretic peptides cause sodium and water to pass into the urine thereby reducing the strain on the heart. Natriuretic peptides also reduce blood pressure and protect the heart from developing fibrosis (scar tissue) that occurs in heart failure.

Valsartan is an 'angiotensin-II-receptor antagonist', which means that it blocks the action of a hormone called angiotensin II. The effects of angiotensin II can be harmful in patients with heart failure. By blocking the receptors to which angiotensin II normally attaches, valsartan stops the hormone's harmful effects on the heart and it also reduces blood pressure by allowing blood vessels to widen.

What benefits of Neparvis have been shown in studies?

Neparvis has been shown to be effective in treating heart failure in one main study. In the study, Neparvis was compared to enalapril, another medicine used for heart failure. Patients in the study had long-term heart failure with symptoms of the disease and reduced ejection fraction (the proportion of blood leaving the heart). In the group treated with Neparvis, 21.8% (914 of 4,187) patients either died as a result of heart and circulation problems or were admitted to hospital with heart failure compared to 26.5% (1,117 of 4,212) patients treated with enalapril. In general, patients were monitored for about 27 months, during which they took the medicine for about 24 months on average. The study was stopped early because there was compelling evidence that Neparvis was more effective than enalapril.

What are the risks associated with Neparvis?

The most common side effects with Neparvis (which may affect more than 1 in 10 people) are high blood potassium levels, low blood pressure and the kidneys working less well. A potentially severe side effect, angioedema (rapid swelling of deeper skin tissues as well as the tissues around the throat, causing breathing difficulty), can occur uncommonly (affecting fewer than 1 in 100 people). For the full list of all side effects reported with Neparvis, see the package leaflet.

Neparvis must not be taken with medicines known as ACE inhibitors (which are used to treat heart failure and high blood pressure). It must not be taken by patients who have suffered angioedema, those who have severe liver disease or by women who are pregnant. For the full list of restrictions see the package leaflet.

Why is Neparvis approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that the benefits of Neparvis are greater than its risks and recommended that it be approved for use in the EU. The main study found that Neparvis reduced deaths from heart and circulation problems or hospital admissions for heart failure.

The serious side effects of Neparvis in the main study were similar to those of enalapril, which is already authorised for use in heart failure. Valsartan, one of the active substances in the medicine, is well established for the treatment of high blood pressure and heart failure; its side effects are well known.

What measures are being taken to ensure the safe and effective use of Neparvis?

A risk management plan has been developed to ensure that Neparvis 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 for Neparvis, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Neparvis

The European Commission granted a marketing authorisation valid throughout the European Union for Neparvis on 26 May 2016.

The full EPAR for Neparvis can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Neparvis, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2016.