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Brinavess (*vernakalant*)

An overview of Brinavess and why it is authorised in the EU

What is Brinavess and what is it used for?

Brinavess is a medicine used to rapidly restore normal heart rhythm in adult patients who have recently started having atrial fibrillation. Atrial fibrillation happens when the atria (the upper chambers of the heart) contract irregularly and rapidly, resulting in abnormal heart rhythm. Brinavess is to be used for atrial fibrillation that has started within the last seven days, or within the last three days if the patient had recently had heart surgery.

Brinavess contains the active substance vernakalant hydrochloride.

How is Brinavess used?

Brinavess can only be obtained with a prescription and should be given by a qualified healthcare professional in a setting where the patient's heart can be properly monitored. The healthcare professional should monitor the patient's blood pressure and heart rate while the medicine is being given and for at least 15 minutes afterwards.

Brinavess is a solution that is given by infusion (drip) into a vein over a period of 10 minutes. The dose of Brinavess depends on the patient's body weight. If the heart rhythm has not returned to normal 15 minutes after the end of the first infusion, a second, smaller dose may be given. Patients should not be given more than 5 mg of Brinavess per kg body weight within any 24-hour period, or a maximum of 565 mg in patients weighing more than 113 kg. If the blood pressure or heart rate suddenly decreases the infusion should be stopped immediately. For more information about using Brinavess, see the package leaflet or contact your doctor or pharmacist.

How does Brinavess work?

Brinavess contains vernakalant, a type of substance known as an anti-arrhythmic. It restores normal heart rhythm by blocking channels through which charged particles of potassium and sodium move in and out of the muscle cells in the atria. By blocking these channels, vernakalant can prevent abnormal electrical activity that can lead to atrial fibrillation. Vernakalant acts mainly in the atria rather than in the ventricles (the lower chambers of the heart).

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What benefits of Brinavess have been shown in studies?

In two main studies involving 596 adults with atrial fibrillation, Brinavess was compared with placebo (a dummy treatment). A third main study compared Brinavess with placebo in 161 adults who had had atrial fibrillation following heart surgery. The main measure of effectiveness was the proportion of patients whose heart rhythm returned to normal.

Brinavess was more effective than placebo at treating patients who had recently started having atrial fibrillation. In the first two studies, among patients who had recently started having atrial fibrillation, heart rhythm returned to normal in 51% of those receiving Brinavess (118 out of 231) compared with 4% (6 out of 159) of those taking placebo. In the third study, heart rhythm returned to normal in 47% of the patients receiving Brinavess compared with 14% of those receiving placebo.

What are the risks associated with Brinavess?

The most common side effects with Brinavess (which may affect more than 1 person in 10) are dysgeusia (taste disturbances) and sneezing. For the full list of side effects of Brinavess, see the package leaflet.

Brinavess must not be used in patients with severe aortic stenosis (narrowing of the aorta), low systolic blood pressure (blood pressure when the heart is contracting), advanced heart failure (when the heart does not pump enough blood around the body), some types of altered electrical activity in the heart or a very slow heart rate. Brinavess must not be given within 30 days of having acute coronary syndrome (a group of heart problems that include unstable angina and heart attacks). Patients on Brinavess must not be given medicines called 'class I and III anti-arrhythmics' intravenously during the four hours before or after their Brinavess infusion. For the full list of restrictions, see the package leaflet.

Why has Brinavess been authorised in the EU?

The European Medicines Agency decided that Brinavess's benefits are greater than its risks and it can be authorised for use in the EU.

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

The company that markets Brinavess will ensure that healthcare professionals expected to use the medicine are provided with educational material explaining how the medicine should be used.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Brinavess have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Brinavess are continuously monitored. Side effects reported with Brinavess are carefully evaluated and any necessary action taken to protect patients.

Other information about Brinavess

Brinavess received a marketing authorisation valid throughout the European Union on 01 September 2010.

Further information on Brinavess can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/brinavess.

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