EMEA/H/C/002510

EPAR summary for the public

Sabervel

irbesartan

This is a summary of the European public assessment report (EPAR) for Sabervel. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Sabervel.

What is Sabervel?

Sabervel is a medicine that contains the active substance irbesartan. It is available as tablets (75, 150 and 300 mg).

Sabervel is a 'generic medicine'. This means that Sabervel is similar to a 'reference medicine' already authorised in the European Union (EU) called Aprovel. For more information on generic medicines, see the question-and-answer document here.

What is Sabervel used for?

Sabervel is used in adults who have essential hypertension (high blood pressure). 'Essential' means that the hypertension has no obvious cause. Sabervel is also used to treat kidney disease in adults with hypertension and type 2 diabetes.

The medicine can only be obtained with a prescription.

How is Sabervel used?

The usual recommended dose of Sabervel is 150 mg once a day. If the blood pressure is not sufficiently controlled, the dose can be increased to 300 mg a day or other medicines for hypertension can be added, such as hydrochlorothiazide. A starting dose of 75 mg can be used in patients receiving haemodialysis (a blood clearance technique) or in patients over 75 years of age.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

In patients with hypertension and type 2 diabetes, Sabervel is added to other treatments for hypertension. Treatment is started at 150 mg once a day and is usually increased to 300 mg once a day.

How does Sabervel work?

The active substance in Sabervel, irbesartan, is an 'angiotensin II receptor antagonist', which means that it blocks the action of a hormone in the body called angiotensin II. Angiotensin II is a powerful vasoconstrictor (a substance that narrows blood vessels). By blocking the receptors to which angiotensin II normally attaches, irbesartan stops the hormone having an effect, allowing the blood vessels to widen. This allows the blood pressure to drop, reducing the risks associated with high blood pressure, such as having a stroke.

How has Sabervel been studied?

Because Sabervel is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Aprovel. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Sabervel?

Because Sabervel is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Sabervel been approved?

The CHMP concluded that, in accordance with EU requirements, Sabervel has been shown to have comparable quality and to be bioequivalent to Aprovel. Therefore, the CHMP's view was that, as for Aprovel, the benefit outweighs the identified risk. The Committee recommended that Sabervel be given marketing authorisation.

Other information about Sabervel

The European Commission granted a marketing authorisation valid throughout the European Union for Sabervel on 13 April 2012.

The full EPAR for Sabervel 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 Sabervel, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 03-2012.