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EPAR summary for the public

Ablavar[1]

gadofosveset trisodium

This document is a summary of the European public assessment report (EPAR) for Ablavar. 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 Ablavar.

What is Ablavar?

Ablavar is a solution for injection that contains the active substance gadofosveset trisodium.

What is Ablavar used for?

Ablavar is for diagnostic use. It is used in patients who are undergoing magnetic resonance angiography (MRA), a procedure where pictures of the flow of the blood in the body are taken using a scan called magnetic resonance imaging (MRI). Ablavar is used to obtain a clearer scan in patients who have suspected or known problems with blood vessels in the abdomen (tummy) or limbs.

The medicine can only be obtained with a prescription.

How is Ablavar used?

Ablavar should only be used by doctors who have experience in diagnostic imaging.

Ablavar is given as an injection into a vein lasting about 30 seconds. Imaging can start immediately after the injection, and can continue for up to one hour after Ablavar is injected.

Doctors should avoid using Ablavar in patients who have severe kidney problems or who have recently had or are about to have a liver transplant. If Ablavar is essential, these patients should receive no

[1] Previously known as Vasovist.

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more than one dose during each MRI scan, and there should be a gap of at least a week between each Ablavar injection.

How does Ablavar work?

The active substance in Ablavar, gadofosveset trisodium, contains gadolinium, a 'rare-earth' metal element. Gadolinium is used as a 'contrast enhancer' to help obtain better pictures with MRI scanners. MRI is an imaging method that relies on the tiny magnetic fields produced by water molecules in the body. Once injected, gadolinium interacts with the water molecules. As a result of this interaction, the water molecules give a stronger signal, and this helps to obtain a brighter picture. In Ablavar, the gadolinium is attached to another chemical so that the metal is not released in the body, and prepared so that it attaches to proteins in the blood. This means that the gadolinium stays in the blood long enough for a good scan to be obtained.

How has Ablavar been studied?

Ablavar was studied in four studies involving 693 patients. Patients were having scans because of potential problems with the blood vessels that supply blood to the legs, the kidneys or the feet. All of the patients first had a scan using the standard X-ray method (angiography), followed by MRI scans without or with Ablavar used as a contrast enhancer. The measure of effectiveness was based on the improvement in the detection of stenoses (narrowing of the blood vessels) that reduced the width of the vessel by 50% or more.

What benefit has Ablavar shown during the studies?

Using Ablavar as an enhancer improved the performance of the scans. The sensitivity was improved by between 6 and 42%, which means that between 6 and 42% more stenoses were detected when Ablavar was used than when it was not used. Ablavar also improved the accuracy and specificity of the diagnosis.

What is the risk associated with Ablavar?

The most common side effects with Ablavar (seen in more than 1 patient in 100) are headache, paraesthesia (unusual sensations like pins and needles), dysgeusia (taste disturbances), a burning sensation, vasodilatation (widening of the blood vessels, including reddening of the skin), nausea (feeling sick), pruritus (itching) and feeling cold. For the full list of all side effects reported with Ablavar, see the package leaflet.

Ablavar should not be used in people who may be hypersensitive (allergic) to gadofosveset trisodium or any of the other ingredients.

Why has Ablavar been approved?

The CHMP decided that Ablavar's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Ablavar:

The European Commission granted a marketing authorisation valid throughout the European Union for Vasovist on 3 October 2005. The name of the medicine was changed to Ablavar on 10 January 2011.

The marketing authorisation holder is TMC Pharma Services Ltd. The marketing authorisation is valid for an unlimited period. The full EPAR for Ablavar can be found here. For more information about treatment with Ablavar, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2011.