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EPAR summary for the public

Optimark

gadoversetamide

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

What is Optimark?

Optimark is a solution for injection that contains the active substance gadoversetamide. It is available in prefilled syringes and in vials.

What is Optimark used for?

Optimark is for diagnostic use. It is used in adults and in children from two years of age who are undergoing magnetic resonance imaging (MRI), a type of scan where images of the internal organs are taken. Optimark is used to obtain a clearer scan in patients who have or are thought to have abnormalities in the brain, spine or liver.

The medicine can only be obtained with a prescription.

How is Optimark used?

Optimark should only be given by a doctor who has experience in using MRI. It is given as an injection into a vein, usually a vein in an arm. The recommended dose is 0.2 ml per kilogram body weight.

Optimark allows images to be taken for up to an hour after it has been injected, although the best time to take a scan depends on the location and type of abnormality that is being examined. When looking at certain abnormalities in the brain, Optimark may need to be used at a higher dose, or the dose may need to be repeated. A repeated dose is not recommended in children, in patients with kidney problems or in elderly patients.

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Patients who have moderate problems with their kidneys should only receive Optimark if their doctor has carefully balanced the benefits and risks of using it. These patients should receive no more than one dose of Optimark during each MRI scan, and there should be a gap of at least a week between each Optimark injection.

How does Optimark work?

The active substance in Optimark, gadoversetamide, contains gadolinium, a 'rare-earth' metal element. Gadolinium is used as a 'contrast agent' to help obtain better images with MRI scans. 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 Optimark, the gadolinium is attached to another chemical so that the metal is not released in the body but stays 'trapped' until it is eliminated from the body in the urine.

How has Optimark been studied?

Optimark has been studied in four main studies involving a total of 804 patients who had or were thought to have abnormalities in the brain or spine (two studies in 401 patients) or in the liver (two studies in 403 patients). In all of the studies, the effects of Optimark were compared with those of gadopentetate dimeglumine (another contrast agent containing gadolinium). The main measure of effectiveness was the difference in the ability to see the abnormalities on MRI scans taken with and without the contrast agent. Each scan's clarity was scored on a four-point scale. The scans were analysed by three radiologists (doctors specialised in carrying out and interpreting scans of the body). The radiologists did not know what treatment the patient had received beforehand, to make sure that the studies' findings were as accurate as possible.

What benefit has Optimark shown during the studies?

In all of the studies, Optimark was as effective as the comparator contrast agent in improving the ability to see abnormalities on the scans.

In the two studies of brain and spine abnormalities taken together, scans taken with Optimark had a score increase of 0.63 points on average from a 'baseline' of 1.58 points without Optimark. This compared with an increase of 0.66 points with the comparator contrast agent, from a baseline of 1.60 points.

In the studies of liver abnormalities, both medicines increased the score by an average of 0.38 points from a baseline of 1.82 points.

What is the risk associated with Optimark?

The most common side effects with Optimark (seen in between 1 and 10 patients in 100) are headache, dysgeusia (taste disturbances) and feeling hot. For the full list of all side effects reported with Optimark, see the package leaflet.

Optimark must not be used in people who are hypersensitive (allergic) to gadoversetamide, any of the other ingredients or other medicines containing gadolinium. It must not be used in patients who have severely reduced kidney function, in patients who have had or are about to have a liver transplant, or in babies aged less than four weeks, due to a risk of a condition called nephrogenic systemic fibrosis (NSF). NSF causes thickening of the skin and connective tissues.

Why has Optimark been approved?

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

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

The company that markets Optimark will ensure that all healthcare professionals who are expected to use this medicine are informed that it should not be used in children below 2 years as the effect of the medicine in this age group, such as its effect on immature kidneys, has not been studied.

In addition, the company will provide annual reviews of cases of NSF and conduct a study on the accumulation of gadolinium in the bone.

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

Other information about Optimark:

The European Commission granted a marketing authorisation valid throughout the European Union for Optimark on 23 July 2007.

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

This summary was last updated in 05-2016.