



Gadolinium-based contrast agents: update on MHLW decision in Japan

Villepinte (France), December 6, 2017 (6pm CET) – Guerbet (FR0000032526 GBT), a global specialist in contrast agents and solutions for medical imaging, takes note of the decision issued on November 28 by the Japanese Ministry of Health, Labour and Welfare (MHLW), regarding the mandatory revision of the precautions section in the package insert of gadolinium-based contrast agents (GBCAs), with immediate effect.

In parallel to the European Commission’s decision to suspend the use of non-specific linear gadolinium agents in body scans, the MHLW has decided to restrict the use of non-specific linear GBCAs only in cases where there is no alternative, based on the “higher Gadolinium accumulation in brain reported with these linear agents”.

For all GBCAs, “the necessity of MRI scan using gadolinium-based contrast agents should be determined carefully” as stated in the Japanese new package insert.

Magnetic resonance imaging (MRI) is a widely used diagnostic procedure which is critical to patient health and contrast enhanced MRI exams are vital to give physicians a sharper, more accurate picture of tissue than they would otherwise be able to have.

There are two kinds of gadolinium based contrast agents (GBCAs), linear and macrocyclic. Although there are many similarities amongst these agents, they differ in their kinetic and thermodynamic stability. Linear GBCAs are generally less stable, and for this reason, more likely than macrocyclic agents to deposit gadolinium in tissue. Guerbet’s GBCA, Dotarem®, distributed under the brand name Magnescape® (Meglumine gadoterate) in Japan, is a macrocyclic agent.

Revision of precautions for Linear GdCAs:*

“1. It has been reported that high signal intensity was observed in the cerebellar dentate nucleus and globus pallidus on unenhanced T1-weighted MR images and that gadolinium was detected in autopsied brain tissues in patients who received a gadolinium-based contrast agent several times. The necessity of MRI scan using gadolinium-based contrast agents should be determined carefully.

2. It has been reported that more gadolinium remained in the brain with linear gadolinium-based contrast agents containing this drug than with macrocyclic gadolinium-based contrast agents. This drug should be administered when macrocyclic gadolinium-based contrast agents are not appropriate.”

Press release

Revision of precautions for Macrocytic GdCAs:*

“It has been reported that high signal intensity was observed in the cerebellar dentate nucleus and globus pallidus on unenhanced T1-weighted MR images and that gadolinium was detected in autopsied brain tissues in patients who received a gadolinium-based contrast agent several times. The necessity of MRI scan using gadolinium-based contrast agents should be determined carefully.”

“Following the European and Japanese Health Agencies decisions regarding the evolution of label changes for linear and for macrocyclic GBCAs, other important regulatory positions are expected soon” said Pierre Desché, Development, Medical & Regulatory Affairs Vice President.

In the meantime, Guerbet has immediately proceeded to the requested revision of precautions for Magnescope® and will continue to work with Health Authorities to further understand the mechanisms and consequences of gadolinium deposition in tissue.

* English version on the Revision of precautions for Linear GBCAs and for Macrocytic GBCAs are published in PMDA-HP <http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0005.html>.

About Guerbet

Guerbet is a pioneer in the contrast-agent field, with more than 90 years' experience, and is a leader in medical imaging worldwide. It offers a comprehensive range of pharmaceutical products, medical devices and services for x-ray scans, magnetic resonance imaging (MRI) and interventional radiology and theranostics (IRT), to improve the diagnosis and treatment of patients. With 7% of revenue dedicated to R&D and more than 200 employees distributed amongst its three centers in France and the United States, Guerbet is a substantial investor in research and innovation. Guerbet (GBT) is listed on Euronext Paris (segment B – mid caps) and generated €776 million in revenue in 2016. For more information about Guerbet, visit www.guerbet.com

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