Revision of Precautions

Gadodiamide hydrate
Meglumine gadopentetate

November 28, 2017

Non-proprietary name
Gadodiamide hydrate, meglumine gadopentetate

Safety measure
Precautions should be revised in the package insert.

The Precautions of Indications section should be created and the following text should be added (underlined parts are revised):

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.

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.