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*This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

## 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.