



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

Gadoxetate sodium
Gadoteridol
Meglumine gadoterate
Gadobutrol

November 28, 2017

Non-proprietary name

Gadoxetate sodium, gadoteridol, meglumine gadoterate, gadobutrol

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.