

*This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.
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

Gadobutrol

July 17, 2024

Therapeutic category

Other diagnostic agents (except extracorporeal diagnostic medicines)

Non-proprietary name

Gadobutrol

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

Revised language is underlined.

Current	Revision
<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Shock, anaphylaxis</p> <p>Shock or anaphylaxis (decreased blood pressure, dyspnoea, loss of consciousness, pharyngeal/laryngeal oedema, face oedema, respiratory arrest, cardiac arrest, etc.) may occur. <u>It may be accompanied by pulmonary oedema in some cases.</u></p> <p>(N/A)</p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Shock, anaphylaxis</p> <p>Shock or anaphylaxis (decreased blood pressure, dyspnoea, loss of consciousness, pharyngeal/laryngeal oedema, face oedema, respiratory arrest, cardiac arrest, etc.) may occur.</p> <p><u>Acute respiratory distress syndrome, pulmonary oedema</u></p> <p><u>If rapidly progressive dyspnoea, hypoxaemia, or chest X-ray abnormalities such as diffuse infiltrative shadow in both lungs are observed, appropriate measures should be taken as necessary.</u></p>

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.

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