



---

*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 Formalin

November 22, 2016

### **Non-proprietary name**

Formalin

### **Safety measure**

Precautions should be revised in the package insert.

The Contraindication section should be newly added and the following text should be added in the section (underlined parts are revised):

When used in the dentistry field:

Patients with a history of hypersensitivity to any of the ingredients of this product

The Clinically Significant Adverse Reactions subsection should be newly added in the Adverse Reactions section of the package insert. In this new Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text should be added (underlined parts are revised):

When used in the dentistry field:

Shock and anaphylaxis:

Shock or anaphylaxis may occur. Patients should be carefully monitored. If any abnormalities such as urticaria, pruritus, dyspnoea, and decreased blood pressure are observed, appropriate measures should be adopted.