



Summary of investigation results

Products Containing Formalin

November 22, 2016

Non-proprietary name

- (1) Formalin
- (2) Formalin/Cresol
- (3) Cresol/formalin/ clove oil/zinc oxide mixt
- (4) Formalin/Guaiacol

Brand name (Marketing authorization holder)

Refer to the attachment below.

Indications

Refer to the attachment below.

Summary of revision

(1)

1. Contraindications section should be newly added in the package insert and “<When used in the dentistry field> Patients with a history of hypersensitivity to any of the ingredients of this product” should be added in the Contraindications section.
2. Clinically Significant Adverse Reactions subsection should be newly added in the Adverse Reactions section in the package insert, and “<When used in the dentistry field> “shock, anaphylaxis” should be added in the Clinically Significant Adverse Reactions subsection.

(2), (3), (4)

1. Contraindications section should be newly added in the package insert, and “Patients with a history of hypersensitivity to any of the ingredients of this product” should be added in the Contraindications section.



2. Clinically Significant Adverse Reactions subsection should be newly added in the Adverse Reactions section in the package insert, and “shock, anaphylaxis” should be presented in the Clinically Significant Adverse Reactions subsection.

Background of the revision and investigation results

Cases of shock or anaphylaxis have been reported in patients treated with the above products in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

The following cases associated with shock or anaphylaxis have been reported after administration of the following products:

(1)

No cases have been reported.

(2)

A total of 2 cases have been reported (including 1 case for which a causal relationship to the product could not be ruled out). No fatality has been reported.

(3)

No cases have been reported.

(4)

No cases have been reported.



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

Attachment

Non-proprietary name	Brand name (Marketing authorization holder)	Indications
(1) Formalin	Formalin Kenei (Kenei Pharmaceutical Co., Ltd.)	1. Sterilization of medical devices; sterilization of operating rooms, hospital rooms, furniture, instruments, materials, etc. 2. Disinfection of infected root canals in dentistry
	Formalin Kozakai M (Kozakai Pharmaceutical Co., Ltd.)	
	Junsei Formalin (Junsei Yakuhin Kogyo)	
	Formalin Tatsumi M (Tatsumi Yakuhin Kogyo)	
	Formalin Taisei (Taisei Yakuhin Kogyo)	
	Formalin Tokai (Tokai Seiyaku)	
	Formalin Yamazen (Yamazen Pharmaceutical Co., Ltd.)	
	Formalinum Ebisu (Ebisu Yakuhin Kako Corporate)	
	Formalin Nikko (Nikko Pharmaceutical Co., Ltd.)	
(2) Formalin-cresol	Clear FC (Agsa Japan Co., Ltd.)	Disinfection of the root canal of extirpated pulp; disinfection of infected root canals
	Formocresol Dental Disinfectants "Showa" (Showa Yakuhin Kako Co., Ltd.)	Disinfection of root canals
	Formcresol FC Neo (Neo Dental Chemical Products Co., Ltd)	



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	Dental Formcresol Murakami (Agsa Japan Co., Ltd.)	
	Dental Formalin Cresol (Nippon Shika Yakuhin Co., Ltd.)	
(3) Cresol-formalin-clove oil- zinc oxide	Palpack V (Nippon Shika Yakuhin Co., Ltd.)	Sealing, pain relief, sedation, and pulp capping in pediatric dentistry
(4) Formalin-guaiacol	Formalin Guaiacol FG Neo (Neo Dental Chemical Products Co., Ltd.)	Disinfection or sterilization of cariou cavity, the root canal of extirpated pulp, and infected root canals