



## Summary of investigation results

### Products containing chlorhexidine gluconate or products containing chlorhexidine hydrochloride (OTC drugs)

October 17, 2017

#### Non-proprietary name

- a. chlorhexidine gluconate
- b. chlorhexidine hydrochloride

#### Brand name (Marketing authorization holder)

- a. Oronine H Ointment (Otsuka Pharmaceutical Factory, Inc.), Memo-A (S S Pharmaceutical Co., Ltd.), Stericlon 0.05% Cotton Ball P (KENEI Pharmaceutical Co., Ltd.), and others. (refer to the attachment below)
- b. Preser S Ointment (Taisho Pharmaceutical Co., Ltd.), Tamuchinki Powder Spray C (Kobayashi Pharmaceutical Co., Ltd.), Shionogi D Ointment (Shionogi Healthcare & Co., Ltd.), and others (refer to the attachment below)

#### Indications

a and b. refer to the attachment below.

#### Summary of revision

a and b.

1. "Patients who have had an allergic symptom to this product, its ingredients, or chlorhexidine" should be added in the When not to use the product section.
2. "Shock (anaphylaxis)" should be added in the Consultation section.

#### Background of the revision and investigation results

Following reports of cases of shock in patients treated with products containing chlorhexidine gluconate with the indication for the use in the oral cavity in Japan, a precaution against shock (anaphylaxis) was added in the package inserts of the products containing chlorhexidine gluconate with the indication for the use in the oral cavity by a notification of Revision of Precautions in 2003. Recently in the U.S., revision of package



inserts to add a warning was requested in February 2017 about serious allergic reactions associated with over-the-counter skin antiseptic products containing chlorhexidine gluconate. Cases of anaphylaxis have been reported in Japan in patients treated with products containing chlorhexidine gluconate or chlorhexidine hydrochloride without the indication for the use in the oral cavity, and the package inserts of the prescription drugs will be revised. Following investigation results based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package inserts of the OTC drugs was also necessary.

**The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan (in and after FY 2014)**

a. Chlorhexidine gluconate

A case associated with shock or anaphylaxis has been reported (a causal relationship to the product could not be ruled out for this patient). No fatality has been reported.

b. Chlorhexidine hydrochloride

A total of 3 cases associated with shock or anaphylaxis have been reported (including no case for which a causal relationship to the product could not be ruled out). No fatality has 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

	Therapeutic Category	Examples of Products	
		Brand Name (Marketing authorization holder)	Indications
a. chlorhexidine gluconate	Suppurative dermatosis agents	Oronine H Ointment (Otsuka Pharmaceutical Factory, Inc.)	Acne, pimples, skin flaking, light burns, chapped skin, chillblains, scratches, dry athlete's foot, jock itch, and tinea capitis
	Gargles	New S Venan Gargle (Showa Seiyaku Co., Ltd.)	Sterilization, disinfection, and cleaning of the oral cavity and throat, and elimination of bad breath
	Antimicrobial agents (including special adhesive plasters)	Memo A (S S Pharmaceutical Co., Ltd.)	Cuts, scratches, puncture wounds, scrapes, shoe sores, sterilization/disinfection of wound surfaces, light burns
		Stericlone 0.05% Cotton Ball P (KENEI Pharmaceutical Co., Ltd.)	Scratches, cuts, scrapes, puncture wounds, shoe sores, sterilization/disinfection of wound surfaces
b. chlorhexidine hydrochloride	Hemorrhoidal preparations for external use	Preser S Ointment (Taisho Pharmaceutical Co., Ltd.)	Relief of anal tear (bleeding piles), pain of hemorrhoidal polyps, bleeding, swelling, and itchiness
	Athlete's foot/tinea remedies	Tamuchinki Powder Spray C (Kobayashi Pharmaceutical Co., Ltd.)	Athlete's foot, jock itch, tinea corporis
	Suppurative dermatosis agents	New Marlen (Taisho Pharmaceutical Co., Ltd.)	Suppurative dermatological diseases (folliculitis, facial furuncle, contagious impetigo)
	Oral cavity/throat remedies (including troches not intended for cough/phlegm)	Madre Troche (Kyoto Pharmaceutical Industries, Ltd.)	Sterilization/disinfection of the oral cavity, elimination of bad breath, hoarse voice due to throat inflammation, throat irritation, throat discomfort, sore throat, throat swelling



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b. chlorhexidine hydrochloride	Toothache/ pyorrhea relieving agents	LaCarte MediCure (S S Pharmaceutical Co., Ltd.)	Alleviation of symptoms associated with pyorrhea/gingivitis (gingival redness, swelling and pus; bad breath)
	Analgesics, anti-itchings, astringents, anti-inflammatory agents (including poultices)	Shionogi D Ointment (Shionogi Healthcare & Co., Ltd.)	Eczema, itchiness, insect bites, contact dermatitis, dermatitis, prickly heat, urticaria, chillblains
	Antimicrobial agents (including special adhesive plasters)	Futavadia Ointment S (Shinshin Pharmaceutical Co., Ltd.)	Cuts, scratches, puncture wounds, scrapes, shoe sores, sterilization/disinfection of wound surfaces