

Summary of Investigation Results

Tacrolimus hydrate (ointment)

Non-proprietary name Brand name	Non-proprietary name	Brand name (marketing authorization holder)
	Tacrolimus hydrate	a. Protopic Ointment 0.03% for Pediatric b. Protopic Ointment 0.1% (Maruho Co., Ltd.)
Japanese market launch	a. December 2003 b. November 1999	
Indications	Atopic dermatitis	
Summary of revisions	a. - The statement in the 2. CONTRAINDICATIONS section should be revised from “low birth weight infants, neonates, infants, or children under 2 years of age” to “low birth weight infants, neonates, or infants under 6 months of age.” Accordingly, the relevant language in the 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS section should also be revised. - A recommended maximum amount per application for children aged 6 months to under 2 years (body weight: less than 10 kg) should be added to the 7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION section. - The results of a post-marketing clinical study in pediatric patients with atopic dermatitis aged 6 months to under 2 years should be added to the 16. PHARMACOKINETICS and 17. CLINICAL STUDIES sections. b. - The relevant language in the 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS section should be revised.	
Investigation results and background of the revision	The results of the clinical study in patients with atopic dermatitis aged 6 months to under 2 years were evaluated. As a result of consultation with expert advisors, MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.	

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).