



# Summary of investigation results

## Benzoyl peroxide

### Non-proprietary name

Benzoyl peroxide

### Brand name (Marketing authorization holder)

Bepio Gel 2.5% (Maruho Co., Ltd.)

### Indications

Acne vulgaris

### Summary of revision

Reports of erythema and swelling spreading to the entire face and neck should be added to the Important precautions section.

### Background of the revision and investigation results

Cases of erythema and swelling spreading to the entire face and neck have been reported in patients treated with benzoyl peroxide 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

A total of 7 cases associated with cutaneous symptoms have been reported (including 6 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.