



Summary of investigation results

Clindamycin phosphate hydrate / Benzoyl peroxide

Non-proprietary name

Clindamycin phosphate hydrate/Benzoyl peroxide

Brand name (Marketing authorization holder)

Duac combination gel (Pola Pharma Inc.)

Indications

<Applicable microorganisms>

Clindamycin phosphate hydrate/Benzoyl peroxide-susceptible strains of genus
Staphylococcus and *Propionibacterium acnes*

<Applicable conditions>

Acne vulgaris

Summary of revision

Reports of erythema and swelling spreading to the entire face and neck as well as serious blister and erosion 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 as well as serious blister and erosion have been reported in patients treated with the combination product of clindamycin phosphate hydrate/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.



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.

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

A total of 5 cases associated with cutaneous symptoms have been reported (including 5 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.