



# Summary of investigation results

## Hydroxyzine hydrochloride, Hydroxyzine pamoate

February 14, 2017

### Non-proprietary name

- a. Hydroxyzine hydrochloride
- b. Hydroxyzine pamoate

### Brand name (Marketing authorization holder)

- a. Atarax Tablets 10 mg, 25 mg, Atarax-P Parenteral Solution 25 mg/mL, 50 mg/mL (Pfizer Japan Inc.)
- b. Atarax-P Powder 10%, Atarax-P Capsules 25 mg, 50 mg, Atarax-P Syrup 0.5%, Atarax-P Dry Syrup 2.5% (Pfizer Japan Inc.), and the others

### Indications

Refer to the attachment below.

### Summary of revision

'Acute generalized exanthematous pustulosis' should be newly added in the Clinically Significant Adverse Reactions section.

### Background of the revision and investigation results

Cases of acute generalized exanthematous pustulosis have been reported in patients treated with hydroxyzine hydrochloride or hydroxyzine pamoate both in Japan and overseas, and the United States package insert has been revised. 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

No case associated with acute generalized exanthematous pustulosis 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

	Non-proprietary name	Brand name (Marketing authorization holder)	Indication
a	Hydroxyzine hydrochloride	Atarax Tablets 10 mg, 25 mg (Pfizer Japan Inc.)	Urticaria, pruritus associated with skin disease (eczema, dermatitis, cutaneous pruritus) Anxiety, tension, depressed mood in neurosis
		Atarax-P Parenteral Solution 25 mg/mL, 50 mg/mL (Pfizer Japan Inc.)	Anxiety, tension, depressed mood in neurosis Anaesthetic premedication Prophylaxis of preoperative or postoperative nausea/vomiting
b	Hydroxyzine pamoate	Atarax-P Powder 10%, Atarax-P Capsules 25 mg, 50 mg Atarax-P Syrup 0.5% Atarax-P Dry Syrup 2.5% (Pfizer Japan Inc.), and the others	Urticaria, pruritus associated with skin disease (eczema, dermatitis, cutaneous pruritus) Anxiety, tension, depressed mood in neurosis