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.

Summary of investigation results

Hydroxyzine hydrochloride, Hydroxyzine pamoate

August 6, 2015

Non-proprietary name

a. Hydroxyzine hydrochloride
b. Hydroxyzine pamoate

Brand name (Marketing authorization holder)

a. Atarax Tablets 10 mg and 25 mg and Atarax-P Parenteral Solution 25 mg/ml and 50 mg/ml (Pfizer Japan Inc.)
b. Atarax-P Powder 10%, Atarax-P Capsules 25 mg and 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

1. "Patients with prolonged QT interval (including those with long QT interval syndrome congenital), patients being administered drugs known to prolong QT interval, and patients with significant bradycardia or hypokalaemia" should be newly added in the Careful Administration section.
2. "QT interval prolongation and ventricular tachycardia (including torsades de pointes)" should be newly added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of prolonged QT interval and ventricular tachycardia have been reported in patients treated with hydroxyzine hydrochloride or hydroxyzine pamoate both in Japan and overseas. In addition, EU-EMA had taken action to minimize the risks of effects on heart rhythm with hydroxyzine-containing medicines. Following an investigation result based on the opinions

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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. No case associated with QT interval prolongation nor ventricular tachycardia has been reported.
b. A case associated with QT interval prolongation or ventricular tachycardia has been reported (a causal relationship to the product could not be ruled out for the patient). The one reported case did not have a fatal outcome.

Attachment

	Non-proprietary name	Brand name	Indication
a	Hydroxyzine hydrochloride	Atarax Tablet 10 mg and 25 mg	Urticaria, pruritus associated with skin disease (eczema, dermatitis, cutaneous pruritus) Anxiety, tension, depressed mood in neurosis
		Atarax-P Parental Solution 25 mg/mL and 50 mg/mL	Anxiety, tension, depressed mood in neurosis Anaesthetic premedication Prophylaxis of preoperative or postoperative nausea/vomiting
b	Hydroxyzine pamoate	Atarax-P Powder 10%	Urticaria, pruritus associated with skin disease (eczema, dermatitis, cutaneous pruritus) Anxiety, tension, depressed mood in neurosis
		Atarax-P Capsule 25 mg and 50 mg	
		Atarax-P Syrup 0.5%	
		Atarax-P Dry Syrup 2.5%	

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