Summary of Investigation Results

Bilastine

December 3, 2019

Non-proprietary name

Bilastine

Branded name (Marketing authorization holder)

Bilanoa Tablet 20 mg (Taiho Pharmaceutical Co., Ltd.)

Indications

Allergic rhinitis, urticaria, itching accompanying cutaneous disease (eczema and dermatitis, cutaneous pruritus)

Summary of revisions

A Clinically Significant Adverse Reactions section should be created to add “Shock, anaphylaxis”.

Investigation results and background of the revision

Cases of shock or anaphylaxis have been reported in patients treated with bilastine in Japan and overseas. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 6 cases involving shock, anaphylaxis have been reported to date (including 3 cases for which a causal relationship between the drug and event could not be ruled out).

No patient mortalities have been reported to date.

(Japanese market launch: November 2016)

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