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

Atovaquone and Atovaquone/Proguanil Hydrochloride

January 12, 2016

Non-proprietary name

a. Atovaquone

b. Atovaquone/Proguanil Hydrochloride

Brand name (Marketing authorization holder)

a. Samitrel Oral Suspension 15% (GlaxoSmithKline K.K.)

b. Malarone Combination Tablets (GlaxoSmithKline K.K.)

Indications

a. <Applicable microorganisms>

Pneumocystis jirovecii

<Applicable conditions>

Pneumocystis pneumonia, Prophylaxis of *Pneumocystis* pneumonia

b. Malaria

Summary of revision

a. “Agranulocytosis and leukopenia” should be newly added in the Clinically significant adverse reaction section.

b. “Agranulocytosis and leukopenia” should be added to the “pancytopenia” subsection in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of agranulocytosis and leukopenia have been reported in patients treated with atovaquone 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.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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 reaction and fatal cases in the last 3 fiscal years in Japan

a. Atovaquone

A total of 11 cases associated with agranulocytosis and leukopenia have been reported (including 5 cases for which a causal relationship to the product could not be ruled out).

Of the 11 cases, 2 fatal cases have been reported (a causal relationship between the product and the fatal outcome could not be established for these patients).

b. Atovaquone/proguanil hydrochloride

No case of agranulocytosis or leukopenia has been reported.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp