



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of Precautions Atovaquone/Proguanil Hydrochloride

January 12, 2016

Non-proprietary name

Atovaquone/Proguanil Hydrochloride

Safety measure

Precautions should be revised in the package insert.

In the Clinically significant adverse reaction subsection regarding pancytopenia of the Adverse reaction section, the following text should be revised (underlined parts are revised):

Pancytopenia, agranulocytosis, and leukopenia:

Pancytopenia, agranulocytosis, or leukopenia may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be adopted.