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

Hydroxychloroquine sulfate

January 17, 2023

Non-proprietary name

Hydroxychloroquine sulfate

Brand name (marketing authorization holder)

Plaquenil Tablets 200 mg (Sanofi K.K.)

Japanese market launch

September 2015

Indications

Cutaneous lupus erythematosus, systemic lupus erythematosus

Summary of revisions

“Acute febrile neutrophilic dermatosis (Sweet’s syndrome)” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases involving acute febrile neutrophilic dermatosis reported in Japan and overseas were evaluated. Cases for which a causal relationship between hydroxychloroquine sulfate and acute febrile neutrophilic dermatosis was reasonably possible have been reported overseas. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of Precautions, MHLW/PMDA concluded that revision of Precautions was necessary.

Reference: Number of cases* and patient mortalities involving acute febrile neutrophilic dermatosis reported in Japan and overseas

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

1 case has been reported in Japan to date (A causal relationship between the drug and event could not be established for this case).
No patient mortalities have been reported in Japan to date.

A total of 5 cases have been reported overseas to date. (A causal relationship between the drug and event was reasonably possible for 4 cases, including 3 cases in which the drug was administered outside the indications approved in Japan.)
No patient mortalities have been reported overseas to date.

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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