Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Trastuzumab (genetical recombination)

Trastuzumab (genetical recombination) follow-on biologic 1

Trastuzumab (genetical recombination) follow-on biologic 2

Trastuzumab (genetical recombination) follow-on biologic 3

February 12, 2019

Non-proprietary name

Trastuzumab (genetical recombination)
Trastuzumab (genetical recombination) follow-on biologic 1
Trastuzumab (genetical recombination) follow-on biologic 2
Trastuzumab (genetical recombination) follow-on biologic 3

Safety measure

Precautions should be revised in the package insert.

The following language should be added to the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section (revised language is underlined):

Tumour lysis syndrome:

Pharmaceuticals and Medical Devices Agency

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

Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

Tumour lysis syndrome may occur. Patients should be carefully monitored by checking serum electrolyte levels and renal function, etc. If any abnormalities are observed, administration of this drug should be discontinued, appropriate measures (e.g. administration of physiological saline solution and/or hyperuricaemia therapeutics, and dialysis) should be taken, and patients should be carefully monitored until recovery from such symptoms is observed.

Pharmaceuticals and Medical Devices Agency

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