



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

Cetuximab

April 1, 2015

Non-proprietary name

Cetuximab (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

In the Precautions of Indications section, information on KRAS mutation should be revised to include the following text (underlined parts are revised):

Prior to initiation of treatment for the patient with EGFR-positive, incurable, unresectable, advanced/recurrent colorectal cancer, assess RAS (KRAS and NRAS) mutation status and select a suitable patient.

NOTE

- This drug is designated to prepare a Drug Guide for Patients.