



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

Montelukast sodium

February 17, 2015

Non-proprietary Name

montelukast sodium

Safety measure

Precautions should be revised in the package insert.

In the Clinically significant adverse reactions subsection of the Adverse reactions section, the following texts should be added (underlined parts are revised):

Thrombocytopenia

Thrombocytopenia may occur (initial signs and symptoms are bleeding tendencies including purpura, epistaxis, and gingival bleeding). If these symptoms are observed, administration of this drug should be discontinued and appropriate measures should be taken.