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Revision of PRECAUTIONS

imatinib mesilate

September 16, 2014

Non-proprietary Name

imatinib mesilate

Safety measure

Precautions should be revised in the package insert.

Information on haemorrhage in Clinically significant adverse reactions subsection of Adverse Reactions section should be revised as follows:

Haemorrhage (cerebral haemorrhage and subdural haemorrhage):
Cerebral haemorrhage and/or subdural haemorrhage may occur. Patients should be carefully monitored through periodic blood tests, etc. If any abnormalities are observed, dose of this drug should be reduced or administration of this drug should be discontinued, and appropriate measures should be taken.

Gastrointestinal haemorrhage and gastric antral vascular ectasia (GAVE):
Gastrointestinal haemorrhage may occur. Patients should be carefully monitored through periodic blood tests, etc. If any abnormalities are observed, dose of this drug should be reduced or administration of this drug should be discontinued, and appropriate measures should be taken.
In addition, caution should be exercised because sometimes anaemia progresses without apparent symptoms such as melaena and/or haematemesis in gastrointestinal haemorrhage caused by GAVE.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp