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Revision of Precautions

Lenvatinib mesilate

November 24, 2015

Non-proprietary name

Lenvatinib mesilate

Safety measure

Precautions should be revised in the package insert.

In the Careful administration section, the following text should be added (underlined parts are revised):

> Patients with tumour invasion in the carotid arteries, veins, etc.

In the Important precautions section, the following text should be added (underlined parts are revised):

> Carotid artery exposure, carotid artery haemorrhage, and tumour haemorrhage associated with tumour shrinkage or necrosis may occur during administration of this drug. Furthermore, there were case reports of development of massive bleeding from exposed carotid artery sites or fistula formation sites.There is a risk of haemoptysis or haematemesis in a patient with a tracheal fistula or oesophageal fistula. Caution should be exercised before administration of this drug by confirming tumour invasion in the carotid arteries, veins, etc. During administration of this drug, patients should be carefully monitored, and fully carried out to confirm the presence or absence of fistula formation. If any haemorrhage are observed, administration of this drug should be discontinued as necessary, and appropriate measures should be adopted. Furthermore, particular caution should be exercised for anaplastic thyroid cancer patients as many of these patients suffer from tumour invasion in the carotid arteries, veins, etc.

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In the Clinically significant adverse reaction subsection regarding haemorrhage of the Adverse reaction section, the following text should be revised (underlined parts are revised):

Haemorrhage:
Haemorrhage such as epistaxis, haematuria, haemoptysis, gingival bleeding, pulmonary haemorrhage, rectal haemorrhage, intracranial tumour haemorrhage, arterial haemorrhage, subarachnoid haemorrhage, cerebral haemorrhage, and gastrointestinal haemorrhage may occur. In addition, carotid artery haemorrhage and tumour haemorrhage associated with tumour shrinkage or necrosis may occur.
Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as dose reduction or drug suspension should be adopted. If severe haemorrhage occurs, administration of this drug should be discontinued, and appropriate measures should be adopted.

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