This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Cabergoline

August 22, 2019

Non-proprietary name

Cabergoline

Branded name (Marketing authorization holder)

Cabaser Tablets 0.25 mg, 1.0 mg (Pfizer Japan Inc.), and the others

Indications

Parkinson’s disease

Galactorrhea

Hyperprolactinemic ovulation disorder

Hyperprolactinemic pituitary adenoma (limited to cases not requiring surgical procedures)

Postpartum lactation suppression

Summary of revisions

1. A precaution regarding cerebrospinal fluid rhinorrhea in patients with hyperprolactinemic pituitary adenoma that has grown beyond the sella turcica and a precaution regarding recurrence of visual field disorders in patients with hyperprolactinemic pituitary adenoma with visual field disorders should be added in the Important Precautions section.
2. The "Patients with marked visual field disorders, etc. caused by pituitary tumors that have grown beyond the sella turcica" in the Careful Administration section should be revised to "Patients with hyperprolactinemic pituitary adenoma who have marked visual impairment, etc. caused by pituitary tumors that have grown beyond the sella turcica".

Pharmaceuticals and Medical Devices Agency

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Investigation results and background of the revision

Cases of cerebrospinal fluid rhinorrhea and recurrent visual field disorders have been reported in patients treated with cabergoline in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 3 cases involving cerebrospinal fluid rhinorrhea have been reported to date (including 3 cases for which a causal relationship between the drug and event could not be ruled out). No patient mortalities have been reported to date.

A total of 2 cases involving recurrent visual field disorders have been reported to date (including 1 case for which a causal relationship between the drug and event could not be ruled out). No patient mortalities have been reported to date.

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