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Translated by
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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

Cabergoline

August 22, 2019

Therapeutic category

Antiparkinsonian agents

Non-proprietary name

Cabergoline

Safety measure

Precautions should be revised in the package insert.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions):

Revised language is underlined.

Current	Revision
<p>Precautions concerning Dosage and Administration</p> <p><u>When dose reduction or discontinuation of this drug is necessary for treatment of Parkinson's disease, the dose should be gradually reduced.</u></p>	<p>Precautions concerning Dosage and Administration</p> <p>(deleted)</p>
<p>Careful Administration</p> <p>Patients with marked visual impairment, etc. caused by pituitary tumors that have grown beyond the sella turcica</p>	<p>Careful Administration</p> <p>Patients with <u>hyperprolactinemic pituitary adenoma who have</u> marked visual impairment, etc. caused by pituitary tumors that have grown beyond the sella turcica</p>
<p>Important Precautions</p> <p>(N/A)</p>	<p>Important Precautions</p> <p><u>Patients with hyperprolactinemic pituitary adenoma that has grown beyond the sella turcica may have cerebrospinal fluid rhinorrhea because of adenoma shrunk by treatment with this drug, leading to meningitis. When any abnormalities are observed, appropriate measures should be taken such as dose reduction or discontinuation of the drug.</u></p> <p><u>It has been reported that in patients with hyperprolactinemic pituitary adenoma who had visual field disorders, this drug shrunk the adenoma and improved the visual field disorders, which</u></p>

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<p>Adverse Reactions</p> <p>Other Adverse Reactions</p> <p><Parkinson's disease></p> <p>(N/A)</p>	<p><u>recurred later through invagination of the optic chiasm into the sella caused by the sella turcica's cavitation. When any abnormalities are observed, appropriate measures should be taken such as dose reduction or discontinuation of the drug.</u></p> <p><u>When dose reduction or discontinuation of this drug is necessary for treatment of Parkinson's disease, the dose should be gradually reduced. Rapid dose reduction or discontinuation may cause syndrome malin. In addition, rapid dose reduction or discontinuation of dopamine receptor agonists may cause drug withdrawal syndrome (characterized by apathy, anxiety, depression, fatigue, sweating, pain, etc.).</u></p> <p>Adverse Reactions</p> <p>Other Adverse Reactions</p> <p><Parkinson's disease></p> <p><u>Drug withdrawal syndrome* (apathy, anxiety, depression, fatigue, sweating, pain, etc.)</u></p> <p><u>*When any abnormalities are observed, appropriate measures should be taken such as resuming administration or returning the dose to the level prior to reduction.</u></p>
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N/A: Not Applicable, because the section is not included in the current package insert.

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