Published by Ministry of Health, Labour and Welfare

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Translated by Pharmaceuticals and Medical Devices Agency



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

Eletriptan hydrobromide

Zolmitriptan

Naratriptan hydrochloride

Rizatriptan benzoate

June 4, 2019

Therapeutic category

Vasoconstrictors

Non-proprietary name

Eletriptan hydrobromide, zolmitriptan, naratriptan hydrochloride, rizatriptan benzoate

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan E-mail: <u>safety.info@pmda.go.jp</u> Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General ofPharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions):Revised language is underlined.

Current	Revision
Important Precautions	Important Precautions
(N/A)	Triptans including this drug may lead to an exacerbation of
	headache. If headache does not improve, consider a possibility of
	"medication overuse headache" and appropriate measures such as
	discontinuation of administration should be taken.
Adverse Reactions	Adverse reactions
Clinically Significant Adverse Reactions	Clinically significant Adverse Reactions
(N/A)	Medication overuse headache:
	Medication overuse headache may occur. If any abnormalities are
	observed, appropriate measures such as discontinuation of
	administration should be taken.

(Reference) International Headache Society:Cephalalgia 2018;38(1):1-211

N/A: Not Applicable, because the section is not included in the current package insert.

* This drug is designated as a drug requiring preparation of a Drug Guide for Patients.

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