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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Sumatriptan succinate (injectable dosage form, kit)

June 4, 2019

Therapeutic category

Vasoconstrictors

Non-proprietary name

Sumatriptan succinate

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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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
Important Precautions (N/A)	Important Precautions <u>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.</u>
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse reactions Clinically significant Adverse Reactions <u>Medication overuse headache may occur. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be taken.</u>

(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.

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