



Summary of investigation results

Triptans

June 4, 2019

Non-proprietary name

- a. Sumatriptan succinate
- b. Sumatriptan
- c. Naratriptan hydrochloride
- d. Eletriptan hydrobromide
- e. Zolmitriptan
- f. Rizatriptan benzoate

Branded name (Marketing authorization holder)

- a. Imigran Tablets 50 mg, Imigran Injection 3 mg, Imigran Kit Subcutaneous Injection 3 mg (GlaxoSmithKline K.K.), and the others
- b. Imigran Nasal Spray 20 mg (GlaxoSmithKline K.K.)
- c. Amerge Tablets 2.5 mg (GlaxoSmithKline K.K.)
- d. Relpax Tablets 20 mg (Pfizer Japan Inc.), and the others
- e. Zomig Tablets 2.5 mg, Zomig RM Tablets 2.5 mg (Sawai Pharmaceutical Co., Ltd.), and the others
- f. Maxalt Tablets 10 mg, Maxalt RPD Tablets 10 mg (Kyorin Pharmaceutical Co., Ltd.), and the others

Indications

a

Imigran Tablets 50 mg: migraine

Imigran Injection 3 mg, Imigran Kit Subcutaneous Injection 3 mg: migraine, cluster headache

b to f

Migraine

Summary of revision

1. Language concerning medication-overuse headache should be added to the Important Precautions section.
2. “Medication overuse headache” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Although only a small number of cases of medication overuse headache have been reported in patients treated with triptans 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 in light of the language used in the relevant overseas package inserts and prescription practice survey results from the national database (NDB) of health insurance claims and specific health checkups of Japan.

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

Cases involving medication overuse headache:

- a. Sumatriptan succinate
No cases have been reported to date.
- b. Sumatriptan
No cases have been reported to date.
- c. Naratriptan hydrochloride
1 case has been reported to date. (A causal relationship between the drug and event could not be established for this case.)
No patient mortalities have been reported to date.
- d. Eletriptan hydrobromide
3 cases have been reported to date. (A causal relationship between the drug and event could not be established for any of these cases.)
No patient mortalities have been reported to date.
- e. Zolmitriptan
1 case has been reported to date. (A causal relationship between the drug and event could not be established for this case.)



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.

No patient mortalities have been reported to date.

f. Rizatriptan benzoate

1 case has been reported to date. (A causal relationship between the drug and event could not be established for this case.)

No patient mortalities have been reported to date.