PMDA Alert for Proper Use of Drugs

Pharmaceuticals and Medical Devices Agency

No. 2 October 2011

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.

Automobile accidents associated with the use of smoking cessation aid CHAMPIX (varenicline tartrate)

*** CHAMPIX in Japan and EU, CHAMTIX in the USA**

Healthcare professionals should advise CHAMPIX Tablet users to refrain from engaging in potentially hazardous machine operations including driving!

Some cases of disturbed consciousness, after taking CHMPIX, leading to automobile accidents have been reported. Although MHLW has issued an alert to refrain from engaging in potentially hazardous machine operations including driving, automobile accidents involving CHAMPIX users are still being reported.

Case summaries

Case 1 A male patient in his 60s with underlying chronic obstructive pulmonary disease

The patient started receiving varenicline tartrate 0.5 mg/day for smoking cessation therapy. On Day 4, the dose of varenicline tartrate was increased to 1 mg/day. On Day 8, the dose of varenicline tartrate was increased to 2 mg/day. The patient took varenicline tartrate 1 mg after breakfast. About 20 minutes later, the patient had salivation, tremulousness in the whole body and loss of consciousness while driving. When the patient came to consciousness, the car was in a roadside ditch. The patient took varenicline tartrate 1 mg after dinner. About 20 minutes later, the patient had salivation, tremulousness in the whole body and loss of consciousness while driving again. He almost drove into an electric pole. The symptoms improved without treatment. Administration of varenicline tartrate was discontinued. The patient has never had these symptoms again.

Case 2 A male patient in his 60s with underlying asthma, otitis media, chronic sinusitis and essential tremor

The patient started receiving varenicline tartrate 0.5 mg/day for smoking cessation therapy. The dose of varenicline tartrate was increased to 1 mg/day on Day 4 and to 2 mg/day on Day 10. On Day 29, the patient suddenly had unusual vision while driving, and the crossing in front started to turn around. He subsequently lost visual perception and drove over the left curve. He temporarily lost consciousness and memory. He felt fuzzy. After resting for a while he went home. On Day 30, the cranial CT showed no abnormality. On Day 31, the patient had symptoms of a common cold secondary to summer lethargy such as slight fever (37.4˚C), and nausea and queasiness. An intravenous drip infusion was performed. On Day 34, administration of varenicline tartrate was discontinued.

Package insert of Varenicline tartrate (excerpt)

Important Precautions

Some cases of dizziness, somnolence and disturbed consciousness leading to automobile accidents have been reported. Patients should be advised to refrain from engaging in potentially hazardous machine operations including driving.

Clinically Significant Adverse Reactions

Disturbed consciousness: Disturbed consciousness including decreased level of consciousness and loss of consciousness may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued, and appropriate measures should be taken.

Other Adverse Reactions

Somnolence and dizziness

For the other precautions relating to varenicline tartrate, please see the Pharmaceuticals and Medical Devices Information Website (in Japanese)
http://www.info.pmda.go.jp/psearch/html/menu_tenpu_base.html

Product name of varenicline tartrate (Name of Marketing Authorization Holder) :
CHAMPIX Tablets 0.5 mg, 1 mg (Pfizer Japan Inc.)

About this information

* "PMDA Alert for Proper Use of Drugs" communicates to healthcare providers with clear information from the perspective of promoting the proper use of drugs. The information presented here includes such cases where the reporting frequencies of similar reports have not decreased despite relevant alerts provided in package inserts, among Adverse Drug Reaction/infection cases reported in accordance with the Pharmaceutical Affairs Law.
* We have tried to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy in the future.
* This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibilities on them, but is provided to promote the proper use of drugs.

Contact: Office of Safety Ⅱ Email :safety.info@pmda.go.jp