



Safety Information 003/09

29 May 2009

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations
- Area Directors, Mental Health
- Clinical Directors, Mental Health

Expert Reference Group

Content reviewed by

- Mental Health and Drug and Alcohol Office
- Chief Psychiatrist, NSW
- Clinical Excellence Commission

Quality and Safety Branch

NSW Department of Health
Tel. 02 9391 9200
Fax. 02 9391 9556
Email
quality@doh.health.nsw.gov.au

Website

<http://www.health.nsw.gov.au/quality/sabs/index.html>

Varenicline (CHAMPIX)-Serious Psychiatric Side Effects

This Safety Information is designed to highlight possible suicidal and aggressive behaviour associated with Varenicline in patients with a history of psychiatric illness.

Background

NSW Health has been notified of a suspected suicide that may be linked to Varenicline (Champix) which is a drug sometimes used to help quit smoking. The United States Food and Drug Administration and manufacturer have previously warned consumers about the possible risk of suicidal behaviour associated with this drug. Recent information from the Institute for Safe Medication Practices also suggests a possible link to violence, physical assaults, homicidal thoughts and aggression.

Steps to Minimise Risk

Varenicline is not generally prescribed in NSW hospitals, however patients with a history of psychiatric illness presenting to Emergency Departments and Mental Health facilities are at risk of a worsening psychiatric illness or exacerbation of an old psychiatric illness if they are taking, or have taken Varenicline. Staff should advise patients who have a current or previous psychiatric illness of the psychiatric symptoms associated with Varenicline including suicidal thoughts, and should be reviewed. Family and carers should be advised to report any changes in behaviour, especially in smokers as symptoms may appear similar to nicotine withdrawal.

Staff should be aware of the following potential side effects:

- Agitation
- Depressed mood
- Abnormal dreams
- Insomnia
- Hallucination
- Anger
- Suicidal ideation
- Attempted and completed suicide
- Seizures

Varenicline should only be prescribed in conjunction with a comprehensive smoking-cessation support, counselling program and medication review. Varenicline is taken orally in tablet form with water. The recommended dosage is 0.5 mg increasing to 1 mg per day during the first week of treatment. Dosage for weeks 2 to 12 of the course is 2 mg per day.

PBS guidelines include the following information:

- Only one course of PBS-subsidised smoking cessation therapy per year will be authorised
- Clinical review is recommended within two to three weeks of the original prescription
- It is administered only to those over 18 years of age.

References

The Cancer Council NSW Information Fact Sheet

http://www.cancercouncil.com.au/html/prevention/smoking_tobacco/downloads/facts%20Varenicline_Champix.pdf?pageid=2228

Therapeutic Goods Administration Australian Adverse Drug Reactions Bulletin, Volume 27, Number 6, December 2008 <http://www.tga.health.gov.au/adr/aadrb/aadr0812.htm>

Institute for Safe Medication Practices Newsletter, 7 May 2009.

<http://www.ismp.org/Newsletters/acutecare/articles/20090507.asp?ptr=y>

Recommended actions by Area Health Services

1. Ensure this safety Information is distributed to all relevant staff to ensure they are aware of the psychiatric symptoms associated with Varenicline in patients with a current or previous psychiatric illness
2. Ensure staff members are aware of the steps to minimise risk to patients