

## Public Summary

**Summary for ARTG Entry:** 124941 CHAMPIX varenicline (as tartrate) 1.0mg tablet blister pack

**ARTG entry for** Medicine Registered  
**Sponsor** Pfizer Australia Pty Ltd  
**Postal Address** 38-42 Wharf Road, WEST RYDE, NSW, 2114  
 Australia  
**ARTG Start Date** 15/02/2007  
**Product category** Medicine  
**Status** Active  
**Approval area** Drug Safety Evaluation Branch

**Conditions**

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

**Products****1. CHAMPIX varenicline (as tartrate) 1.0mg tablet blister pack**

**Product Type** Single Medicine Product **Effective date** 29/10/2015

**Warnings**

See Product Information and Consumer Medicine Information for this product

**Standard Indications****Specific Indications**

Champix is indicated as an aid for smoking cessation in adults over the age of 18 years

**Additional Product information****Container information**

| Type         | Material             | Life Time | Temperature                    | Closure      | Conditions   |
|--------------|----------------------|-----------|--------------------------------|--------------|--------------|
| Blister Pack | PVC/Al               | 2 Years   | Store below 30 degrees Celsius | Not recorded | Not recorded |
| Blister Pack | PVC/PCTFE (Aclar)/Al | 2 Years   | Store below 30 degrees Celsius | Not recorded | Not recorded |
| Blister Pack | PVC/Al               | 2 Years   | Store below 30 degrees Celsius | Not recorded | Not recorded |

**Pack Size/Poison information****Pack Size**

28 tablets  
 56 tablets  
 1 mg x 14 tablets  
 140 tablets

**Poison Schedule**

(S4) Prescription Only Medicine  
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**Components****1. medicine component****Dosage Form**

Tablet, film coated

**Route of Administration**

Oral

**Visual Identification**

Capsular biconvex, light-blue film-coated tablet, debossed "Pfizer" on one side, "CHX 1.0" on the other

**Active Ingredients**

varenicline tartrate 1.17 mg