

# CHAMPIX®

(*tshamp-iks*)

Varenicline tartrate

---

## Consumer Medicine Information

---

### What is in this leaflet

This leaflet answers some common questions about Champix. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Champix against the benefits it is expected to have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

---

### What CHAMPIX is used for

Champix is a medicine to help adults stop smoking. It can help to reduce craving and withdrawal symptoms that happen while you give up smoking.

People giving up smoking are often affected by nicotine withdrawal. Symptoms of nicotine withdrawal can include craving for tobacco, irritability, frustration, feeling angry, sleep problems, depressed mood, feeling anxious, difficulty in concentrating, restlessness, decreased heart rate, increased appetite or weight gain. Not everybody is affected by some or all of the symptoms of nicotine withdrawal.

Although it is not recommended that you smoke after the first one to two

weeks of treatment, if you smoke while you are taking Champix it will also reduce your enjoyment of cigarettes.

### How Champix works

Champix works by blocking the effects of nicotine in your body. There are receptors for nicotine in the brain. When cigarette smoke is inhaled, nicotine attaches to these receptors. This sends a message to a different part of the brain to release a chemical called dopamine. Dopamine gives a feeling of pleasure which only lasts for a short time. The body wants to repeat this feeling reinforcing the need to keep smoking. Based on research, it is believed that Champix works by activating these receptors and blocking nicotine from attaching to them.

To find out how well Champix works, two groups of people who tried to stop smoking were included in a clinical study: one group took Champix and the other was given sugar pills. People who took Champix had a four times higher chance of quitting smoking after 12 weeks of treatment than those who did not. People in the Champix group had a three times higher chance of still being non-smokers one year after taking this medicine.

You will normally need to take Champix for 12 weeks. Your doctor may advise you to take Champix for a further 12 weeks after your first treatment. This may increase your chances of stopping in the long term.

Champix does not contain nicotine and it is not addictive.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

Champix is only available with a doctor's prescription.

### Use in children

There is not enough information to recommend the use of this medicine in children under the age of 18 years.

---

### Deciding to stop smoking

Champix helps you give up smoking. Other things you need include:

- willpower
- a quit plan
- support from your family and friends
- counselling, advice or additional support
- changes to your behaviour, so you avoid situations where you are likely to smoke.

Research has found that most people who try to quit are unable to give up without outside support. Your doctor and pharmacist can give you advice, support and sources of information to help ensure your attempt to stop smoking is successful. You can also get advice and support from Quitline by calling 13 7848 (13 QUIT) if you are in Australia and 0800 778 778 if

you are in New Zealand. Quitline is a free confidential telephone smoking cessation information and advice service available throughout Australia and New Zealand.

A free internet based program that offers support and advice for people taking Champix is available in Australia at [www.mytimetoquit.com.au](http://www.mytimetoquit.com.au) and in New Zealand at [www.liferewards.co.nz](http://www.liferewards.co.nz)

---

## Before you take CHAMPIX

---

### *When you must not take it*

**Do not take Champix if you have an allergy to:**

- any medicine containing varenicline tartrate
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

**Do not take Champix after the expiry date printed on the carton or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**Talk to your doctor if you are not sure whether you should take this medicine.**

### *Before you start to take it*

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- mental illness

This could mean having low mood, depression or anxiety that has interfered or interferes with your everyday life or that has required or requires medication.

Your doctor will discuss the risks and benefits involved in taking Champix if you suffer from mental illness. Your family or carer should be asked to monitor any changes in your behaviour, thinking or mood.

Champix has not been studied in patients with severe mental illnesses.

- **kidney problems**
- **repeated fits or convulsions (epilepsy)**

Champix has not been studied in patients with epilepsy.

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.**

It is not recommended that you take Champix while you are pregnant or breast-feeding. If you plan to become pregnant, your treatment should be timed so that you have completed the course before becoming pregnant.

If you have not told your doctor about any of the above, tell him/her before you start taking Champix.

### *Taking other medicines*

**Tell your doctor or pharmacist if you are taking any other medicines, including:**

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

This includes other medicines to help you stop smoking such as nicotine replacement therapy (NRT) and bupropion (e.g. Zyban).

NRT includes patches, gum, lozenges, sublingual tablets and inhalers (such as Nicorette, Nicabate, QuitX).

The safety and benefits of taking Champix in combination with other medicines for stopping smoking have not been studied. Therefore, Champix in combination with other smoking cessation therapies is not recommended.

Some medicines may be affected by Champix or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

**Tell your doctor or pharmacist if you are taking any of the following:**

- insulin
- theophylline, a medicine used to treat asthma
- warfarin, a medicine used to thin the blood

When you stop smoking, there may be a change in how these and other medicines work for you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

---

## How to take CHAMPIX

---

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information in this leaflet.

**If you do not understand the instructions on the carton, ask your doctor or pharmacist for help.**

You are more likely to stop smoking if you are motivated to stop. Your doctor and pharmacist can provide advice, support and sources of further information to help ensure your attempt to stop smoking is successful.

## **Before you start**

**Choose a date when you will stop smoking. Write this date on the carton of Pack 1.**

You start taking Champix 1 week to 2 weeks (7 to 14 days) before your quit date. This lets Champix build up in your body and allows it to start working. You can keep smoking during this time. Make sure that you try and stop smoking on your quit date. If you slip, try to quit again.

## **How much to take**

Champix comes as a white tablet (0.5 mg) and a light blue tablet (1 mg). You start by taking a low dose to help your body get used to Champix. Start with the white tablet and then increase the dose up to the light blue tablet.

The usual dosage instructions are listed below. If you have severe kidney disease your doctor may prescribe a different dose.

### **Days 1 - 3**

Take one white tablet once a day.

### **Days 4 - 7**

Take one white tablet in the morning and one in the evening.

### **Weeks 2 - 4**

Take one light blue tablet in the morning and one in the evening.

Your first box of Champix will cover your first four weeks of treatment. You will need to visit your doctor before the end of the fourth week that you take Champix for a check-up and for a new prescription. At this appointment, your doctor will check your progress and give you a new prescription for the tablets you need to complete the remaining 8 weeks of treatment.

### **Weeks 5 - 12**

Take one light blue tablet in the morning and one in the evening.

After 12 weeks of treatment, if you have stopped smoking, your doctor may recommend another 12 weeks of treatment with Champix. This may increase your chances of stopping

smoking long term. For this course, take one light blue 1 mg tablet in the morning and one in the evening.

If you do not stop smoking during the first 12 weeks of treatment or if you start smoking again after treatment, you can make another attempt at stopping smoking. However, before you make another attempt, you should try to understand the reasons why your attempt to stop smoking failed, so that your next attempt has a better chance of success.

## **How to take it**

**Swallow the tablets whole with a full glass of water.**

## **When to take it**

**Take your medicine at about the same time each day.**

This will have the best effect and help you remember when to take it.

**It does not matter if you take Champix before or after food.**

Some people find it helpful to take Champix with food.

## **How long to take it**

Most people will keep taking Champix for 12 weeks. If you have completely quit smoking by 12 weeks, ask your doctor if another 12 weeks of Champix may help you stay cigarette-free.

## **If you forget to take it**

**If it is less than 6 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

**Do not take a double dose to make up for the dose that you missed.**

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

## **If you take too much (overdose)**

**Immediately telephone your doctor or contact the Poisons Information Centre for advice (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766), or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much Champix. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

**Take your tablets with you to hospital.**

---

## **While you are taking CHAMPIX**

---

### **Things you must do**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Champix.**

**Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant while taking this medicine, tell your doctor immediately.**

### **Things you must not do**

**Do not stop taking Champix until you have completed all 12 weeks, even if you have stopped smoking.**

It is important to keep taking Champix for the full 12 weeks.

**Do not stop taking Champix or change the dosage without checking with your doctor.**

**Do not take Champix to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they are also trying to stop smoking.**

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how Champix affects you.**

Champix may cause dizziness and sleepiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

### ***Things that could help while you are giving up smoking***

Examples of strategies to help you quit include the following:

- Reduce your consumption of caffeine.  
Drinking coffee may be a smoking trigger for you and, without nicotine, your body will retain more caffeine, possibly making you restless, irritable or sleepless.
- Reduce your consumption of alcohol.  
Drinking alcohol may be a smoking trigger for you and it can also weaken your resolve to quit.
- Socialise with non-smoking friends in smoke-free venues.
- Do something else to take your mind off smoking; for example, drink water slowly, chew sugar-free gum, eat a healthy snack or exercise.

---

## **Side effects**

---

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Champix.**

This medicine helps many people give up smoking, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious,

most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects.**

You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

### ***Pay special attention to...***

**You and your family or carer need to pay special attention to your mood, behaviour and thinking while you are taking Champix.**

Some people have reported changes in behaviour, thinking or mood when they start taking Champix. These may include depression, anxiety, agitation, feelings of aggression, mood swings, seeing, hearing or sensing things that are not there, thoughts of self-harm or self-harm. Worsening of these symptoms has also been reported in people who already had mental health problems.

It is not known whether these are related to Champix. It is known that mood changes can be due to the effects of stopping smoking, with or without treatment.

**Stop taking Champix and tell your doctor immediately if you or your family/carers notice any changes in your behaviour or thinking, if you become agitated or depressed, or have thoughts of self-harm.**

### ***Tell your doctor if...***

**Tell your doctor or pharmacist if you have nausea (feel sick) while taking Champix and it worries you.**

In clinical studies with Champix, up to 3 in 10 people had nausea. It usually started in the first week. Most people who had nausea still felt able to keep on taking the medicine. Some people find it helpful to take Champix with food.

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- **stomach or bowel problems**
  - constipation
  - feeling bloated
  - indigestion
  - wind
  - dry mouth
  - vomiting
  - stomach discomfort
- **headache**
- **dizziness**
- **sleep problems**
  - difficulty sleeping
  - sleepiness
  - abnormal dreams
- **feeling tired, fatigue**
- **increased appetite**
- **changes in taste**

These are the more common side effects of Champix. They are usually mild.

### ***Tell your doctor as soon as possible if...***

**Tell your doctor as soon as possible if you notice any of the following:**

- trembling
- problems with your vision or pain in your eyes
- red blood in stools
- stomach pain
- skin problems such as rash, itching or reddening of the skin

This list includes serious side effects which may require medical attention.

### ***Go to hospital if...***

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital and stop taking Champix if you experience any of the following:**

- **sudden severe itchy swellings on the skin**
- **severe painful red blisters on the skin with chills, fever, aching muscles and generally feeling unwell**
- **breathing problems**

- wheezing
- difficulty breathing
- shortness of breath
- **swelling of the face, lips, mouth, tongue, throat, hands or feet**

Some people have reported swelling of parts of their face and body after taking Champix.

- **chest pain, which may spread to the neck and shoulders**
- **collapse, numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech or loss of speech**
- **abnormal or fast heartbeat**
- **blood in vomit**

This list includes very serious side effects. If you have some of them, you may have had a serious allergic reaction to Champix. You may need urgent medical attention or hospitalisation.

Very serious side effects are rare.

---

## After taking CHAMPIX

---

### Storage

**Keep your tablets in the pack until it is time to take them.**

If you take the tablets out of the pack they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 30 degrees.**

**Do not store Champix or any other medicine in the bathroom or near a sink.**

**Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

---

## Product description

---

### What it looks like

Champix 0.5 mg tablets are white, film-coated, modified capsular shaped tablets marked "Pfizer" on one side and "CHX 0.5" on the other.

Champix 1 mg tablets are light blue, film-coated, modified capsular shaped tablets, marked "Pfizer" on one side and "CHX 1.0" on the other.

In Australia, a combination pack containing 11 x Champix 0.5 mg tablets and 14 x Champix 1 mg tablets as Pack 1 and 28 x Champix 1 mg tablets as Pack 2, are available to assist with the initial dose schedule required when commencing Champix.

For continuing treatment, Champix 1 mg tablets are available in a pack of 56 tablets.

In New Zealand, a pack containing 11 x Champix 0.5 mg tablets and 14 x Champix 1 mg tablets and a pack containing 28 x Champix 1 mg tablets are available to assist with the initial dose schedule required when commencing Champix.

For continuing treatment, Champix 1 mg tablets are available in a pack of 56 tablets.

### Ingredients

#### Active Ingredients

Champix 0.5 mg tablets contain the equivalent of 0.5 mg of varenicline.

Champix 1 mg tablets contain the equivalent of 1 mg of varenicline.

#### Inactive Ingredients

Each tablet of Champix contains the following inactive ingredients:

- Cellulose - microcrystalline
- Calcium hydrogen phosphate anhydrous
- Croscarmellose sodium
- Silica-colloidal anhydrous
- Magnesium stearate
- Opadry Blue, Opadry White and Opadry Clear

Champix is gluten free.

### Supplier

Champix is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Australia.

Toll Free Number: 1800 675 229

Champix is supplied in New Zealand by:

Pfizer New Zealand Ltd

PO Box 3998

Auckland, New Zealand.

Toll Free Number: 0800 736 363

### Australian Registration Numbers

Combination Pack containing Champix 0.5 mg and 1 mg Tablet Blisters: AUST R No. 124940

Champix 1 mg Tablet Blister Pack: AUST R No. 124941.

This leaflet was prepared in November 2011.

® Registered Trademark

© Pfizer Australia Pty Ltd 2011.