

## Varenicline: a prescribed medicine

(sold under the brand name “Champix”)

*Please note: This information is not intended to replace the Consumer Medicine Information that comes with varenicline. Ask your pharmacist for this leaflet if it is not in the pack when you buy it.*

### Introduction

Research shows that people who have the best chance of quitting are those who get some coaching and use quitting medications.<sup>1,2</sup>

Varenicline has been proven to help people quit smoking. It is well tolerated by most people who use it. However, users of varenicline may have a higher risk of serious side effects than people not using this medicine.<sup>3</sup> Varenicline must be prescribed by your doctor, as it is not suitable for everyone.<sup>4</sup> It is important to talk to your doctor about possible side effects.

### Is varenicline suitable for me?

Varenicline is helpful for people who smoke 10 or more cigarettes per day, and who want to quit.<sup>3</sup> It is not clear whether smokers of less than 10 cigarettes per day would benefit from using varenicline as most study participants are not in this group.<sup>1,3</sup> Varenicline is not suitable for everyone and you must discuss with your doctor whether you should use it. Read the section *What I should tell my doctor*.

In general, quitting medications work best for people who are addicted to nicotine in tobacco. Signs of nicotine addiction are:

- You smoke your first cigarette within 30 minutes of waking up.<sup>5,6</sup>
- You smoke more than 10 cigarettes per day.<sup>5,6</sup> (There is no difference between smoking stronger or weaker tasting cigarettes.<sup>7</sup>)
- You suffer from withdrawal symptoms within 24 hours of stopping smoking, such as cravings, irritability, anxiety, depression, restlessness, hunger, poor concentration and sleep disturbances.<sup>5,8</sup>

### How can varenicline help me quit?

Varenicline is sold as tablets on prescription only, under the brand name ‘Champix’.<sup>4</sup> The active ingredient is varenicline tartrate.<sup>9</sup> They do not contain nicotine.<sup>4</sup>

Varenicline works by reducing withdrawal symptoms, and by reducing the satisfying effects of smoking. When you puff on a cigarette, nicotine travels through your lungs, into your bloodstream and to your brain. It attaches to receptors in your brain to release a brain reward chemical called dopamine. Varenicline attaches to the receptors instead of the nicotine, and releases a smaller amount of dopamine.<sup>3, 10</sup> This reduces withdrawal symptoms when you stop smoking, such as cravings, poor moods, poor concentration and restlessness.<sup>3, 11</sup> However, it may not stop withdrawal symptoms completely.

Varenicline also blocks nicotine from attaching to the receptors. So if you smoke while using varenicline, the nicotine does not have its full effect, and the cigarette may not be as enjoyable or satisfying.<sup>3, 10</sup>

## **How well does varenicline work?**

People who use varenicline together with counselling are more than twice as likely to quit and stayed stopped, compared to those not using quitting medications.<sup>3</sup> Advice or counselling is provided by the Quitline 13 7848 or from your doctor, pharmacist or other trained advisor.

Varenicline reduces the weight gain which may occur after quitting, but the effect doesn't appear to last beyond its use.<sup>12</sup>

## **Buying varenicline**

Varenicline is available only on prescription. It is approved by the Pharmaceutical Benefits Scheme (PBS) for people who take part in a support and counselling program, such as that provided by the Quitline.<sup>5</sup> Your doctor will issue you a prescription for 53 tablets on your first visit, and then, on your second visit, a prescription for 112 tablets. Together, these two prescriptions will last 12 weeks. If you finish this 12 weeks of treatment, you may buy a further 12 weeks of tablets on the PBS if you wish. Overall, you can buy up to 24 week of tablets per year on the PBS. In 2012, general patients pay \$35.40 (PBS price) for each prescription and concession holders pay \$5.80. You can buy it on a private prescription, but it costs over \$300 for a 12 week course.

After buying your first packet of tablets, you will need to have a second appointment with your doctor within four weeks of starting treatment, before your first packet runs out.

## What I should tell my doctor

You should not take varenicline if you:

- are allergic to varenicline tartrate (symptoms are listed in the Consumer Medicine Information)
- are pregnant, trying to become pregnant or are breast feeding
- are under 18 years of age.<sup>4</sup>

Before you are prescribed varenicline, you must tell your doctor if you have or have had:

- a mental illness or a history of mental illness, including low mood, depression, anxiety, bipolar disorder, or any other mental illness<sup>4</sup>
- kidney problems<sup>4</sup>
- haemodialysis treatment<sup>4</sup>
- repeated fits or convulsions<sup>4</sup>
- heart disease or other cardiovascular condition.<sup>9, 13, 14</sup>

You must tell you doctor as soon as possible if you have unexpected changes in behaviour or mood while you are taking varenicline, or right after you stop taking it (read *Side effects* below).<sup>4</sup>

Before you are prescribed varenicline, tell your doctor if you have any other illness.

You must tell your doctor about any other medicines you are taking, including pharmacy medicines, herbal preparations, diet pills, medicines sold in the supermarket, or other products used for quitting smoking. Also, tell your doctor if you have allergies to any foods, preservatives or dyes, or to any medicines.<sup>4</sup>

In some cases, you may require monitoring, advice, a change in medication, a reduced dose of varenicline or you may be advised not to use it.

If you intend to start new medicines, become ill, or become pregnant while taking varenicline, you must tell your doctor.<sup>4</sup>

## Using varenicline

You should follow your doctor's advice when using varenicline.

Once you've bought the varenicline, set a quit date one to two weeks into your treatment.<sup>4</sup> Continue smoking as normal in the first week of treatment, because it takes about one week or so for varenicline to start working properly.<sup>4</sup> Try not to delay quitting past five weeks into treatment.<sup>15</sup>

Not smoking at all after your quit date gives you the best chance of stopping for good. If you slip up and have a cigarette after your quit date, you may still succeed at

quitting if you keep taking your course of varenicline and recommit to stopping smoking.<sup>16</sup>

Your doctor will tell you how many tablets you should take. The usual dose is also described in the Consumer Medicine Information. However, your doctor might decide to reduce the number of tablets you take based on your individual needs.<sup>4</sup>

You should take your tablets at the same time each day. If you forget to take it, take it as soon as you remember. If it is almost time for your next dose, you should just skip the tablet you missed. Do not take a double dose of this medicine.<sup>4</sup>

Varenicline should be swallowed whole with a full glass of water. It can be taken with or without food.<sup>4</sup> Some people find it helpful to take it with food, as it can help to reduce nausea.<sup>10</sup>

You should take varenicline for the full 12 weeks of treatment, even if you have stopped smoking.<sup>4</sup>

Do not use nicotine replacement products while using varenicline. They do not work well together and it may increase unwanted side effects. The safety of using varenicline with bupropion (brand name Zyban or Prexaton) has not been tested and is not recommended.<sup>9</sup>

## Why may I still have cravings when using varenicline?

Cravings (the urge or desire to smoke) can be due to nicotine withdrawal. However, you may also have an urge or desire to smoke when you are in situations where you are used to smoking.

Certain things may trigger cravings, such as<sup>17</sup>:

- *places* where you normally smoke, such as home, work, or the pub
- *people* who you usually smoke with, such as family or friends; or being alone
- *habits or routines* where you are used to smoking, such as when drinking coffee or alcohol, talking on the telephone, after meals, or when you want to relax
- *emotions*, such as anger, boredom, being tense or upset; or for some people, when they are happy.

Quitting medications work best when you also reduce your triggers for cravings.<sup>18</sup> You need to understand why you smoke in order to plan how to cope in these situations. People most successful at resisting urges to smoke use a range of coping strategies to help them.<sup>17</sup> Making your home smokefree and getting rid of cigarettes in your home and car are helpful strategies.<sup>18</sup> Information, advice and support is available for the cost of a local call from the Quitline 13 7848.

## Side effects

### Common side effects

The most common side effect is nausea, affecting about three out of 10 people.<sup>3, 4</sup> This might be eased by taking varenicline with food, or your doctor may recommend reducing your dose.<sup>10</sup> Nausea is usually mild to moderate and fades with time.<sup>3</sup> Other side effects include stomach or bowel problems (e.g. constipation, gas, dry mouth, vomiting, indigestion), headache, dizziness, sleeping problems, unusual dreams, feeling tired, increased appetite and changes in taste.<sup>3, 4, 19</sup> They are usually mild and they generally appear in the first week of taking the medicine.<sup>4, 9</sup> Varenicline may cause other less common side effects.<sup>4</sup> Talk to your doctor or pharmacist if you have any symptoms that concern you.

### Serious side effects

Serious side effects related to varenicline are uncommon and very serious side effects are rare.<sup>3, 4, 9</sup> Symptoms of serious side effects are listed in the Consumer Medicine Information (CMI). If you have any of these symptoms, you need to tell your doctor as soon as possible. For very serious side effects, stop taking varenicline and go to hospital.<sup>4</sup>

Some people have reported changes in mood or behaviour when taking varenicline, usually within the first few weeks.<sup>4, 20</sup> These may include depression, agitation, aggression, thoughts of self harm, self harm, thinking about suicide, suicidal behaviour and hallucinations (seeing, hearing or sensing things that are not there).<sup>4</sup> If you have any symptoms that concern you, you should stop taking varenicline and seek medical advice as soon as possible.<sup>9</sup>

Symptoms can occur in people with no known history of mental illness.<sup>20</sup> You should let family members and close friends know that you are taking varenicline and ask them to be alert for unusual changes in your behaviour or mood.<sup>4</sup> Several people who have experienced unexpected behaviour changes also reported having sleep disorders, especially nightmares, from the beginning of varenicline use.<sup>20</sup> Although, it should be noted that having abnormal dreams is a common side effect of varenicline, while the risk of serious behavioural changes is low.<sup>3</sup> Varenicline may worsen symptoms in people with certain types of mental illness, so it is important to discuss your history with your doctor before taking varenicline.<sup>4, 9</sup>

It has been difficult for researchers to prove whether varenicline is a cause of these mood and behaviour symptoms, as they are not common and some symptoms may also be due to nicotine withdrawal. Also, people who smoke have two to three times the risk of suicide compared to non-smokers.<sup>3</sup>

One study found that there may be a small increased risk for heart attack or stroke in people with heart or cardiovascular disease when using varenicline, however this link has not been confirmed.<sup>3, 21</sup>

## Safety

The risk of serious side effects in varenicline users is low. For example, across 17 studies, 3.2% (32 in 1000) participants using varenicline reported serious health problems that required medical attention, while 2.4% (24 in 1000) participants in the group *not* taking varenicline had serious health problems. This research suggests that the risk of serious side effects among varenicline users may be one-third higher than in those not using the drug.<sup>3</sup>

The risk of serious side effects may be higher in people already affected by certain illnesses. A possible link between varenicline and serious mental health and cardiovascular problems, while not proven, cannot be ruled out.<sup>3</sup> If you have a history of mental illness, or of any other illness listed under *What I should tell my doctor* (above), you need to discuss the risks and benefits of varenicline with your doctor before you decide whether to use it. Family and carers of any person using varenicline should look out for mood and behaviour changes (read *Side effects* above).

Varenicline may make some people dizzy or sleepy. You need to know how it affects you before you drive a car, operate machinery, or do anything else that could be dangerous.<sup>4</sup> In the United States, workers such as pilots and truck drivers are banned from using this medicine.<sup>22</sup>

It is important to use varenicline correctly, with your doctor's supervision. Read the Consumer Medicine Information carefully and keep it until you've finished using the medicine. Never use any medication that has been prescribed for somebody else.

Taking too many tablets of varenicline can cause serious side effects. If you think that you or someone else may have overdosed, immediately call your doctor or the Poisons Information Centre (131126) for advice, even if there does not appear to be any effects. Or, go to hospital. Keep varenicline out of reach of children.<sup>4</sup>

## What do I do if I start smoking again despite using varenicline?

If you slip-up and have a puff or a cigarette, don't let it lead you back to full-time smoking. Keep using varenicline and re-commit to stopping smoking. Think of your reasons for quitting and what you have achieved so far. Talk to your doctor, pharmacist or call the Quitline if you want to discuss your smoking.

It is common for smokers to try to quit a number of times before successfully staying stopped, even when using quitting medications.<sup>1</sup> For many people re-adjusting to living without cigarettes is a learning process. It may take a while to figure out alternatives to cigarettes in certain situations.

## Where can I get more information?

- Your doctor is an important source of information, particularly if you have an illness, or you are taking any other medicines.
- Your pharmacist can give you advice about stopping smoking.
- Quitline 13 7848: Quitline advisors can help you with support, advice, information and a variety of resources, whether you have already quit or are just thinking about it.

## Online resources

The Quit website [www.quit.org.au](http://www.quit.org.au) provides a range of information that you can read, interact with and download. You can find out more about the Quitline, QuitCoach and QuitTxt.

The QuitCoach is a free interactive website that asks you a series of questions about your smoking, and then gives you advice about quitting which is tailored to your situation. To find out more go to [www.quitcoach.org.au](http://www.quitcoach.org.au).

QuitTxt provides regular SMS messages including tips and encouragement to help you keep on track throughout your quit attempt. To begin, all you need to do is register and complete a brief questionnaire at [www.quit.org.au/quittxt](http://www.quit.org.au/quittxt).

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