

medicineupdate

Asking the right questions about new medicines

Varenicline (Champix) – for quitting smoking

What this medicine is	1
What this medicine is for	2
Other ways to stop smoking	3
How well it works compared with other medicines	4
Important side effects to consider	5
How these side effects compare with other medicines	6
How to reduce your risk of side effects	7
What else you should know about this medicine	8
Who can be prescribed this medicine on the PBS	9
Other ways to help this condition	10
How new medicines are tested and approved for use in Australia	11

get to know your medicines

to find out more about this medicine

- call Medicines Line on 1300 888 763 to speak to a pharmacist (Mon-Fri 9am-6pm EST – cost of a local call, mobile calls more)
- read the Consumer Medicine Information (CMI) for this medicine (available from your doctor or pharmacist, the consumer section at www.nps.org.au, or from the manufacturer).



When you are considering a new medicine, it is important to weigh up the expected benefits and the possible risks of the new medicine, compared with other available medicines or treatments.

Remember that risks and benefits differ between medicines and from person to person.

Your doctor can help you compare different medicines and treatments to decide what is best for your particular situation.

1.
**What this
medicine is**

Varenicline (pronounced **VA-ren-i-kleen**) is a tablet specifically developed to help people quit smoking.

The active ingredient is **varenicline** and the brand name is **Champix**.

The active ingredient attaches to the part of the brain where the nicotine in cigarettes normally attaches, and the active ingredient partially mimics the effects of nicotine.

It can work in two ways. One is by reducing cravings and other symptoms of nicotine withdrawal. Another is by decreasing the enjoyable effects of smoking – people may be less likely to smoke if smoking is less satisfying.

Varenicline does not contain nicotine and it is not addictive. You set a date to stop smoking and start varenicline 1 – 2 weeks before your quit date, as this will help reduce the enjoyable effects of smoking.

The active ingredient is the chemical in the medicine that makes the medicine work.

2.
**What this
medicine is for**

Varenicline is used together with counselling to help people stop smoking cigarettes. Every year, nearly half of all Australian smokers try to quit. However, less than 10% actually stop smoking for one month or more.

Smokers risk getting serious diseases such as emphysema, lung cancer, heart attack, stroke and gangrene. Smoking is bad for smokers and the people around them.

3. Other ways to stop smoking

People quit smoking in several different ways.

- The most common way is simply to quit — to go **cold turkey**. This usually involves planning to quit, setting a date and sticking to your guns. Other people just put out a cigarette and decide “never again”.
- **Counselling** can help, whether it be group counselling or individual counselling.
- **Nicotine replacement therapy**. Brands include Chemists’ Own Nicotine, Nicabate CQ, Nicorette and QuitX. Nicotine replacement therapy works by reducing cravings for nicotine, which is the most addictive ingredient in cigarettes. Nicotine replacement therapy is available as a lozenge, inhaler, gum, patch or micro-tab, and all forms are effective. It is recommended as the first treatment to try because it is safe for most people, and because doctors and pharmacists are experienced in its use.
- **Bupropion**. Brands include Bupropion-RL, Clorprax, Prexaton and Zyban SR. This tablet works differently to varenicline. It is known to affect levels of certain chemicals in the brain. It is roughly as effective as nicotine replacement therapy, but it has important side-effects and interactions with other medications that may make it unsuitable for some people.

While medicines play an important role in helping people quit, most people quit without medicines. Going cold turkey works for some people. Supportive counselling and the help of your family and friends can be vital. A doctor, pharmacist, practice nurse or Quitline advisor can give you important tips for success.

Talk with your doctor about all of the treatment options for quitting.

Call the Quitline on 131 848 or go to www.quitnow.info.au

4. How well this medicine works compared with other medicines

We don’t know if varenicline is better than nicotine replacement therapy because varenicline and nicotine replacement therapy have not been compared directly in clinical trials. They appear to be as good as each other.

There have been a number of trials comparing varenicline with bupropion or a placebo (sugar pill). In two important trials, varenicline was more effective than bupropion or a placebo. In one of those trials, a year after treatment started, 23% of people taking varenicline were not smoking, compared with 15% taking bupropion and 10% taking placebo.

It is not known how well varenicline works in the longer term.

5. Important side effects to consider

All medicines can have side effects. Sometimes the side effects are serious but most of the time they are not.

Varenicline is a new drug, so there may be side effects which are not yet known.

The most common side effect of varenicline is nausea, or a feeling of wanting to be sick, which affects about one in three people. It is usually mild to moderate and settles with time. Taking the tablets with food and a glass of water may help to reduce this.

Other side effects may include:

- difficulty sleeping
- abnormal dreams
- headache
- constipation.

Changes in mood and other psychological effects

It can be difficult to tell the difference between the side effects of varenicline and withdrawal from smoking. Withdrawal can cause an increase in irritability, the urge to smoke, depression and problems with sleeping. You may also experience these side effects when you stop taking varenicline at the end of your treatment.

It is important that you contact your doctor if you experience changes in your mood or unusual behaviour while you are taking varenicline. There have been recent reports from the USA about suicidal thoughts, aggression and unusual behaviours in some people taking varenicline. Some of these people had a previous psychiatric condition but others didn't. It is not clear if these mood effects are caused by varenicline, but it is important to discuss any such feelings with your doctor.

If you have a psychiatric condition, such as depression, bipolar disorder or schizophrenia, you should discuss this with your doctor when deciding whether to take varenicline. Varenicline has not been tested in people with psychiatric conditions, and there are a handful of reports of worsening psychiatric illness in some people who have taken it.

Drowsiness

Varenicline can cause drowsiness, so it is important to take care when you are driving or operating machinery until you know how varenicline affects you.

Who should not use varenicline

At this stage, varenicline should not be used if you are taking bupropion because the combination is not known to be safe or effective. Varenicline in combination with nicotine replacement therapy is probably safe, but is very poorly tolerated by smokers – nausea is a particular problem – and it cannot be recommended.

continued next page...

For a complete list of possible side effects, see the CMI leaflet for varenicline.

Talk to your doctor about the possible side effects of this medicine before you use it.

Always tell your doctor about any changes to your condition if you are taking a new medicine.

...continued

5. Important side effects to consider

Although there are no proven problems, if you have a serious or unstable medical or psychiatric condition it may be wise to use other ways of quitting until there is more specific information that varenicline is safe for people with such conditions.

Do not use varenicline if you are pregnant or breastfeeding, or are under 18.

Does varenicline cause weight gain?

Varenicline does not cause weight gain, but many people who stop smoking do put on a small amount of weight (2–4 kg on average). Your doctor can help you with ways to minimise unwanted weight gain during and after quitting smoking. Generally, exercising moderately is better than a very strict diet.

6. How these side effects compare with other medicines

The side effects of nicotine replacement therapy, such as hiccoughs, are usually short lived and minor. Different forms of nicotine replacement therapy can have different side effects. For example, the gum may cause stomach upset, and the patch may cause skin irritation.

Bupropion has some serious side effects, including allergic reactions and fits. It also has some less important effects, such as headache, difficulty sleeping, dry mouth and upset stomach, which usually settle with time.

At this stage, the more common side-effects of varenicline seem to be similar to the more common side effects of nicotine replacement therapy and bupropion. However, it is a new medicine and has not been used for long enough for anybody to know what all its side effects may be. That means it is also difficult to compare it to other medicines.

7. How to reduce your risk of side effects

Varenicline often causes nausea, and this may settle over time. Taking varenicline with food and a full glass of water may help reduce nausea. You will initially start with a low dose and gradually build up to the recommended dose of varenicline for quitting smoking. The instructions are on the packet. Tell your doctor if nausea is troubling you, or if it is stopping you from taking your medication — you may be able to adjust the dose.

It is important to tell your doctor if you have kidney disease, as you may need a smaller dose.

8. What else you should know about this medicine

Read the Consumer Medicine Information (CMI) leaflet.

Before you start taking a new medicine, you should read the CMI leaflet. The CMI leaflet will tell you:

- who should not take the medicine
- which medicines should not be taken at the same time (drug interactions)
- how to take the medicine
- the most possible side effects
- the ingredients.

continued next page...

Consumer medicine information leaflets are available for most prescription medicines.

...continued

8. What else you should know about this medicine

You can get the CMI for varenicline from:

- your doctor or pharmacist
- www.nps.org.au/consumers (click on 'Consumer Medicine Information' in the Quicklinks column on the left of the screen)
- Pfizer Australia Pty Ltd, the makers of varenicline, on 1800 675 229 or at www.pfizer.com.au.

9. Who can be prescribed this medicine on the PBS

You can be prescribed a 12-week course of varenicline on the PBS once each year if:

- you are an adult, and
- you wish to stop smoking, and
- you are enrolled in, or intend to enrol in, a comprehensive support and counselling program (your doctor, pharmacist or the Quitline can advise you on these).

You will need to visit the doctor twice to get two separate prescriptions – the first for four weeks and the second for eight weeks.

You will need to pay an amount towards the cost of each prescription. In January 2008, the patient contribution for each prescription was:

- \$31.30 for people without a concession card
- \$5.00 for concession card holders.

For people who pay concessional rates for their prescriptions, the cost to the Australian Government is \$97.78 for the first varenicline prescription, and \$115.19 for the second prescription. For people who do not pay concessional rates, the cost to the Government is \$71.48 for the first varenicline prescription, and \$88.89 for the second prescription.

10. Other ways to help this condition

The most important first step is to decide to quit. That is the key – you have to want to quit.

The next step is to plan how to do it. The Quitline or your doctor can help you increase your chance of success and help you learn from any past failures. Don't forget to ask your friends and family for support. Set a date – today, tomorrow or two weeks' time – and go for it.

There are a number of ways to quit smoking, and different methods work for different people. Approaches include:

- going cold turkey
- gradually reducing, then quitting
- getting counselling
- using nicotine replacement therapy or other medicines.

Those not confident about quitting immediately, can try to gradually reduce smoking, while using nicotine replacement therapy, with the aim of quitting in the future.

Quitting at any time helps – the health of people who quit starts to improve within days.

It often takes more than one attempt to be successful, even with all the best support and medicines. If the first attempt doesn't work, try again. It is worth it.

Most medicines prescribed by your doctor are covered by the PBS. This means that the Australian government pays part of the cost of your medicine.

You will need to pay the full price if the medicine is not available on the PBS, or is not available on the PBS for your specific condition.

For more information, contact the Quitline on 131 848 or get yourself an online quitting coach from www.quitcoach.org.au.

11.

How new medicines are tested and approved for use in Australia

Prescription medicines go through many tests and clinical trials before they can be prescribed in Australia. All medicines go through four types of tests for their effectiveness, side effects and safety:

- laboratory tests (not involving people)
- phase 1 clinical trials, typically with 20–80 healthy volunteers, to test the safety and dosage in people with normal physical health
- phase 2 clinical trials, typically with 100–500 volunteers with the condition, to test the effectiveness and safety
- phase 3 clinical trials, typically with 1000–3000 volunteers with the condition, to confirm the medicine’s effectiveness and find out more about its side effects.

Sometimes, less common side effects do not become obvious until large numbers of people have used the medicine.

The Therapeutic Goods Administration (Australia’s regulatory agency for medicines) checks these results before it approves the registration of the medicine for use in Australia.

Medicines are made available on the PBS if they are shown to be as good or better than other available medicines for the same condition.

Why Medicine Update?

Medicine Update lets you know about new drugs and new PBS listings. When medicines are new, less is known about their expected benefits and possible harms than for older medicines. It’s important to understand what evidence is available about both benefits and harms. Medicine Update provides balanced information to help you decide if a medicine is right for you.

Who wrote Medicine Update?

National Prescribing Service Limited (NPS), an independent, non-profit, government-funded organisation, wrote this information in consultation with consumers and health professionals

Who is it for?

Medicine Update is written for people who are thinking about a new medicine, or have had a medicine suggested or prescribed for them and want to find out more.

Date published: January 2008

Visit the NPS website to find out about our free activities and resources for consumers www.nps.org.au/consumers



National Prescribing Service Limited

ABN 61 082 034 393 | Level 7/418A Elizabeth Street Surry Hills NSW 2010 | PO Box 1147 Strawberry Hills NSW 2012
Phone: 02 8217 8700 | Fax: 02 9211 7578 | email: info@nps.org.au | web: www.nps.org.au

National Prescribing Service Limited (NPS) is an independent, non-profit organisation for Quality Use of Medicines, funded by the Australian Government Department of Health and Ageing.