

## Champix - Questions and Answers

### Dosage and Administration

#### **1. Can you cut the tablets in half?**

Champix tablets are film coated and are not scored. We do not recommend that Champix tablets are cut in half. We cannot guarantee the effectiveness of the product if the tablet is cut. We would suggest the patient discuss this with their doctor for further advice.

If the doctor does recommend that the tablets are cut in half, it would be best for the doctor/pharmacist to monitor the patient for any problems.

#### **2. Can you crush the tablets?**

Champix tablets are film coated. We do not recommend that Champix tablets are crushed. We cannot guarantee the effectiveness of the product if the tablet is crushed. We would suggest the patient discuss this with their doctor for further advice.

If the doctor does recommend that the tablets are crushed, it would be best for the doctor/pharmacist to monitor the patient for any problems

#### **3. Do you need to decrease dose based on weight? E.g, <49kg Zyban dose is decreased.**

Patients in the main clinical trials whose weight was less than 45.5kg were not included.

Our recommended dose for adults is:

Days 1 – 3:	0.5 mg one daily
Days 4 – 7:	0.5 mg twice daily
Day 8 – End of Treatment:	1 mg twice daily

For patients with severe kidney failure, their dose may be reduced. Patients should be advised to discuss concerns regarding dosing with their doctor.

#### **4. If a person continues smoking after taking Champix for 1-2 weeks do you continue taking Champix?**

Yes.

We recommend that patients set a quit date and then start Champix 1-2 weeks prior to this date.

If a patient slips up and smokes after their quit date, they should continue taking Champix. Keeping in mind that Champix works by reducing cravings and withdrawal symptoms, as well as reducing the pleasure obtained from smoking. These actions can continue to help the patient towards a successful quit attempt.

#### **5. Do people start cutting down smoking when taking Champix?**

We recommend that patients on Champix stop smoking 1-2 weeks after starting the medication. This allows time for the drug to build up in the body and start working. This means that during the time before the quit date, the patient can continue to smoke. Whether they reduce the amount they smoke gradually prior to the set quit date, or continue their smoking levels and then quit on the set date, is up to the patient.

**6. Do you have to continue smoking up until Day 8 to 14? Eg, Some patients with emphysema or other health conditions may be advised by their doctors to stop smoking ASAP.**

Although we recommend that patients stop smoking 1-2 weeks after starting Champix, some doctors may advise to stop smoking ASAP or immediately, due to particular health conditions. For these cases, it is up to the doctor and patient to discuss this quit date. Champix can still help to reduce their craving and withdrawal symptoms, as well as reduce the potential for relapse (by blocking the benefits of smoking whilst taking Champix).

**7. If a person takes a 2-3 day break from Champix, do they need to titrate back up to 1mg bd or just continue taking 1mg bd?**

We do not have any specific recommendations on this, the patient is best to check with their doctor.

**8. What if a person misses a tablet?**

Our CMI states that-

“If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the tablet that you have missed. Do not take a double dose to make up for a forgotten tablet. It is important that you take Champix regularly at the same time each day.”

**9. Should Champix be taken a certain number of hours apart? - Zyban is 8 hours apart**

Champix is recommended as a twice daily dose. We have not set specific times in the morning or evening for which the patient should take them. Usually for medicines which are recommended twice daily, this could be an approximate interval of 12 hours. We would suggest that patients try and take their Champix at approximately the same time each day.

**Drug Interactions.**

**10. Can Champix and Zyban be taken together because of their differing mechanism of action?**

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. It is unknown whether combining both smoking cessation aids will increase chances of quitting. Patients should be directed to discuss this with their doctor.

The Pharmaceutical Benefits Scheme (PBS) Authority criteria require that only ONE smoking cessation aid (i.e., Zyban OR Champix) be prescribed within a 12 month period. Therefore, if a doctor was to prescribe both treatments at the same time, the patient would need to pay for one of those treatments privately.

**11. Is there an interaction with alcohol? E.g, precautions with Zyban – decreased seizure threshold.**

There is no listed interaction between Champix and Alcohol in the Product Information. Patients with a history of alcohol abuse and dependence were not included in Champix clinical trials.

We have the following warning in the Champix CMI:

“Champix may cause dizziness and sleepiness in some people. Make sure you know how you react to Champix before you drive a car or operate machinery. As you are aware, alcohol can increase the effects of drowsiness and reduced co-ordination.” Patients should be advised to know how their medication and alcohol affects them prior to driving or operating machinery.

**12. If Champix is taken away from bedtime, is the insomnia less? Will it interact with coffee at bedtime?**

Insomnia was reported in 13.8 % of patients taking Champix in clinical trials.

Looking in the Zyban Product Information, Insomnia was reported in 40% of patients in their clinical trials.

At this point in time, we have not determined whether avoiding bedtime doses will reduce the incidence of insomnia. If a patient is affected by insomnia whilst taking Champix and it is worrying them, they should be recommended to discuss this with their doctor. FORWARD ADVERSE EVENT DETAILS (if possible) TO PFIZER AUSTRALIA OR ADRAC.

**13. Any interactions with psychoactive drugs (eg antipsychotics, antidepressants)?**

The specific interactions between Champix and these medications have not been studied. Importantly, we have not studied Champix in patients with a history of psychiatric illness. Based on Champix characteristics and clinical experience to date, Champix has no known clinically meaningful drug interactions. If a doctor decides to prescribe Champix in a patient with psychiatric illness, it should be done cautiously with regular monitoring of the patient's symptoms.

**14. Can someone take Champix and NRT together?**

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.

We wouldn't advise that patients take these in combination. In a small study, it was found that patients who used Champix and the NRT patch together, were more likely to experience side effects and their blood pressure also dropped.

## **Side Effects**

**15. Does Champix cause seizures?**

There is no clinical experience with Champix in patients with epilepsy. Refer to doctor.

**16. Does Champix have a better safety profile than Zyban?**

Both drugs have a different mechanism of action, and are hence likely to have different side effects and different incidence rates.

The treatment discontinuation rate was 11.4% for Champix compared with 9.7% for placebo. The most common side effects that have been reported for Champix are:

- Nausea (28.6% versus 8.8% for placebo)
- Headache (10.1% versus 8.4% for placebo)
- Insomnia (13.8% versus 10.6% for placebo)
- Abnormal Dreams (12.4% versus 4.5% for placebo)

**17. What does abnormal thinking mean (in the CMI)?**

There are many terms which fall under this category. Some include: not thinking clearly; unclear thoughts; bizarre thinking; dullness in thinking- fogginess; mind clouded; distant or vague thinking.

**18. Do people experience side effects when the 12 week course Champix is finished?**

At the end of treatment, discontinuation of Champix was associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of patients.

Patients who experience side effects after stopping the course of Champix should be advised to discuss them with their doctor.

**19. What about people with mental health issues?**

Champix is not an antidepressant.

Stopping smoking with or without treatment is associated with various nicotine withdrawal symptoms including: dysphoric or depressed mood; insomnia, irritability, frustration or anger; anxiety; difficulty concentrating; restlessness; decreased heart rate; increased appetite or weight gain.

We currently do not have any information regarding the safety and efficacy of Champix in this group of patients.

See also Q20 regarding suicide.

**20. In the real world, is there information about use in people with mental illness? - eg experience in USA**

There are a small number of case reports of Champix being used in patients with mental illness.

Please note that accumulated case reports cannot be used to estimate the safety of a medicine.

**21. Can you discuss the reports of suicide in patients who took Champix?**

Pfizer records spontaneous reports of side effects from consumers and healthcare professionals. Essentially, this means that all side effects reported to us from consumers and healthcare professionals are documented and monitored. Pfizer takes reports of all side effects seriously. We regularly report these side effects to the Therapeutic Goods Administration (TGA), regardless of causality. As a result, Pfizer has updated the Champix Product Information with the following:

The following adverse events have been reported during post-approval use of CHAMPIX. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

There have been reports of depressed mood, agitation, changes in behaviour, suicidal ideation and suicide in patients attempting to quit smoking while taking CHAMPIX. Smoking cessation with or without treatment is associated with nicotine withdrawal symptoms and the exacerbation of underlying psychiatric illness. Not all patients had known pre-existing psychiatric illness and not all had discontinued smoking. The role of CHAMPIX in these reports is not known.

## **Clinical Trials**

### **22. What behavioural support was provided to people on the clinical trials?**

All participants were dispensed study drug at the baseline visit (randomisation); and given *Clearing the Air: Quit Smoking Today* (available online: [http://www.smokefree.gov/pubs/clearing\\_the\\_air.pdf](http://www.smokefree.gov/pubs/clearing_the_air.pdf)), a smoking cessation self help booklet as a guide to the quitting process; and instructed to take their first dose the next day.

Brief (<10 minute), standardised, individual counselling was provided to assist in problem solving and skills training for relapse prevention following recommendations in the Public Health Service Clinical Practice Guideline (available online: [http://www.surgeongeneral.gov/tobacco/treating\\_tobacco\\_use.pdf](http://www.surgeongeneral.gov/tobacco/treating_tobacco_use.pdf)). This occurred at the baseline visit and at each weekly visit during the following 12 weeks. Each participant also received a 5-minute telephone call 3 days after the target quit date. At each weekly study visit, participants were asked about their use of cigarettes and other forms of nicotine since their last study visit and in the past 7 days.

Following the week 12 visit, participants completed a 40-week nontreatment follow-up period. Clinic visits were held at weeks 13, 24, 36, 44, and 52. Each clinic visit included brief smoking cessation counselling, assessment of cigarette and other tobacco use since the previous contact and over the previous 7 days, assessment of vital signs and expired carbon monoxide, and use of medications for smoking cessation. Brief telephone contacts at weeks 16, 20, 28, 32, 40, and 48 assessed cigarette and other tobacco use as well as use of medications for smoking cessation.

### **23. How many cigarettes were people smoking on average in the trials, and for how long?**

On average, the number of cigarettes smoked per day was around 22; and the number of years smoked was around 25 years.

### **24. Were any people in the trials cannabis users?**

No, people who were “Drug abuse or dependence within the past 12 months” were not included

## **Other**

### **25. Do nicotine receptors exist in all people?**

Yes, nicotine receptors (also known as acetylcholine receptors) are present in the brain, as well as many areas in the body. Champix works on a specific type of receptor which is involved in the cycle of nicotine addiction, within the brain.

### **26. Do you have to wait 12 months before you can take Champix if you have been on Zyban? - i.e. 12 months from starting the product**

The PBS Authority requirements for Champix mean that only ONE smoking cessation aid will be subsidised by the PBS in a 12 month period. This means that if a patient has received Zyban for example in June 2007, they will not be able to receive PBS subsidised Champix within this 12 month period.

If a patient did not wish to wait for this 12 month period, they are still able to receive Champix via a **private** prescription. This would require the patient to pay for the full price of the medication. For this group of patients, they are best to contact their pharmacist for a price. Pfizer Australia does not set the prices for our medications charged via pharmacy. Some

patients will have **private health insurance**. They should contact their health insurance provider to find out what percentage rebate (if any) they will receive.

This will change as of 1<sup>st</sup> March 2008, where ONLY 6 MONTHS is required between prescribing Zyban and Champix. Note that only one course of Champix will be authorised per year.

**27. Is there a support program in Australia? What is the duration of the program?**

My Time To Quit is a support program which has been developed for patients taking Champix. It is an online program which runs for 12-16 weeks.

**28. What are we doing to improve GPs' undertaking of the need for counselling support?**

Pfizer has sponsored several initiatives which are RACGP accredited to provide CPD points. These include "Clearing the Smoke" workshops, as well as online educational programs designed to improve knowledge and encourage a more proactive approach to smoking cessation.

**29. People will ask Why can't I have Champix now? - don't want to wait for 12 months because I've taken Zyban. Can we please provide Quitline with a suitable statement to communicate to smokers. People will ask Which one will I choose?**

The PBS Authority requirements for Champix mean that only ONE smoking cessation aid will be subsidised by the PBS in a 12 month period. This means that if a patient has received Zyban for example in June 2007, they will not be able to receive PBS subsidised Champix within this 12 month period.

If a patient did not wish to wait for this 12 month period, they are still able to receive Champix via a **private** prescription. This would require the patient to pay for the full price of the medication. For this group of patients, they are best to contact their pharmacist for a price. Pfizer Australia does not set the prices for our medications charged via pharmacy. Some patients will have **private health insurance**. They should contact their health insurance provider to find out what percentage rebate (if any) they will receive.

If patients ask Quitline: "Which one will I choose?" The patient needs to discuss this with their doctor to determine what form of smoking cessation aid is most suitable for them.

**30. Does a patient require a registration number from Quitline in order to get an authority prescription from the doctor for Champix?**

No. When a doctor applies for an authority prescription for Champix, they will be asked what form of comprehensive support or counselling program the patient will be receiving. The doctor only needs to provide the name of the support or counselling. They DO NOT need any registration numbers to prove to the PBS Authorities.

**31. What happens if a person only takes 4 weeks (or less) of Champix and then wants to take Zyban?**

They should discuss the benefits and risks of changing therapy with their doctor.

We do not have any information which discusses the efficacy when patients on Champix are switched to Zyban.

**32. Will there be other products like Champix in the future?**

We understand that there are some drugs which are still in their development stages which are claimed to work in the same way as Champix.

**33. What is the cost of Champix on a private prescription?**

Prices will vary from pharmacy to pharmacy. The cost to the patient can vary from \$350-450 for the 3 month course.

**34. What future studies will be happening with Champix?**

Patients with cardiovascular disease, mental illness, chronic obstructive pulmonary disease (COPD). There is also a registry study to determine the effect of Champix during pregnancy. Please note that as there is insufficient information on the safety of Champix during pregnancy, Pfizer does not recommend its use in women who are pregnant. This registry study collates data from doctors who have prescribed Champix during pregnancy. Pfizer is not specifically recruiting pregnant women to take part in this study.

References:

1. Champix® (varenicline tartrate) Approved Product Information [pfpchamt10907 Pfizer Australia Pty Limited
2. Champix® (varenicline tartrate) Consumer Medicines Information [pfcchamt10907] Pfizer Australia Pty Limited
3. Zyban SR® (bupropion hydrochloride) Product Information. eMIMS last update September 2007.
4. National Cancer Institute. Clearing the Air: Quit Smoking Today. Washington, DC: National Institutes of Health; 2003. NIH publication 03-1647.
5. Fiore MC, Bailey WC, Cohen SJ, et al. *Treating Tobacco Use and Dependence: Clinical Practice Guideline*. Rockville, Md: US Dept of Health and Human Services, Public Health Service; 2000.

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