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EPAR summary for the public

Champix

varenicline

This is a summary of the European public assessment report (EPAR) for Champix. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Champix.

What is Champix?

Champix is a medicine that contains the active substance varenicline. It is available as tablets (0.5 and 1 mg).

What is Champix used for?

Champix is used in adults to help them stop smoking.

The medicine can only be obtained with a prescription.

How is Champix used?

Treatment with Champix is more likely to succeed in smokers who are motivated to stop smoking and who are also receiving additional advice and support. Patients set themselves a target date for quitting and will usually start taking Champix one to two weeks before this date. Patients who are unwilling or unable to set a target date within one to two weeks could be offered the treatment first and then later choose their target date to fall within five weeks of starting treatment.

Treatment with Champix lasts for 12 weeks. The tablets are swallowed whole with water. In the first week the patient takes one 0.5 mg tablet once a day for three days, followed by one 0.5 mg tablet twice a day for four days. For the remaining 11 weeks of treatment, the patient takes one 1 mg tablet twice a day. Reduced doses may be used in patients who do not tolerate the medicine or who have kidney problems.

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For patients who have successfully stopped smoking after 12 weeks of treatment, doctors may choose to carry on treatment for another 12 weeks.

How does Champix work?

People who smoke become addicted to nicotine, a chemical in tobacco. Nicotine acts in the nervous system, where it binds to receptors and triggers the release of a chemical messenger, dopamine, which plays a part in the pleasure derived from smoking.

The active substance in Champix, varenicline, can bind to some of these receptors, the α4β2 nicotinic acetylcholine receptors. When binding to these receptors, varenicline acts in two ways: it acts like nicotine (partial agonist) and this helps to relieve craving symptoms, but it also acts against nicotine (antagonist), by taking its place, and this helps to reduce the pleasurable effects of smoking.

How has Champix been studied?

In two main studies 2,052 smokers received 12-week treatment with Champix, bupropion (another non-nicotine medicine) or placebo (a dummy treatment). The patients' target date for quitting was set at one week after starting treatment and the patients were followed up for a further 40 weeks after their treatment to see if they started smoking again. The main measure of effectiveness was the number of patients who had completely stopped smoking for four weeks (between week 9 and week 12 of the study), confirmed by laboratory testing of the patients' breath for signs of smoking.

Another study compared Champix with placebo in patients who were allowed to choose their own target dates for quitting, which could be between one week and five weeks of starting treatment.

What benefit has Champix shown during the studies?

In both studies, Champix was more effective than bupropion or placebo in helping patients to stop smoking. The percentage of patients who had not smoked at all during weeks 9-12 was 44% with Champix, 30% with bupropion, and 18% with placebo. More patients remained non-smokers after treatment with Champix than after placebo: 40 weeks after the end of the treatment period, the percentage of patients who were still non-smokers was 23% among those who had taken Champix, and 9% among those who had taken a placebo. The percentage in the patients who had taken bupropion was 16%.

In the study where patients were allowed to set their own target dates, Champix was also shown to be effective in helping patients to quit.

What is the risk associated with Champix?

The most common side-effects with Champix (seen in more than 1 patient in 10) are nausea (feeling sick), insomnia (difficulty sleeping), abnormal dreams, headache and nasopharyngitis (inflammation of the nose and throat). For the full list of all side effects and restrictions with Champix, see the package leaflet.

Why has Champix been approved?

The CHMP concluded that the benefits of Champix outweigh its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Champix?

A risk management plan has been developed to ensure that Champix is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Champix, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Champix

The European Commission granted a marketing authorisation valid throughout the European Union for Champix on 26 September 2006.

The full EPAR for Champix can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Champix, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2014.