



Questions on supply of nitrosamine-compliant, unlicensed varenicline: Information for patients

Background

Following the initial disruption to supply of varenicline (Champix) in June 2021 because of the presence of nitrosamines above the acceptable level of daily intake, Pfizer announced a wholesale and pharmacy recall of Champix in October 2021.

A nitrosamine-compliant, unlicensed varenicline supply is now available in the UK should your doctor wish to prescribe it for you and this briefing gives details of this medication and how it can be obtained.

We asked Thistle Pharma (who is the supplier of this unlicensed varenicline) several questions and their answers are reproduced in the following pages.

Varenicline: effectiveness and safety

Varenicline was licensed for use in England in 2006 and is available on prescription only. Compared to placebo varenicline has been shown to more than double long-term abstinence rates. Clinical trials indicate that varenicline is almost twice as effective as bupropion (Zyban) and is more effective than single forms of NRT.

A large randomised controlled trial (EAGLES) suggested that varenicline did not significantly increase the risk of neuropsychiatric adverse events compared to placebo or nicotine patch (Niquitin), in patients with or without a history of psychiatric disorder.

Reference: Anthenelli RM, Benowitz NL, West R, St Aubin L, McRae T, Lawrence D, Ascher J, Russ C, Krishen A, Evins AE. Neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine patch in smokers with and without psychiatric disorders (EAGLES): a double-blind, randomised, placebo-controlled clinical trial. *Lancet*. 2016 Jun 18;387(10037):2507-20. doi: 10.1016/S0140-6736(16)30272-0. Epub 2016 Apr 22. PMID: 27116918.

More information on varenicline, and other stop smoking medications can be found in the NCSCT stop smoking aids quick reference sheet:

https://www.ncsct.co.uk/publication_stop_smoking_medications_quick_reference.php

Information for patients

1. How does unlicensed varenicline differ from licenced varenicline? What does unlicensed mean?

The UK licensed presentation of your medicine is currently unavailable; however, the UK regulator (the MHRA) has consented to the importation of this US presentation of the same medicine to support UK patients with otherwise unmet need in the absence of the licensed brand. Although the product itself does not have a product licence (i.e., is unlicensed) in the UK, this US product is in English language labelling and contains the same active ingredient in the same strengths as the UK licensed brand which is unavailable.

Your doctor is prescribing this UK unlicensed varenicline to you because Champix® (the UK licensed version of varenicline) is currently unavailable and it is unknown when it will be available again for UK patients.

2. Is it safe to take?

In prescribing this UK unlicensed version of Varenicline, your doctor has considered the varied treatment options and determined that it is a safe and effective treatment for you.

Unlicensed medicines are only prescribed after careful consideration of other options available and whether there is otherwise an unmet need. Your doctor will have read information from medical publications supporting its use and may have taken advice from other experts and an unlicensed medicine will only be used if it is the most appropriate medicine for you and your specific clinical needs.

If you have any concerns about taking your medicine, please speak to your doctor or pharmacist. They can help you to make the right choice and it is important that they understand your concerns.

There may be other treatment options. Your doctor or pharmacist can talk to you about these options if you decide not to take an unlicensed medicine.

3. Will it work?

If your doctor prescribes an unlicensed medicine, they feel that it is a safe and effective treatment for you.

Unlicensed medicines are only prescribed after careful consideration of other options available. Your doctor will have read information from medical publications supporting its use and may have taken advice from other experts and an unlicensed medicine will only be used if it is the most appropriate medicine for you and your specific clinical needs.

If you have any concerns about taking your medicine, please speak to your doctor or pharmacist. They can help you to make the right choice and it is important that they understand your concerns.

There may be other treatment options. Your doctor or pharmacist can talk to you about these options if you decide not to take an unlicensed medicine.

4. How do I know which of the two doses to take and when?

The 0.5 mg tablets are white, and the 1 mg tablets are blue.

It's important that you always take the medicine how your doctor tells you and as it says on the medicines label.

5. What else do I need to know?

Sometimes it will take a little longer for the pharmacist to get you a supply of an unlicensed medicine when compared to a readily available licensed medicine

For supply solutions, your doctor or Pharmacist can contactus@thistlepharma.com