



## Questions on supply of nitrosamine-compliant, unlicensed varenicline: Information for individual stop smoking practitioners and other health and social care professionals

### 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 and this briefing gives details of this medication and how it can be obtained.

We asked Thistle Pharma 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 NCSCCT stop smoking aids quick reference sheet:

[https://www.ncsct.co.uk/publication\\_stop\\_smoking\\_medications\\_quick\\_reference.php](https://www.ncsct.co.uk/publication_stop_smoking_medications_quick_reference.php)

## Information for individual stop smoking practitioners and other health and social care professionals

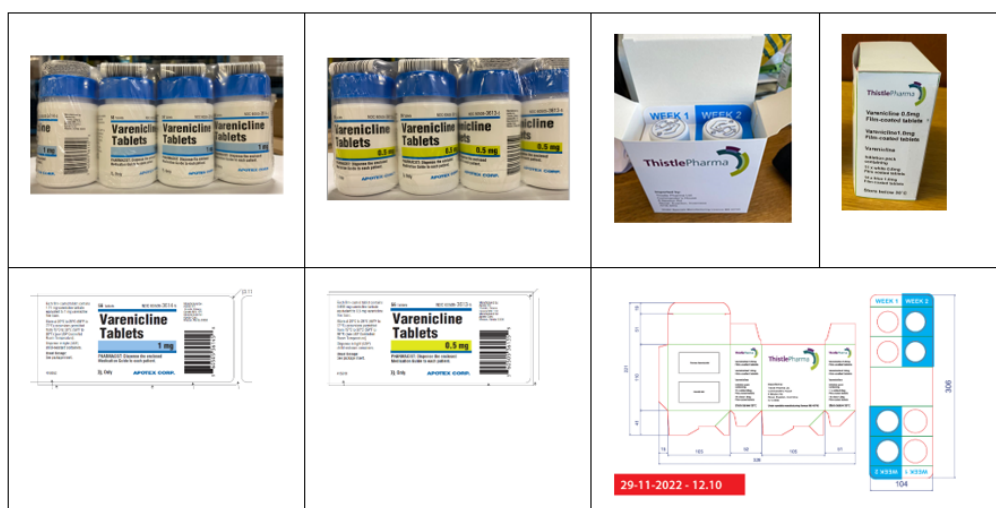
### 1. Are there any differences to Champix?

This is an “unlicensed” medicine. There is specific legislation regarding unlicensed medicines and their supply in the UK. Champix® is not currently available for use by patients in the UK and therefore unlicensed varenicline is available as an alternative where there is unmet need. Champix® contains the active ingredient varenicline. Varenicline is Champix®’s generic name.

### 2. What do the *Starter packs* and *Maintenance packs* look like? How do patients know what to take and when?

The starter packs consist of an outer carton with two amber glass bottles. One of these bottles contains 0.5 mg (white) tablets x11 and the other bottle contains 1 mg (blue) tablets x14. The bottles are clearly marked.

Maintenance packs are single bottles of 56 tablets of either 0.5 mg or 1 mg tablets, depending on the patient’s needs. These bottles are clearly labelled with their relevant strength.



The prescriber will determine what patients should take and when and this will be set out on the dispensing label on the pack concerned.

### 3. Is a patient information leaflet (PILs) included in the packs?

This is an unlicensed medicine, so no UK-Specific PIL has been developed for the starter packs, however, the US PIL is included with the maintenance packs

### 4. Where can I access the Summaries of Product Characteristics (SPCs) and PILs?

This is an unlicensed medicine, so consequently, it does not have an approved UK Summary of Product Characteristics (SmPC) or patient information leaflet (PIL). These are documents associated with medicines that have been licensed by the MHRA. However, the maintenance packs are presented with their US English language PIL which could be referenced.

Summary detail can be shared with physicians and Pharmacists on request via [contactus@thistlepharma.com](mailto:contactus@thistlepharma.com)

**5. Is it safe?**

Physicians and prescribers should only prescribe unlicensed medicines for patients, where they have been able to form a view that it is a safe and effective treatment for the patient with an unmet need.

The MHRA has given Thistle Pharma consent to import and supply this unlicensed medicine to support UK patient's unmet need following a review of all product quality documentation.

**6. Does the medication work in an identical way to Champix?**

The active ingredient in Thistle Pharma's product is identical to Champix®: varenicline. It therefore works in the same way as Champix®.

**7. Are there any materials / resources available for use with patients to help explain how to take the medication?**

These could be developed collaboratively on a service-by-service basis.

Please reach out to us at [contactus@thistlepharma.com](mailto:contactus@thistlepharma.com) to discuss.

**8. What is the side effect profile?**

The active ingredient in Thistle Pharma's product is identical to Champix®: varenicline. The side effect profile is expected to be in line with that of Champix®'s.

**9. Is there a process for analysing uptake, outcomes, adverse events, and cost?**

MHRA Yellow Card and ADR reporting applies to all UK unlicensed medicines. We will have distribution and site data and could develop an outcome data set otherwise re uptake etc., but this has not been costed.

Uptake and outcome reports could be developed collaboratively on a service-by-service basis. Should these be required, please reach out to [contactus@thistlepharma.com](mailto:contactus@thistlepharma.com).