Varenicline

Varenicline was introduced into the UK in August 2024 by Teva Pharmaceuticals, on behalf of Brown & Burk and Wave Pharma, as a licensed, prescription-only generic medication.

The two generic versions are simply called varenicline and:

- are nitrosamine-compliant
- are on the British National Formulary
- have identical Summaries of Product Characteristics (SPCs) to Champix

Following rigorous safety and compliance checks, a nitrosamine-compliant propriety version of varenicline (Champix) was reintroduced to the UK in July 2025 by Pfizer.

Generic varenicline and Champix do not differ pharmacologically. We refer to 'varenicline' throughout to refer to both generic varenicline and Champix.

Varenicline is a safe, effective and cost-effective treatment for smoking cessation in adults. It is a first-choice stop smoking aid and is recommended by NICE for the treatment of tobacco dependence.

Varenicline is one of the most effective treatments available to help people quit smoking. It is slightly more effective than combination NRT, and significantly more effective than single-form NRT and bupropion.

As an effective stop smoking aid, the reintroduction of varenicline is of huge benefit to people who want to quit smoking, and it widens the available choice of stop smoking aids.

Varenicline should be offered as a first-choice stop smoking aid, including for people with mental health problems. The other first-choice stop smoking aids are combination NRT, nicotine vapes and cytisinicline.

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Service actions for Integrated Care Boards, Commissioners, Local Pharmacy Committees, Pharmacy Leads and Local Stop Smoking Service Leads

Communicate widely to stakeholders, including pharmacies, stop smoking practitioners and General Practice surgeries, about the availability of varenicline and the actions that they need to take:

Action		✓
1.	Inform pharmacy colleagues of the availability of varenicline and ensure that they know how to order supplies.	
2.	Review Patient Group Directions (PGDs) to ensure that they are up to date. See the Resources section for an example PGD.	
3.	Make sure that all patient management systems include varenicline.	
4.	Ensure that Service Leads update local practice protocols (e.g. Standard Operating Procedures (SOPs) and Evidence-Based Intervention (EBI) service protocols) so that they refer to generic varenicline and Champix correctly.	
5.	Require that new stop smoking practitioners appointed since 2021 take the relevant NCSCT online courses and read the varenicline briefings, linked in the resources section.	
6.	Longer-serving staff can be pointed to the same resources to refresh their knowledge and skills.	
7.	Send out comms via social media and update service websites to include news of the availability of generic varenicline and the branded form, Champix, with an explanation of why they are available again and that they are nitrosamine compliant.	
8.	Ensure that all staff are aware of resources to support the use of varenicline (see the **Resources** section)	

A **Resources** section at the end of this briefing contains links that support these actions.

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Varenicline: a refresher

Varenicline works by reducing symptoms of withdrawal and blocking some of the 'rewarding' effects of smoking, making quitting easier and relapse less likely.

The treatment course is 12 weeks:

- Day 1–3: 0.5mg tablet, swallowed whole once daily after food
- Day 4–7: 0.5mg tablet, swallowed whole twice daily after food
- Day 8 onwards: 1mg tablet, swallowed whole twice daily after food

The quit date is usually between Day 8 and Day 14.

14-day prescription packs should be issued throughout the course, with weekly behavioural support for at least four weeks after the quit date, then fortnightly.

Patients who cannot tolerate the adverse effects of varenicline can have the dose lowered temporarily or permanently to 0.5mg twice daily.

A gradual approach to quitting smoking with varenicline should be considered for patients who are not able or willing to quit abruptly. Patients should reduce smoking during the first 12 weeks of treatment and quit by the end of that treatment period.

Dose tapering, to 0.5mg twice daily for two weeks, may be considered at the end of the course (normally 12 weeks) to prevent relapse.

For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment with varenicline at 1mg twice daily may be considered for the maintenance of abstinence. Patients should then continue taking varenicline for an additional 12 weeks for a total of 24 weeks of treatment.

Both 0.5mg and 1mg tablets are be available. A three-month NHS prescription pre-payment certificate at a cost of £32.05 is an option for people who pay prescription charges.

Varenicline is not licensed for people who smoke under 18 years of age or for pregnant women. Apart from this, it has no significant contraindications or side effects. Varenicline has no known drug interactions.

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Summary of Product Characteristics

Pfizer

Champix 0.5mg
https://www.medicines.org.uk/emc/product/266/smpc

Champix 1mg (maintenance pack)
https://www.medicines.org.uk/emc/product/7944/smpc

Champix 0.5mg and 1mg (initiation pack)
https://www.medicines.org.uk/emc/product/13451/smpc

Brown & Burk

Varenicline 0.5mg
https://www.medicines.org.uk/emc/product/100152/smpc

Varenicline 1mg
https://www.medicines.org.uk/emc/product/100136/smpc

Varenicline 0.5mg and 1mg
https://www.ncsct.co.uk/library/view/pdf/Brown-and-Burke-Varenicline-0-5mg-and-1mg.pdf

Wave Pharma

Varenicline 0.5mg
https://www.ncsct.co.uk/library/view/pdf/Wave-Pharma-Varenicline-0-5mg.pdf

Varenicline 0.5mg and 1mg
https://www.ncsct.co.uk/library/view/pdf/Wave-Pharma-Varenicline-0-5mg-ands-1mg.pdf

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Why Champix (varenicline) was previously taken off the market

Pfizer announced a wholesale and pharmacy recall of Champix in October 2021 after all Champix batches were found to contain levels of N-nitroso-varenicline above the acceptable level of intake set by the European Medicines Agency and the Medicines and Healthcare products Regulatory Agency.

N-nitroso-varenicline is a nitrosamine. Nitrosamines are classified as probable human carcinogens – substances that could cause cancer. Nitrosamines can be found at very low levels in water and foods, including cured and grilled meats, dairy products and vegetables. Nitrosamine impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time. Tobacco smoke contains high levels of nitrosamines called tobacco-specific nitrosamines (TSNAs) that are very potent carcinogens.

Champix was reintroduced to the UK market by Pfizer in July 2025. The newly available Champix complies with current nitrosamine limits set by regulatory authorities, ensuring it meets standards set by the European Medicines Agency and the Medicines and Healthcare products Regulatory Agency.

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Resources

NCSCT online Stop smoking aids module
The effectiveness of stop smoking aids can be increased through guidance and support from a trained stop smoking practitioner. This course focuses on how to maximise the effects of stop smoking aids.
https://elearning.ncsct.co.uk/stop_smoking_medications-launch

Varenicline: effectiveness and safety
This NCSCT briefing is intended as a resource for commissioners, managers and staff of stop smoking services and is set out as answers to a series of questions.
https://www.ncsct.co.uk/publications/Varenicline_effectiveness_and_safety

Cardiovascular disease and varenicline
This NCSCT briefing reports on two meta-analyses evaluating the association of cardiovascular serious adverse events with the use of varenicline. Based on the findings of these reviews, the risk of cardiovascular events associated with the use of varenicline is judged to be minimal and clinically insignificant.
https://www.ncsct.co.uk/publications/cardiovascular_disease_and_varenicline

See the varenicline and stop smoking aids resources sections of our site for further information:

> *NCSCT website: Varenicline*
> https://www.ncsct.co.uk/publications/category/varenicline
>
> *NCSCT website: Stop smoking aids resources*
> https://www.ncsct.co.uk/publications/category/stop-smoking-aids-resources

National Institute for Health and Care Excellence: Tobacco: preventing uptake, promoting quitting and treating dependence (NG209)
https://www.nice.org.uk/guidance/ng209

Nicotine receptor partial agonists for smoking cessation
A Cochrane Review which found high-certainty evidence for the efficacy of varenicline.
https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006103.pub9/full

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