



## Varenicline

Varenicline is being reintroduced into the UK by Teva Pharmaceuticals on behalf of Brown & Burk, and Wave Pharma. It is licensed and available as a prescription-only medication.

Varenicline is being introduced in August 2024 as a generic medication after the proprietary version (Champix) was withdrawn in October 2021.

The two generic versions are simply called Varenicline and:

- are nitrosamine-compliant
- are on the British National Formulary
- have unchanged Summary of Product Characteristics (SPC)
- will have limited supplies for the first couple of months
- will not have initiation (starter) packs for the first couple of months

Varenicline is a safe, effective and cost-effective treatment for smoking cessation in adults. It is a first line stop smoking aid and is recommended by NICE for 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.

The reintroduction of varenicline as an effective stop smoking aid will be of huge benefit to people who smoke and want to quit, and it widens the available choice of stop smoking aids.

Varenicline should be offered as a first-line stop smoking aid, including for people with mental health problems. Other first-line stop smoking aids are combination NRT, nicotine-containing vapes and cytisine.



## 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, the impending availability of varenicline and the actions that they need to take:

Action	✓
1. Inform pharmacy colleagues of the impending 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 example of PGDs.	
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 varenicline and not Champix.	
5. Require that new stop smoking practitioners appointed since 2021 take the relevant NCSCT online courses and read the varenicline briefings.	
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 reintroduction of varenicline, with an explanation of why it is available again and that it is nitrosamine compliant.	
8. Replace all stocks of materials containing reference to Champix and Pfizer with materials referencing generic varenicline as they become available. Communicate availability of new materials to relevant staff groups.	

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



## 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: 0.5 mg 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 1 mg 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.

For now, there will be no initiation pack meaning that two separate prescription items will be required for the first two weeks of treatment. Note: only registered pharmacists can split packs. Both 0.5mg and 1mg tablets will be available and there will be a dosing guide to support this. A three-month NHS prescription pre-payment certificate at a cost of £32.05 would be an option for people who pay prescription charges.

Varenicline is not licensed for people who smoke and are under 18 years of age, neither is it licensed for pregnant women. Apart from this, it has no significant contraindications or side effects. Varenicline has no known drug interactions.



## Summary of Product Characteristics

*Brown & Burk*

Varenicline 0.5mg

<https://mhraproducts4853.blob.core.windows.net/docs/76860842ec6329d6caf107ffb1df52b5de55fd04>

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Varenicline 1mg

<https://mhraproducts4853.blob.core.windows.net/docs/9cac3c4e4afa46411caae39b7b1a54e8f1f42293>

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Varenicline 0.5mg and 1mg

<https://mhraproducts4853.blob.core.windows.net/docs/24fbecf3a55e3115a4108a839a9955faaa988a5a>

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*Wave Pharma*

Varenicline 0.5mg

<https://mhraproducts4853.blob.core.windows.net/docs/5b2bdad89b50d21b21bf9ea0602c1493d4abbff9>

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Varenicline 0.5mg and 1mg

<https://mhraproducts4853.blob.core.windows.net/docs/bf8c80297d0926b71fabdf9c884978bf64a2c97a>

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## Why Champix (varenicline) was 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 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.



## Resources

### *NCSCT online Stop smoking medications module*

The effectiveness of stop smoking medications, and vapes, can be increased through guidance and support from trained stop smoking practitioners and this course focuses on how to maximise the effect of stop smoking medications.

[https://elearning.ncsct.co.uk/stop\\_smoking\\_medications-launch](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](https://www.ncsct.co.uk/publications/Varenicline_effectiveness_and_safety)

### *Cardiovascular disease and varenicline*

This NCSCT briefing reports on two recent 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](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>