

Varenicline (Champix) supply disruption: update and guidance on alternatives for clients

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

We understand that supply of varenicline will not recommence in the short term and that it could be many months, or longer, before Pfizer are able to guarantee supply of Champix.

New clients

Any new clients starting a quit attempt should be advised to use an alternative stop smoking product rather than begin a course of Champix at this time. Nicotine replacement therapy (NRT), specifically combination NRT which has a level of effectiveness similar to that of Champix, bupropion (Zyban) and nicotine-containing vapes (e-cigarettes) can all be considered.

Clients who used varenicline in the past

Some ex-clients who used Champix as part of their quit attempt in the past may contact you with concerns over nitrosamines.

Champix was withdrawn because batches of the medication had nitrosamines present above "acceptable levels of daily intake". Some nitrosamines may increase the risk of cancer if people are exposed to them above acceptable levels and over long periods of time. It is likely that the increased cancer risk from varenicline containing these higher levels of nitrosamines is very low given the limited time that someone would take Champix. Pfizer says that there are: "..very low potential risks, if any, posed by nitrosamine exposure from varenicline on top of other common sources over a lifetime."

Volatile (harmful) nitrosamines have been detected in some cured meat (primarily bacon), beer, cheeses and cosmetics. It is also worth remembering that **tobacco smoke contains high levels of nitrosamines called Tobacco-Specific Nitrosamines (TNAs) that are very potent carcinogens**.

Clients continuing to use varenicline

There may be a small number of clients who are still using Champix to help them maintain abstinence (i.e. they are using it long term) who will need help to use an alternative stop smoking medication. These clients may no longer be receiving support from you but may get in contact once they become aware that they are no further supplies of Champix available to them. There is little research evidence on switching from Champix to an alternative stop smoking medication, but many stop smoking practitioners will have been through this process with clients who have experienced side effects with Champix and have wanted to use nicotine replacement therapy (NRT) instead.

NRT would seem a reasonable alternative that can offer almost immediate relief of withdrawal symptoms and urges to smoke. NRT treatment may be with a single product or in the form of a patch in combination with a faster-acting product such as the nicotine lozenge, nasal spray or mouth spray. This switch can be done immediately without any safety issues, in fact Champix and NRT can be taken together in the short term. This is important because varenicline can take a few days to be eliminated from the body; clients should start NRT immediately upon stopping Champix, or shortly before their supply runs out so as to familiarise themselves with their NRT. Clients should be encouraged to use enough NRT to maintain abstinence from smoking. They should be reassured that NRT is an evidence-based stop smoking medication and that the change of treatment plan should in no way disadvantage them in their attempt to quit smoking.

Buproprion (Zyban) isn't an appropriate alternative for those clients already using Champix because of the lead time before a therapeutic dose is achieved. It needs to be taken for at least seven days (when the daily dose is increased from 150mg once a day to 150mg twice a day) before a planned quit date.

Some clients may choose to try **vaping** (either alone or in combination with NRT) as an alternative to Champix and if this is the case, they should be encouraged to see this as supportive of their attempt to maintain abstinence. This could be an opportunity to try direct supply of vapes (either as a one-off starter kit with the client purchasing further supplies for themselves, or as a longer course). A number of Stop Smoking Services already do this, with good results, and advice is available should you want to explore this option. As with NRT, **clients should use enough nicotine to prevent relapse to smoking** and should buy a product from a reputable retailer, taking advice on what to buy and how to use it. If they remain smokefree, they can be counted as a quit on your monitoring system. It is important to code this correctly so that the use of an Unlicensed Nicotine-Containing Product, with or without NRT, can be reflected in national data collection.