



Supply Disruption Alert

SDA/2021/006

Issued: 24 June 2021

Champix® (varenicline) 0.5mg and 1mg tablets – Supply Disruption

Summary

- All Champix® (varenicline) products are unavailable until further notice.
- Very limited residual stock may be available in pharmacies.
- Patients currently prescribed this treatment will require review and switching to nicotine replacement therapy (NRT) unless contraindicated.
- No new patients should be initiated on Champix® (varenicline) products.
- Prescribers initiating smoking cessation treatment for new patients should consider prescribing NRT or bupropion 150mg prolonged release tablets unless contraindicated.
- Helping a patient to stop smoking should not be delayed if they are motivated to stop as other effective options are available.

Actions

All healthcare professionals and trained Stop Smoking advisors in primary, secondary or specialist healthcare services involved in delivering smoking cessation services should ensure the following actions are undertaken.

For patients currently prescribed Champix® (varenicline) tablets, prescribers including those who supply the product via a Patient Group Direction for a Stop Smoking Service should:

- review all patients currently prescribed Champix® (varenicline) tablets and determine the length of treatment remaining;
- for those patients close to completing treatment, liaise with local pharmacy teams to understand local stock availability of Champix® (varenicline) tablets and signpost them appropriately;
- where supplies of Champix® (varenicline) tablets are available, then counsel these patients to provide assurance that any medicines dispensed to them are safe to continue use (see Counselling Points below);
- where supplies are unavailable, ascertain the nicotine dependency levels of patients currently on Champix® (varenicline) tablets and then prescribe NRT taking into consideration the patient's preferences and their required optimal therapeutic dose (see Resources and Counselling Points below).

For new patients, all providers of smoking cessation services should:

- avoid initiating new patients on Champix® (varenicline) 0.5mg and 1mg tablets;
- advise on alternative pharmacotherapy options including nicotine replacement therapy or bupropion 150mg prolonged release tablets taking into consideration patient preference, the individuals required optimal therapeutic dose and any contraindications to treatment.

Product details

The following varenicline products are affected:

- Champix® (varenicline) 0.5mg/1mg 2 week treatment initiation pack
- Champix® (varenicline) 0.5mg/1mg 4 week treatment initiation pack
- Champix® (varenicline) 0.5mg tablets
- Champix® (varenicline) 1mg tablets

Background

Pfizer, the sole supplier of Champix®, stopped the distribution of all Champix® (varenicline) 0.5mg and 1mg tablets in early June 2021. Pfizer are currently unable to confirm when resupplies will become available following global regulatory investigations relating to the presence of nitrosamine impurities above Pfizer's acceptable level of daily intake in several lots.

Pfizer have indicated *"for those patients currently prescribed Champix, we believe the benefits outweigh the very low potential risks, if any, posed by nitrosamine exposure from varenicline on top of other common sources over a lifetime."*

The Medicines and Healthcare products Regulatory Agency (MHRA), who are the regulators of medicines, have advised that batches currently in the market are not subject to a recall, at this stage. This is a developing issue and further updates will be provided as the investigation progresses. Patients are advised not to stop taking their medication prior to consultation with their doctor or pharmacist, as the health risk of discontinuing the medicine is higher than the potential risk presented by the impurity.

Counselling Points

All healthcare professionals and Stop Smoking advisors should be aware of the following when counselling patients:

- Champix® (varenicline) 0.5mg and 1mg tablets are currently unavailable due to product manufacturing and release delay due to product/ingredient testing. The manufacturer has taken precautionary measures to stop distribution whilst further testing takes place.
- Patients are advised not to stop taking their medication prior to consultation with their doctor or pharmacist.
- Where supplies are unavailable:
 - Advise on the possible re-emergence of symptoms of tobacco withdrawal (including an increase in irritability, urge to smoke, depression and/or insomnia) on discontinuation of Champix® (varenicline) tablets.
 - Advise that the right dose and/or combination of nicotine replacement therapy should prevent symptoms of tobacco withdrawal following discontinuation of Champix® (varenicline) tablets. Patients should return to their prescriber/advisor if these symptoms continue.
 - As varenicline is a non-nicotine treatment, after discontinuation of varenicline it may take a few days for the patient to readjust to the new levels of nicotine from NRT and clinicians should work with patients to titrate accordingly.
 - Explain the difference in the mechanism of action of varenicline, NRT and bupropion.

- Patients currently on Champix® (varenicline) tablets are advised not switch to bupropion 150mg prolonged release tablets, as switching to a starter dose of bupropion for up to 2 weeks would be suboptimal and risk a relapse (further information can be found [here](#).)

Resources

- Please refer to your local smoking cessation guidelines
- [BNF section: smoking cessation](#)
- [NICE CKS guidelines: smoking cessation](#)
- [NCSCT guidance on switching from Champix \(varenicline\) to an alternative stop smoking medication](#)

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Chief pharmacists
- Clinical governance leads
- Community hospitals
- Community midwives
- Community nurses
- District nurses
- Hospital pharmacies
- Hospital pharmacists
- Medical directors
- Mental Health Trusts
- Outpatient clinics
- Pharmaceutical advisors
- Pharmacists
- Risk manager

NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- Community pharmacists
- General practitioners

Enquiries

Send enquiries about this notice to the DHSC Medicine Supply Team, quoting reference number SDA/2021/006

Email: DHSCmedicinesupplyteam@dhsc.gov.uk