Department of Health & Social Care

Supply Disruption Alert

SDA/2021/006(U) Issued: 28 October 2021

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

Summary

This supply disruption alert update supersedes the previous update (SDA/2021/006) issued on 24 June 2021 and advises on the following:

- There is no date for resupply of Champix® (varenicline) or availability of varenicline products until further notice.
- The Medicines and Healthcare products Regulatory Agency (MHRA) initiated a class 2 medicines recall (EL 21 A/25) of all strengths of Champix® tablets (all in-date batches) on 14th October 2021 at pharmacy and wholesaler level.
- There are currently no alternative suppliers of varenicline tablets.
- 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 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.

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; and
- where patients have supplies of Champix® (varenicline) tablets, advise them to continue taking their medication until a consultation with their prescriber has taken place;
- determine which patients established on Champix® (varenicline) tablets require switching to an alternative product and ascertain their nicotine dependency levels; then

- prescribe nicotine replacement therapy taking into consideration the patient's preferences, their required optimal therapeutic dose and any contraindications to treatment. These patients should not be switched to bupropion 150mg prolonged release tablets (see Resources and Counselling Points below).

Regulatory Recall

In June 2021, Pfizer, the sole supplier of Champix®, stopped the distribution of all Champix® (varenicline) 0.5mg and 1mg tablets due to the presence of nitrosamine impurities above Pfizer's acceptable level of daily intake in several lots.

Since the original supply disruption alert (SDA/2021/006) was issued on 24th June 2021, the European Medicines Agency Committee for Medicinal Products for Human Use (EMA CHMP) have issued their decision on the acceptable limit of impurities to be present in varenicline products in Europe.

The MHRA advised that they have taken the decision to align with the CHMP's approach on acceptable limits of nitrosamines in varenicline products and initiated a class 2 medicines recall (EL 21 A/25) of all in-date batches of Champix® (varenicline) at pharmacy and wholesaler level. This is a precautionary measure due to presence of levels of N-nitroso-varenicline above the acceptable level of intake set by both European Medicines Agency (EMA) and MHRA.

Advice for healthcare professionals

- Please quarantine all remaining stock of the specified Champix batches and return them to your supplier using your supplier's approved process.
- Healthcare professionals should advise patients undergoing treatment to discuss any questions or concerns with their prescribing healthcare professional.

Parallel Import/Distributed products:

There are specified batches in the recall of Champix 1mg Film-Coated Tablets released for sale in the EU under the Marketing Authorisation of Pfizer Europe MA EEIG and parallel distributed by Drugsrus Limited and repackaged by P.I.E Pharma Ltd. For more information, please contact: Drugsrus Limited recall@drugsrus.co.uk, providing the batch number of the stock and the name of the parallel distributor on the over label on the pack.

- Champix 1mg Film-Coated Tablets, EU/1/06/360/015, EU/1/06/360/016

For batch numbers and further information, please see here.

Product details

The following presentations of Champix® are affected:

- Champix® (varenicline) 0.5mg/1mg film coated tablets
- Champix® (varenicline) 0.5mg film coated tablets
- Champix® (varenicline) 1mg film coated tablets

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 unavailable due to an impurity in the drug product and may not be available long term whilst the issue is being resolved.

- The MHRA advises patients 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. The effects of nitrosamines increases by continued administration of impacted product, over a longer period of time.

- There may be a small number of patients still taking Champix® tablets. These patients are advised not to stop taking their medication prior to consultation with their doctor or pharmacist. The following advice should be provided:

    - 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 to 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
- Pfizer's Champix Dear Healthcare Professional Letter

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 managers

NHS England Regional teams
CAS liaison officers for onward distribution to all relevant staff including:

- Community pharmacists

General Practice
For onward distribution to all relevant staff.

Enquiries

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

Email: DHSCmedicinesupplyteam@dhsc.gov.uk

Send regulatory enquiries to the MHRA Customer Services Team, quoting reference number SDA/2021/006(U)

Email: info@mhra.gov.uk