



Department of
Health

An Roinn Sláinte

Máinnystrie O Poustie

www.health-ni.gov.uk

For Action: Assistant Director Integrated Care, Head of Pharmacy and Medicines Management, HSC Board & BSO
Heads of Pharmacy and Medicines Management of HSC Trusts
Regulation Quality Improvement Authority

From: Chief Pharmaceutical Officer
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Our Ref: PHC-27-2021
Date: 14 October 2021

MEDICINES RECALL
CLASS 2 MEDICINES RECALL
Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Dear Healthcare Professional

Pfizer Limited

Product Name

Champix 0.5mg film-coated tablets

PLGB 00057/1554

Champix 0.5mg + 1mg film coated tablets

PLGB 00057/1555

Champix 1mg film-coated tablets

PLGB 00057/1556

Batch Number	Expiry Date	Pack Size	First Distributed
EX5767	31 Dec 2022	Champix 0.5mg 1x56	13 May 2021
DY1653	31 May 2022	Champix 0.5mg 1x56	20 Nov 2020
00022123	31 Aug 2022	Champix maintenance 2-week 1mg	03 Jan 2020
ED8501	31 Oct 2022	Champix maintenance 2-week 1mg	13 May 2021
ED8498	31 Oct 2022	Champix maintenance 2-week 1mg	08 Apr 2021
DX4579	31 Oct 2022	Champix maintenance 2-week 1mg	17 Dec 2020
DH2706	31 Jul 2022	Champix maintenance 2-week 1mg	31 Mar 2020
DK4800	31 Jul 2022	Champix maintenance 2-week 1mg	31 Mar 2020
DK4802	30 Jun 2022	Champix maintenance 2-week 1mg	31 Mar 2020

DL0986	31 Aug 2022	Champix maintenance 2-week 1mg	31 Mar 2020
DL0987	31 Aug 2022	Champix maintenance 2-week 1mg	14 Apr 2020
DL0988	31 Aug 2022	Champix maintenance 2-week 1mg	19 May 2020
DR4333	31 Oct 2022	Champix maintenance 2-week 1mg	29 May 2020
DR4334	31 Oct 2022	Champix maintenance 2-week 1mg	01 Oct 2020
ED8500	31 Oct 2022	Champix maintenance 2-week 1mg	11 May 2021
00021535	30 Jun 2022	Champix initiation 2 week 0.5&1mg	21 Jan 2020
DP3142	30 Nov 2022	Champix initiation 2 week 0.5&1mg	06 Aug 2020
EH7896	31 Dec 2022	Champix initiation 2 week 0.5&1mg	06 Apr 2021
DT1144	30 Nov 2022	Champix initiation 2 week 0.5&1mg	27 Oct 2020
DM0273	30 Nov 2022	Champix initiation 2 week 0.5&1mg	28 May 2020
00021134	31 May 2022	Champix maintenance 4-week 1mg	13 Nov 2019
00021135	30 Apr 2022	Champix maintenance 4-week 1mg	30 Oct 2019
EH5976	28 Feb 2023	Champix maintenance 4-week 1mg	19 Jan 2021
DH2705	30 Jun 2022	Champix maintenance 4-week 1mg	13 Mar 2020
DR1612	31 Oct 2022	Champix maintenance 4-week 1mg	21 May 2020
EA6772	31 Oct 2022	Champix maintenance 4-week 1mg	17 Sep 2020
EM4806	30 Nov 2022	Champix initiation 4 week 0.5&1mg	06 Apr 2021
EA6793	30 Nov 2022	Champix initiation 4 week 0.5&1mg	17 Dec 2020
DT1145	30 Nov 2022	Champix initiation 4 week 0.5&1mg	10 Jul 2020
00020444	31 Jan 2022	Champix initiation 4 week 0.5&1mg	02 Sep 2019
00022138	31 Mar 2022	Champix initiation 4 week 0.5&1mg	03 Jan 2021

Active Pharmaceutical Ingredient: **Varenicline Tartrate**

Parallel Import/Distributed products:

The below batches 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

Batch Number	Expiry Date	Pack Size	First Distributed
Job Number: J/262 Batch Number: DR2392	07/2022	28	09/07/2020
Job Number: J/263 Batch Number: DR2391	07/2022	28	27/06/2020
Job Number: J/546 Batch Number: DR2392	07/2022	28	28/07/2020
Job Number: L/090 Batch Number: DR2392	07/2022	28	16/04/2021
Job Number: L/091 Batch Number: DR2391	07/2022	28	16/04/2021
Job Number: L/092 or L799 Batch Number: DR1762	10/2022	28	16/04/2021
Job Number: J/245 Batch Number: DK4770	07/2022	56	12/08/2020
Job Number: J/246 Batch Number: DH2704	07/2022	56	27/06/2020
Job Number: L/800 Batch Number: EC8473	10/2022	56	22/01/2020
Job Number: J/328 or J/547 or J/997 Batch Number: DR1611	10/2022	56	22/09/2020

Active Pharmaceutical Ingredient: **Varenicline Tartrate**

Brief description of the problem

Champix (varenicline tartrate) is indicated for smoking cessation in adults. Upon request from MHRA, Pfizer Ltd are recalling the above batches (all stock) of products as 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. The recall is at pharmacy and wholesaler level.

Advice for healthcare professionals

- Please quarantine all remaining stock of the above 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.

See additional advice from the Department of Health and Social Care ([Link to Supply Disruption Alert](#)):

- 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.

Further Information

Pfizer is aware of the current supply constraints related to this product and is working to resolve the issue and resume manufacturing. Further updates relating to potential resupply will be communicated in due course.

If you have any questions, then please contact your local Service Centre Customer Services team.

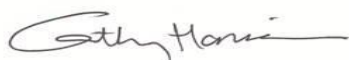
For medical information enquiries, please contact Pfizer Medical Information Department on 01304 616161.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this notice.

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Cathy Harrison', with a long horizontal flourish extending to the right.

Mrs Cathy Harrison
Chief Pharmaceutical Officer