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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

20 February 2025

Dear Healthcare Professional,

DRUG ALERT CLASS 3 – No 7 2025 – CLASS 3 MEDICINES RECALL – ACTION WITHIN 5 DAYS – PARALELL IMPORTS FROM THE ITALIAN MARKET – GLUCOPHAGE SR 500MG, 750MG & 1,000MG PROLONGED - RELEASE TABLETS

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team



MEDICINES RECALL

CLASS 3 MEDICINES RECALL, EL(25)A/07

Action within 5 days

Distribute to Pharmacy/Wholesaler Level Recall

MEDICINE DETAILS

Glucophage SR 500 mg, 750mg and 1000mg Prolonged-release Tablets

PL: Parallel Imports from the Italian market – see below

Active Ingredient: metformin hydrochloride

GLUCOPHAGE SR 500 MG PROLONGED-RELEASE TABLETS

Uni Health Distribution (Savio Industrial S.r.L.or Special Product's Line SpA) PLPI: 45396/0282

AFFECTED LOT BATCH NUMBERS

See Annex A

GLUCOPHAGE SR 750 MG PROLONGED-RELEASE TABLETS

Uni Health Distribution (Savio Industrial S.r.L.or Special Product's Line SpA) PLPI 45396/0209

Star Pharmaceuticals Ltd PLPI 20636/2830

B&S Healthcare PLPI 18799/3083

AFFECTED LOT BATCH NUMBERS

See Annex B

GLUCOPHAGE SR 1000 MG PROLONGED-RELEASE TABLETS

PilsCo Ltd. PLPI 39467/0487

Uni Health Distribution (Savio Industrial S.r.L.or Special Product's Line SpA) PLPI 45396/0253

Star Pharmaceuticals Ltd PLPI: 20636/2831

B&S Healthcare Limited PLPI 18799/3084

Quadrant Pharmaceuticals Limited PLPI 20774/1773

G Pharma Ltd PLPI 16369/1818

AFFECTED LOT BATCH NUMBERS

See Annex C

Background

The batches specified in Annexes A-C of the above products are being recalled by the Marketing Authorisation Holder in Italy and subsequent UK parallel distributor companies as a precautionary measure due to the product being manufactured with the incorrect grade of an excipient. The hydroxypropyl methylcellulose used in the manufacture had a viscosity level out of the authorised specification.

Advice for Healthcare Professionals:

Stop supplying the annexed batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Patients should be advised not to stop any treatments without consulting their relevant healthcare professional. The risks of suddenly stopping medication for type 2 diabetes is higher than the potential risk presented by the incorrect excipient used.

The recall impacts parallel imports from Italy only.

Advice for Patients:

No further action is required by patients as this is a Pharmacy and Wholesaler level recall. There have been no reports of patients being harmed or becoming ill from taking this medicine. Patients should continue to take medicines from these batches as prescribed by your healthcare professional.

Never stop taking medications used for treating diabetes without first seeking medical advice.

Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

Additional information:

For PilsCo Ltd. stock control enquiries please contact pmccourt@ethigen.co.uk

For Uni Health Distribution (Savio Industrial S.r.L.or Special Product's Line SpA) stock control enquiries please contact info@uhdltd.co.uk

For Star Pharmaceuticals Limited stock control and recall enquiries please contact recall@drugsrus.co.uk

For B&S Quality group and Customer Service enquiries please contact qa@bnshealthcare.com & customerservices@bnsdistribution.uk

For Quadrant Pharmaceuticals stock control and recall enquiries please contact Angeline.Rees@Maxearn.co.uk

For further medical information enquiries please contact: info@bruno.org

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk

Annex A

**Uni Health Distribution (Savio Industrial S.r.L.or Special Product's Line SpA)
Glucophage SR 500 mg Prolonged-release Tablets**

Batch No.	Expiry Date	Pack Size	First Distributed
231054/A	31/05/2026	60	31/05/2024
231055/A	31/05/2026	60	22/10/2024
231056/A	31/05/2026	60	22/10/2024
231058/A	31/05/2026	60	22/10/2024
231222/A	31/05/2026	60	22/10/2024
231223/A	31/05/2026	60	27/06/2024
W230272/A	31/03/2026	60	23/09/2024
W230395/A	28/02/2026	60	22/10/2024
W230395/B	28/02/2026	60	26/11/2024

Annex B

**Uni Health Distribution (Savio Industrial S.r.L.or Special Product's Line SpA)
Glucophage SR 750 mg Prolonged-release Tablets**

Batch No.	Expiry Date	Pack Size	First Distributed
241936/A	30/06/2027	30	20/12/2024
231053/A	31/05/2026	30	20/05/2024
232569/A	31/10/2026	30	08/10/2024
241940/A	30/06/2027	30	31/01/2025

Star Pharmaceuticals Limited Glucophage SR 750 mg Prolonged-release Tablets

Batch No.	Expiry Date	Pack Size	First Distributed
232573	31/10/2026	30	19/03/2024

B&S Healthcare Glucophage SR 750 mg Prolonged-release Tablets

Batch No.	Expiry Date	Pack Size	First Distributed
02X0942	30/09/2025	60	24/07/2024 08:44
02X0941	31/10/2025	60	12/07/2024 09:22
08X0842	31/10/2025	60	03/10/2024 09:51
12X0435	31/10/2025	60	03/01/2025 12:33
11X0220	31/10/2025	60	28/11/2024 12:30
09X0766	31/03/2027	60	17/10/2024 09:40
01Y0065	30/06/2027	60	13/01/2025 10:11
12X0460	30/06/2027	60	06/01/2025 16:58

Annex C

PilsCo Ltd. Glucophage SR 1000 mg Prolonged-release Tablets

Batch No.	Expiry Date	Pack Size	First distributed
W220067	31/05/2025	60	28/06/2022
W220412	31/03/2025	60	01/07/2022
220552	30/04/2025	60	29/08/2022
W221027	31/08/2025	60	09/12/2022
W221076	31/08/2025	60	28/12/2022
W221072	31/08/2025	60	10/01/2023
221600	30/09/2025	60	20/02/2023
W221468	30/11/2025	60	02/05/2023
W221468	30/11/2025	60	27/06/2023
W230048	31/01/2026	60	11/07/2023
222675	31/12/2025	60	26/07/2023
W230072	31/01/2026	60	28/07/2023
W230069	31/01/2026	60	03/08/2023
231090	31/05/2026	60	10/11/2023
W221073	31/08/2025	60	15/11/2023
231082	31/05/2026	60	01/12/2023
221748	30/09/2025	60	01/12/2023
W230531	30/04/2026	60	29/12/2023
W230521	30/04/2026	60	02/02/2024
W230753	31/05/2026	60	02/02/2024
W230750	31/05/2026	60	09/02/2024
231089	31/05/2026	60	09/02/2024
231671	31/07/2026	60	13/02/2024
W230769	30/06/2026	60	16/02/2024
240217	31/01/2027	60	02/08/2024
240445	28/02/2027	60	05/08/2024
233167	31/12/2026	60	08/08/2024
240104	31/01/2027	60	12/08/2024
240104	31/01/2027	60	23/08/2024
233170	31/12/2026	60	28/08/2024
240575	28/02/2027	60	10/09/2024
240215	31/01/2027	60	13/09/2024

240833	31/03/2027	60	13/09/2024
242158	31/07/2027	60	17/12/2024
242159	31/07/2027	60	20/12/2024
240445	28/02/2027	60	28/01/2025
242136	31/07/2027	60	28/01/2025
242217	31/07/2027	60	29/01/2025
242157	31/07/2027	60	13/02/2025
242164	31/07/2027	60	13/02/2025
242325	31/08/2027	60	13/02/2025
242862	31/10/2027	60	Not distributed

**Uni Health Distribution (Savio Industrial S.r.L.or Special Product's Line SpA)
Glucophage SR 1000 mg Prolonged-release Tablets**

Batch No.	Expiry Date	Pack Size	First Distributed
242264/A	31/07/2027	30	20/12/2024
W231072/B	31/10/2026	30	23/12/2024
242258/A	31/07/2027	30	24/01/2025
W231072/A	31/10/2026	30	09/09/2024
W231073/A	31/10/2026	30	28/10/2024
W231188/A	31/10/2026	30	28/10/2024
W231219/A	31/10/2026	30	16/09/2024
W240028/A	31/10/2026	30	08/10/2024

Star Pharmaceuticals Limited Glucophage SR 1000 mg Prolonged-release Tablets

Batch No.	Expiry Date	Pack Size	First distributed
W231065	30/09/2026	60	19/03/2024

B&S Healthcare Limited Glucophage SR 1000 mg Prolonged-release Tablets

Batch No.	Expiry Date	Pack Size	First distributed
07X1184	31/07/2026	60	22/08/2024 11:14
07X0725	31/12/2026	60	20/08/2024 07:47
07X1181	31/12/2026	60	30/08/2024 07:38
09X0247	31/12/2026	60	09/10/2024 17:24

Quadrant Pharmaceuticals Limited Glucophage SR 1000 mg Prolonged-release Tablets

Batch No.	Expiry Date	Pack Size	First Distributed
W220873	30/07/2025	60	24/03/2023
W221029	30/08/2025	60	30/03/2023
W221098	31/08/2025	60	29/03/2023
221603	30/09/2025	60	04/04/2023
W221332	31/10/2025	60	16/03/2023

G Pharma Ltd Glucophage SR 1000 mg Prolonged-release Tablets

Batch No.	Expiry Date	Pack Size	First Distributed
W220414	Mar 2025	60	23/08/2022
W220410	Mar 2025	60	23/08/2022
W220411	Mar 2025	60	26/08/2022
W220412	Mar 2025	60	05/10/2022
220553	Apr 2025	60	06/10/2022
W220504	Apr 2025	60	20/10/2022
W220502	Apr 2025	60	06/12/2022
W220590	Apr 2025	60	06/12/2022
W220513	Apr 2025	60	06/12/2022
W220585	Apr 2025	60	06/12/2022
220596	Apr 2025	60	08/12/2022
W220505	Apr 2025	60	09/12/2022
220597	Apr 2025	60	09/12/2022
W220413	Mar 2025	60	09/12/2022
W221069	Aug 2025	60	04/01/2026
W221073	Aug 2025	60	27/01/2023
W221031	Aug 2025	60	30/01/2023
W221039	Aug 2025	60	13/02/2022
W221072	Aug 2025	60	13/02/2023
W220870	Jul 2025	60	23/02/2023
W221119	Sep 2025	60	23/02/2023
W220874	Jul 2025	60	23/02/2023
W221074	Aug 2025	60	23/02/2023
W220848	Jul 2025	60	24/02/2023
W221031	Aug 2025	60	24/02/2023
W221098	Aug 2025	60	02/03/2022
W221103	Sep 2025	60	02/03/2023

MEDICINES NOTIFICATION

221601	Sep 2025	60	16/03/2023
221600	Sep 2025	60	16/03/2023
W221316	Oct 2025	60	16/03/2023
222552	Dec 2025	60	11/05/2023
W221425	Oct 2025	60	01/06/2023
W221426	Oct 2025	60	05/06/2023
W221319	Oct 2025	60	08/06/2023
W221331	Oct 2025	60	08/06/2023
W221112	Sep 2025	60	08/06/2023
W230077	Jan 2026	60	09/06/2023
W221070	Aug 2025	60	09/06/2023
221747	Sep 2025	60	15/06/2023
W230201	Feb 2026	60	22/06/2023
W230070	Jan 2026	60	22/06/2023
W221313	Oct 2025	60	22/06/2023
W221332	Oct 2025	60	22/06/2023
W221330	Oct 2025	60	22/06/2023
W230201	Feb 2026	60	22/06/2023
W230048	Jan 2026	60	11/07/2023
230451	Feb 2026	60	11/07/2023
W230078	Jan 2026	60	11/07/2023
222550	Dec 2025	60	13/07/2023
222395	Nov 2025	60	20/07/2023
222640	Dec 2025	60	22/07/2023
W221478	Dec 2025	60	25/07/2023
222552	Dec 2025	60	25/07/2023
W230077	Jan 2026	60	25/07/2023
222549	Dec 2025	60	25/07/2023
W230065	Jan 2026	60	27/07/2023
230567	Mar 2026	60	27/07/2023
W221327	Oct 2025	60	27/07/2023
W230191	Feb 2026	60	29/07/2023
230452	Feb 2026	60	02/08/2023
230453	Feb 2026	60	17/08/2023
W230202	Feb 2026	60	07/09/2023
230453	Feb 2026	60	22/09/2023
W230072	Jan 2026	60	11/11/2023
W230201	Feb 2026	60	20/11/2023

MEDICINES NOTIFICATION

231789	Jul 2026	60	11/01/2024
W230890	Jul 2026	60	12/02/2024
W230892	Jul 2026	60	12/02/2024
232331	Sep 2026	60	15/02/2024
232512	Oct 2026	60	27/02/2024
W230968	Sep 2026	60	27/02/2024
W230968	Sep 2026	60	28/02/2024
W230895	Jul 2026	60	01/03/2024
W230891	Jul 2026	60	01/03/2024
W230894	Jul 2026	60	01/03/2024
232333	Sep 2026	60	01/03/2024
232508	Oct 2026	60	01/03/2024
W230890	Jul 2026	60	01/03/2024
232510	Oct 2026	60	04/03/2024
232649	Oct 2026	60	22/03/2024
W231100	Sep 2026	60	26/03/2024
232333	Sep 2026	60	11/04/2024
W230969	Sep 2026	60	12/04/2024
W231102	Sep 2026	60	12/04/2024
232652	Oct 2026	60	12/04/2024
232509	Oct 2026	60	12/04/2024
W231069	Sep 2026	60	12/04/2024
W230767	Jun 2026	60	12/04/2024
W231070	Sep 2026	60	18/04/2024
W231071	Sep 2026	60	01/05/2024
W231189	Oct 2026	60	31/05/2024
W231191	Oct 2026	60	10/06/2024
240445	Feb 2027	60	15/08/2024
W231072	Oct 2026	60	11/10/2024