



Medicines & Healthcare products
Regulatory Agency

FMD ALERT*

CLASS 2

Action Within 48 Hours
Pharmacy / Patient Level Recall

Date: 27 June 2019

EL (19) A/15

Our Ref: MDR 123-05/19

Dear Healthcare Professional,

B & S Healthcare

Please see Appendix 1 for list of products and batch numbers

Brief details of issue:

It has recently come to our attention that medicines have been taken out of the regulated medicines' supply chain during distribution and later re-introduced. This means that the correct transport and storage conditions cannot be guaranteed during this period and, while unlikely, could impact their effectiveness. The products have been parallel imported into the UK by B & S Healthcare from Italy and have been re-labelled in B & S Healthcare livery. The same batches of products may have been parallel imported legitimately into the UK by other importers. Only those packs in B & S Healthcare livery are within the scope of this Alert. The products are believed to be legitimate. There is no evidence that they have been tampered with and these medicines are stable at room temperature.

Advice for healthcare professionals:

- Please check your stocks of all the listed products for the relevant batches in B & S Healthcare livery. If any relevant packs are identified, please quarantine and return it to your supplier using your supplier's approved process.
- The MHRA has undertaken a medical assessment to determine whether there is any risk to patients. As a precautionary measure, three medicines are being recalled to a patient level because in the very unlikely event that these medicines are not fully effective there is a potential risk to patient safety. For these three particular medicines, whilst the likelihood of their effectiveness being compromised is low (because they are stable legitimate medicines), the consequences of a lack of effectiveness could be serious which is why we are treating them differently. If patients have any of these affected products, you should advise that they should continue taking their medicines and contact their GP practice to arrange a new prescription. Once they have a new prescription, patients should return the affected batches to their pharmacist.



- The three products that are being recalled to **patient level** are **Clexane 8000iu Injection 0.8ml; Neupro 4mg/24 hr patches; and Vimpat 100mg tablets**. We will use media, social media and will contact patient groups and charities, to help draw the attention of patients to the affected batches of these products.
- As a precaution, all other affected medicines are being recalled at **pharmacy level**. Again, you should advise patients to continue taking their medicines. If they have any of these affected products, they do not need to arrange a new prescription, but if they have any questions, they should speak to their GP or healthcare professional. The products being recalled at **pharmacy level** are: **Dovobet Gel, Incruse Inhaler, Provisacor (Crestor) 10mg Tablets, Seebri Breezhaler, Spiriva Inhalation Powder**.

Contacts for further information:

For general enquiries please contact B & S Healthcare customer services:

Email customerservice@bnshealthcare.com

For medical information enquiries please contact the B & S Healthcare medical information team:

Email medinfo@bnshealthcare.com

Recipients of this Alert should bring it to the attention of relevant contacts by copy of this letter. NHS Regional teams are asked to forward this to relevant clinics, general practitioners and community pharmacists.

Yours faithfully

Defective Medicines Report Centre
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Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6000



*Falsified Medicines Directive Alert

Falsified Medicines Directive (FMD) 2011/62/EU introduced new requirements to enhance the security of the European supply chain. Where the MHRA has identified risks to the security of the supply chain, FMD Alerts will be issued.

For further information about FMD and safety features, please see this [link on GOV.UK](#).



Appendix 1: Table of Products / batches

Product and Pack Size	Italian Batch Number	B & S Batch Number	Expiry Date	Date of First Distribution
Clexane 8000iu 0.8ml 1 x 10	7CK98A	04N0078	30-OCT-20	18-APR-18
Clexane 8000iu 0.8ml 1 x10	7CH63B	04N0016	30-JUN-20	11-APR-18
Clexane 8000iu 0.8ml 1 x 10	7CL23B	03N1722	30-OCT-20	22-MAY-18
Clexane 8000iu 0.8ml 1 x10	7CH36C	03N1721	30-JUN-20	11-APR-18
Clexane 8000iu 0.8ml 1 x 10	7CH77B	03N1721	30-JUN-20	11-APR-18
Clexane 8000iu 0.8ml 1 x 10	7CL82B	03N1720	30-NOV-20	11-MAY-18
Clexane 8000iu 0.8ml 1 x 10	7CL37D	03N1722	30-OCT-20	22-MAY-18
Clexane 8000iu 0.8ml 1 x 10	8CA66C	03N1716	30-DEC-20	10-MAY-18
Dovobet Gel 1 x 30g	A80960	11N0735	30-JUL-20	06-DEC-18
Dovobet Gel 1 x 30g	A79729	11N0734	30-JUN-20	05-DEC-18
Dovobet Gel 1 x 30g	A85747	01P0222	30-OCT-20	09-JAN-19
Dovobet Gel 1 x 30g	A78018	01P0850	30-MAY-20	16-JAN-19
Dovobet Gel 1 x 30g	A80960	01P0221	30-JUL-20	09-JAN-19
Dovobet Gel 1 x 30g	A87671	02P1199	30-OCT-20	02-APR-19
Dovobet Gel 1 x 30g	A85936	02P1206	30-OCT-20	19-MAR-19
Dovobet Gel 1 x 30g	A85747	02P1207	30-OCT-20	29-APR-19
Dovobet Gel 1 x 30g	A88301	02P1205	30-NOV-21	15-MAY-19
Dovobet Gel 1 x 30g	A80960	02P1204	30-JUL-20	30-APR-19
Dovobet Gel 1 x 30g	A89721	04P0609	30-NOV-21	14-MAY-19
Dovobet Gel 1 x 30g	A90279	03P1677	30-DEC-21	12-APR-19
Dovobet Gel 1 x 30g	A85936	03P1679	30-OCT-20	14-MAY-19
Incruse Inhaler 55Mcg 1 x 30 Doses	R829935	06N0036	30-JUN-19	07-JUN-18
Incruse Inhaler 55Mcg 1 x 30 Doses	R834141	05N0506	30-SEP-19	21-MAY-18
Incruse Inhaler 55Mcg 1 x 30 Doses	R839098	05N0750	30-OCT-19	23-MAY-18
Incruse Inhaler 55Mcg 1 x 30 Doses	R838744	05N0659	30-OCT-19	22-MAY-18
Incruse Inhaler 55Mcg 1 x 30 Doses	R844186	05N0657	30-DEC-19	21-MAY-18
Incruse Inhaler 55Mcg 1 x 30 Doses	R851918	11N0754	30-MAR-20	27-NOV-18
Incruse Inhaler 55Mcg 1 x 30 Doses	R856773	11N0753	30-JUL-20	21-NOV-18
Incruse Inhaler 55Mcg 1 x 30 Doses	R853231	11N0755	30-MAR-20	21-NOV-18
Incruse Inhaler 55Mcg 1 x 30 Doses	R849465	11N0752	28-FEB-20	22-NOV-18
Incruse Inhaler 55Mcg 1 x 30 Doses	R853231	01P0344	30-MAR-20	09-JAN-19
Incruse Inhaler 55Mcg 1 x 30 Doses	R851918	01P0345	30-MAR-20	09-JAN-19
Incruse Inhaler 55Mcg 1 x 30 Doses	R856773	12N0071	30-JUL-20	07-DEC-18
Incruse Inhaler 55Mcg 1 x 30 Doses	R858970	01P0343	30-AUG-20	09-JAN-19
Incruse Inhaler 55Mcg 1 x 30 Doses	R856773	12N0808	30-JUL-20	31-DEC-18
Incruse Inhaler 55MCg 1 x 30 Doses	R852223	01P0344	30-MAR-20	09-JAN-19



Incruse Inhaler 55Mcg 1 x 30 Doses	R858970	02P1201	30-AUG-20	11-APR-19
Incruse Inhaler 55Mcg 1 x 30 Doses	R856773	02P1200	30-JUL-20	18-APR-19
Incruse Inhaler 55Mcg 1 x 30 Doses	R851918	02P1209	30-MAR-20	18-APR-19
Incruse Inhaler 55Mcg 1 x 30 Doses	R861997	03P0530	30-SEP-20	28-MAR-19
Incruse Inhaler 55Mcg 1 x 30 Doses	R860226	03P0991	30-AUG-20	27-MAR-19
Incruse Inhaler 55Mcg 1 x 30 Doses	R861997	03P0955	30-SEP-20	03-APR-19
Incruse Inhaler 55Mcg 1 x 30 Doses	R860226	03P1676	30-AUG-20	05-APR-19
Incruse Inhaler 55Mcg 1 x 30 Doses	R861997	03P1675	30-SEP-20	11-APR-19
Incruse Inhaler 55Mcg 1 x 30 Doses	R861997	04P1150	30-SEP-20	29-APR-19
Neupro 4mg/24hrs 1 x 28 Patches	56688403	05N0469	28-FEB-20	01-JUN-18
Neupro 4mg/24hrs 1 x 28 Patches	56679402	06N0592	30-JAN-20	14-JUN-18
Neupro 4mg/24hrs 1 x 28 Patches	56712404	10N1295	30-JUN-20	31-OCT-18
Neupro 4mg/24hrs 1 x 28 Patches	56722401	10N1292	30-JUL-20	02-NOV-18
Neupro 4mg/24hrs 1 x 28 Patches	56728403	10N1296	30-AUG-20	26-OCT-18
Neupro 4mg/24hrs 1 x 28 Patches	56722401	11N0650	30-JUL-20	23-NOV-18
Neupro 4mg/24hrs 1 x 28 Patches	56712403	11N0649	30-JUN-20	22-NOV-18
Neupro 4mg/24hrs 1 x 28 Patches	56742401	11N0651	30-NOV-20	06-DEC-18
Neupro 4mg/24hrs 1 x 28 Patches	56728403	11N0647	30-AUG-20	26-NOV-18
Neupro 4mg/24hrs 1 x 28 Patches	56712404	11N0648	30-JUN-20	26-NOV-18
Neupro 4mg/24hrs 1 x 28 Patches	56699404	04P1286	30-APR-20	14-MAY-19
Neupro 4mg/24hrs 1 x 28 Patches	56728403	01P0366	30-AUG-20	14-JAN-19
Neupro 4mg/24hrs 1 x 28 Patches	56742401	01P0314	30-NOV-20	09-JAN-19
Neupro 4mg/24hrs 1 x 28 Patches	56757104	04P1278	30-JAN-21	03-MAY-19
Neupro 4mg/24hrs 1 x 28 Patches	56763103	04P1279	30-JAN-21	03-MAY-19
Provisacor (Sold as Crestor) 10Mg Tabs 1 x 28	U733A	04N1584	30-APR-20	08-MAY-18
Provisacor (Sold as Crestor) 10Mg Tabs 1 x 28	U571A	05N0155	28-FEB-20	29-MAY-18
SEEBRI BREEZHALER 44mg 1 x 30 Doses	BFD79	04P0113	30-JUL-20	18-APR-19
Spiriva Inhalation Powder 18mcg Cap 1 x 30	802223	01P0226	28-FEB-20	09-JAN-19
Spiriva Inhalation Powder 18mcg Cap 1 x 30	804102	01P0227	30-MAY-20	09-JAN-19
VIMPAT 100MG TABS 1 X 56	254265	01P0324	30-APR-23	11-JAN-19
VIMPAT 100MG TABS 1 X 56	255279	02P1067	30-APR-23	19-MAR-19
VIMPAT 100MG TABS 1 X 56	258582	02P0892	30-JUN-23	25-MAR-19
VIMPAT 100MG TABS 1 X 56	254265	02P0893	30-APR-23	25-MAR-19