



DRUG ALERT

CLASS 2 MEDICINES RECALL

**Action Within 48 Hours
Pharmacy Level Recall**

Date: 22 October 2018

EL (19)A/28

Our Ref: MDR 055-06/19

Dear Healthcare Professional,

Pfizer Limited

Sayana Press 104mg/0.65ml

PL 00057 / 1093

medroxyprogesterone acetate suspension for injection

Batch Number	Expiry Date	Pack Size	First Distributed
L61367	31 January 2020	1	10 April 2015
L61367Y	31 January 2020	1	02 May 2016
T34580	31 July 2020	1	08 November 2017
X49124	30 June 2021	1	09 October 2018

Brief description of the problem

Pfizer Ltd has informed us of an issue related to the sealing process for some units of Sayana Press for subcutaneous (SC) injection potentially impacting the above listed batches. Sayana Press for subcutaneous (SC) injection is provided in a single-dose Uniject pre-filled injection system. During routine re-inspection of unreleased product batches, two related defects were observed;

- injectors with moisture outside the sealed area with a wet label, immediately after their removal from the pouch
- injectors with a temporarily unreadable expiry date on the unit label

The root cause analysis shows that the leak was attributed to a failure in the sealing process of the injection system and may impact the integrity of the product. Pfizer's health assessment of the issue concluded that the use of the impacted product has an unlikely probability of being associated with adverse events and the potential risk to patients is considered to be negligible.

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.

Returns will be credited for all impacted product(s) against a Pfizer validated account up to a 12-week time frame from the start of the recall. No credits will be processed after the 12-week time frame from start of this recall.

Please do not consolidate any stock for return. All returns must be from the original delivery address. Any product(s) returned from non-Pfizer accounts will be retained by the distribution center and not returned. Credit for these returned products must be obtained from the supplier from where the product was purchased.



Reporting of Suspected Adverse Reactions

You can assist us with monitoring the safety of Sayana Press 104mg/0.65ml by reporting suspected adverse reactions. Suspected adverse drug reactions (ADRs) should be reported via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Further Information

Pfizer is aware of the current supply constraints related to this product and is working diligently to resolve the issue and resume manufacturing.

If you have any questions in regards to return of stock, then please contact your local Alliance Healthcare Service Centre Customer Services team.

For medical information enquiries, please contact Pfizer Medical Information Department on +44 (0) 1304 616161.

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

Yours faithfully

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