MPS 2879
MMS 2056

HSC Business Services Organisation

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy / Wholesaler Level

Dear Healthcare Professional

Pfizer Limited

Depo-Medrone with Lidocaine 40 mg/mL (1 mL and 2 mL vials - single vial preparations) **PL 00057/0964**

Batch No	Expiry Date	Pack Size	First Distributed
EL4771	30 September 2022	1X1ML	23 January 2021
FK6842	31January 2023	1X1ML	4 December 2021
EK3997	31 May 2022	1X2ML	2 December 2020
FK6089	31 October 2022	1X2ML	23 October 2021
FN9557	31 August 2023	1X2ML	15 January 2022

Active Pharmaceutical Ingredient: Methylprednisolone acetate and Lidocaine hydrochloride

Brief description of the issue

Pfizer Limited have informed the MHRA that an outdated version of the Patient Information Leaflet (PIL) has been included in the packaging of the above mentioned batches of Depo-Medrone with Lidocaine (Methylprednisolone acetate and Lidocaine hydrochloride) 40 mg/mL 1 mL and 2 mL vials (single vial presentations) to the UK market.

The detailed differences between the incorrect (PAA115821) and correct (PAA123046) PILs are listed in the Table below:

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Section/Parameter	Incorrect leaflet PAA115821	Correct leaflet PAA123046
Warnings and precautions	-	**Peritonitis (Inflammation of the thin lining (peritoneum) around the gut and stomach).**
Pregnancy and breast-feeding	• If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine, as this medicine could slow baby's growth. • If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine, as small amounts of corticosteroid medicines may get into breast milk.	• If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine, as this medicine could slow the baby's growth. **There is a risk associated with low birth weight of the baby; this risk can be reduced by administering a lower dose of the medicine**. • If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine, **since lidocaine as well as** small amounts of corticosteroid medicines **are excreted** into breast milk.

- Additionally, the correct leaflet contains language regarding change of the frequency of several possible side effects from 'common' to 'not known'. This detailed information can be found in **Appendix 1**.

Advice for healthcare professionals

Healthcare professionals should ensure that appropriate patient counselling takes place and patients are aware of the missing information. The impacted product is within product specification and there is no issue with product quality.

Additionally, healthcare professionals should be aware of the risk associated with low birth weight of the baby if used in pregnancy – Depo-Medrone with Lidocaine Suspension for Injection - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk). This risk can be reduced by administering a lower dose of the medicine to patients who are pregnant. Healthcare professionals trained in the administration of this product should ask patients if they could be pregnant before receiving any doses.

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Pfizer has agreed to share copies of the printed PIL upon request and these can be sourced by contacting Pfizer Medical Information on 01304 616161 or via email at medical.information@pfizer.com.

The correct PIL can be found on Patient Information Leaflet (medicines.org.uk).

Advice for patients

Depo-Medrone with Lidocaine is injected by healthcare professionals to reduce inflammation in or near joints. Some batches of these medicines in the UK were supplied with an outdated Patient Information Leaflet. This leaflet is missing known information about the potential risks to the unborn baby of low birth weight if used during pregnancy. To reduce these risks, healthcare professionals should use a lower dose in patients who are pregnant. The leaflet is also missing information for patients about the symptoms of a possible side effect called peritonitis, an inflammation of the thin lining (peritoneum) around the gut and stomach.

This notification informs healthcare professionals about the missing information. [Patients should be given an updated Patient Information Leaflet so they are fully informed about side effects and what to do if they occur.]

Always tell a healthcare professional if you are pregnant or suspect you may be pregnant. They will be able to advise you on the benefits and risks of medicines to both you and the unborn baby.

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Further Information

If you have any questions, please contact Pfizer Medical Information Department on 01304 616161.

Recipients of this Medicines Recall 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.

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TO ALL CHEMISTS, DOCTORS ON THE LISTS

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