



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 21 April 2022

EL (22)A/18

Our Ref: MDR 240-03/22

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	31 January 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Pfizer Limited have informed the MHRA that an outdated version of the Patient Information Leaflet (PIL) has been included in the packaging of the above mentioned batches of Depo-Medrone with Lidocaine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:

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	<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> 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.

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.

Further Information

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

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

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DMRC@mhra.gov.uk



Appendix 1 - change of the frequency of several possible side effects from 'common' to 'not known'

Possible side effects		
Allergic reactions	Allergic reactions, such as skin rash, swelling of the face or wheezing and difficulty breathing. This type of side effect is rare, but can be serious.	Allergic reactions, such as skin rash, swelling of the face or wheezing and difficulty breathing or dizziness . This type of side effect is rare, but can be serious.
Side effect frequencies	The side effects may occur with certain frequencies, which are defined as follows: Common: may affect up to 1 in 10 people Not known: frequency cannot be estimated from the available data.	The side effects may occur with certain frequencies, which are defined as follows: Not known: frequency cannot be estimated from the available data.
Blood, heart and circulation:	Common: <ul style="list-style-type: none"> • High blood pressure, symptoms of which are headaches, or generally feeling unwell. • Slowing heart rate (bradycardia) Not known: <ul style="list-style-type: none"> • Problems with the pumping (...) 	Not known <ul style="list-style-type: none"> • High blood pressure, symptoms of which are headaches, or generally feeling unwell. • Slowing heart rate (bradycardia) (...)
Body water and salts	Common: <ul style="list-style-type: none"> • Swelling and high blood pressure, caused by increased levels of water and salt content. • Cramps and spasms, due to the loss of potassium from your body. In rare cases this can lead to congestive heart failure (when the heart cannot pump properly). 	Not known <ul style="list-style-type: none"> • Swelling and high blood pressure, caused by increased levels of water and salt content. • Cramps and spasms, due to the loss of potassium from your body. In rare cases this can lead to congestive heart failure (when the heart cannot pump properly).
Digestive system	Common: <ul style="list-style-type: none"> • Ulcers. • Vomiting (being sick) Not known: <ul style="list-style-type: none"> • Nausea (feeling sick) (...) 	Not known: <ul style="list-style-type: none"> • Ulcers. • Vomiting (being sick) • Nausea (feeling sick) (...)
Eyes	Common: <ul style="list-style-type: none"> • Glaucoma (raised pressure within the eye, causing pain in the eyes and headaches). • Cataracts (indicated by failing eyesight). Not known: <ul style="list-style-type: none"> • Swollen optic nerve (...) 	Not known: <ul style="list-style-type: none"> • Glaucoma (raised pressure within the eye, causing pain in the eyes and headaches). • Cataracts (indicated by failing eyesight). • Swollen optic nerve (...)
Hepatobiliary disorders	Methylprednisolone can damage your liver, hepatitis and increase of liver enzymes have been reported.	Not known <ul style="list-style-type: none"> • Methylprednisolone can damage your liver, hepatitis and increase of liver enzymes have been reported.
General disorders	Common: <ul style="list-style-type: none"> • Poor wound healing. • Irritability. Not known: <ul style="list-style-type: none"> • Feeling tired or unwell (...) 	Not Known: <ul style="list-style-type: none"> • Poor wound healing. • Irritability. • Feeling tired or unwell (...)
Hormones and metabolic system	Common: <ul style="list-style-type: none"> • Slowing of normal growth in infants, children and adolescents which may be permanent. 	Not known: <ul style="list-style-type: none"> • Slowing of normal growth in infants, children and adolescents which may be permanent.



	<ul style="list-style-type: none"> • Round or moon-shaped face (Cushingoid facies). • Diabetes or worsening of existing diabetes. <p>Not known: Irregular or no periods in women (...)</p>	<ul style="list-style-type: none"> • Round or moon-shaped face (Cushingoid facies). • Diabetes or worsening of existing diabetes. <p>Irregular or no periods in women (...)</p>
Immune system	<p>Common: Increased susceptibility to infections which can hide or change normal reactions to skin tests, such as that for tuberculosis.</p>	<p>Not known: Increased susceptibility to infections which can hide or change normal reactions to skin tests, such as that for tuberculosis.</p>
Metabolism and nutrition disorders	<p>Accumulation of fat tissue on localized parts of the body.</p>	<p>Not known: Accumulation of fat tissue on localized parts of the body.</p>
Muscles, bones and joints	<p>Common:</p> <ul style="list-style-type: none"> • Muscle weakness • Muscle twitching • Brittle bones (bones that break easily) <p>Not known:</p> <ul style="list-style-type: none"> • Broken bones or fractures. (...) 	<p>Not known:</p> <ul style="list-style-type: none"> • Broken bones or fractures. • Muscle wasting. • Breakdown of bone due to poor circulation of blood, this causes pain in the hip. • Joint pain • Torn muscle tendons causing pain and/or swelling. • Muscle cramps or spasms. • Swollen or painful joints due to infection. • Muscle weakness. • Muscle twitching. • Brittle bones (bones that break easily).
Nerves and mood issues	<p>Common:</p> <ul style="list-style-type: none"> • Steroids including methylprednisolone can cause serious mental health problems. These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like methylprednisolone. (...) 	<p>Not known:</p> <ul style="list-style-type: none"> • Steroids including methylprednisolone can cause serious mental health problems. These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like methylprednisolone. (...)
Skin	<p>Common:</p> <ul style="list-style-type: none"> • Acne. • Bruising. <p>Not known:</p> <ul style="list-style-type: none"> • Abscess, especially near injection sites. (...) 	<p>Not known:</p> <ul style="list-style-type: none"> • Acne. • Bruising. • Abscess, especially near injection sites. (...)