Direct Healthcare Professional Communication

28 February 2019

OZURDEX® 700 micrograms intravitreal implant (dexamethasone): Update on silicone particle issue: *Supply of new (defect-free) stock and recall of remaining stock in the market*

Dear Healthcare Professional,

Allergan Pharmaceuticals Ireland, Westport, Co. Mayo, Ireland in agreement with the European Medicines Agency and the Medicines and Healthcare products Regulatory Agency (MHRA) wishes to inform you of the following:

Summary

- **In October 2018, Allergan recalled certain batches of OZURDEX® product due to the potential for a silicone particle from the needle sleeve to be implanted into the eye during product administration.**
- **Following implementation of various preventative actions Allergan has now resupplied the market with new stock. Extensive testing of these batches has been undertaken by Allergan confirming that the actions taken are effective in preventing silicone particles being generated from the needle sleeve.**
- **All remaining packs of the batches of OZURDEX® listed in Attachment 1 are now being recalled and replaced with the new stock.**
- **OZURDEX® can now be prescribed to patients as required based on the re-supply of defect-free product. Monitoring of adverse events should be reported and managed as per your routine process.**

Background on the safety concern

During routine in-process testing of OZURDEX®, a loose particle of silicone was observed. The particle originated from the needle silicone sleeve. The silicone sleeve is an intrinsic part of the OZURDEX® product, and the particle is not an external contaminant. The particle size was approximately 300 microns in diameter. Subsequent testing of retained samples identified that batches distributed in the EU were affected; Allergan quarantined this stock and recall activities commenced in October 2018.

Allergan has implemented preventative actions for the issue and has commenced resupply of new OZURDEX® defect-free stock to the marketplace. The purpose of this letter is to advise that your market has now been resupplied with OZURDEX® product which has been manufactured following implementation of the preventive actions. Allergan's previous OZURDEX® notification provided an outline of any potential safety concerns associated with the presence of a silicone particle in the product. That notification provided an outline of potential patient symptoms and signs to be monitored post administration of OZURDEX®. Allergan recommended regular patient monitoring for the following:

- Uncontrolled or persistent inflammation in patients treated with the OZURDEX implant which are not in keeping with conventional disease course normally seen after treatment with intravitreal OZURDEX therapy.
- A permanent dense floater in the field of vision present more than 12 months after last OZURDEX treatment that is not attributed to underlying ocular diseases.
- Any signs of corneal adverse reactions associated with a small (~300 micron) foreign body in the anterior chamber that is not degrading.

- Any increases in intraocular pressure in patients who did not previously experience increased intraocular pressure with OZURDEX.
- Observation of a blue particle (~300 microns) in the vitreous or in the anterior chamber upon examination.

Allergan has now manufactured and supplied new stock to your market to ensure that sufficient product is available for patient use. Allergan, in association with the MHRA, requests that any remaining packs of the OZURDEX® batches listed in Attachment 1 should be returned. Please contact the Allergan point of contact below to confirm the required arrangements.

Call for reporting

Ozurdex is a medicine. Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle▼

It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789 or
- by downloading and printing a form from the Yellow Card website (see link above)

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

ADRs may also be reported to Allergan.

Company contact point

Phone: +44 (0)808 238 1500 Option 1
Email: ukcustomerservices@allergan.com

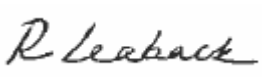
Adverse events: UK_Medinfo@allergan.com

You may also contact our medical information department at:

Allergan Ltd, Marlow International, The Parkway, Marlow, SL7 1YL, United Kingdom
Tel: +44 1628 494026
Email: UK_Medinfo@allergan.com

if you have any questions about the information contained in this letter or the safe and effective use of Ozurdex.

Yours Faithfully,



Richard Leaback
Country Medical Director

Attachment 1

Batches subject to Phase 2 of the recall

Batch	MFG Date	Exp Date
E77679	04/02/2016	04/02/2019
E78070	22/03/2016	22/02/2019
E78276	07/04/2016	07/04/2019
E78460	09/05/2016	09/05/2019
E79045	22/08/2016	22/08/2019
E81736	23/08/2017	23/08/2020
E82243	25/10/2017	25/10/2020
E82876	12/02/2018	12/02/2021