F. No. Imp/Misc/102/2018-DC
Directorate General of Health Services
Central Drugs Standard Control Organization
(Import and Registration Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 17.10.2018

DRUG ALERT

SUBJECT: Recall of OZURDEX® (Dexamethasone Intravitreal Implant 0.7mg) imported by M/S Allergan India Pvt. Ltd., Kasturba Road, Bangalore, Karnataka -Reg.

DRUG

OZURDEX® (Dexamethasone Intravitreal Implant 0.7mg)

BACKGROUND

M/S Allergan India Pvt. Ltd., Kasturba Road, Bangalore, Karnataka, India is registered with this directorate for import and marketing of OZURDEX (Dexamethasone Intravitreal Implant 0.7mg) manufactured by M/s. Allergan Pharmaceutical, Ireland.

OZURDEX (Dexamethasone Intravitreal Implant 0.7mg) is a single use, terminally sterilized implant for intravitreal injection. This product is a sustained-release, biodegradable implant containing the active dexamethasone, corticosteroid, and two biodegradable polymer excipients (resomer). OZURDEX is used to treat the following eye conditions: 1. Swelling of macula (macular edema) following branch retinal vein occlusion or central retinal vein occlusion. 2. Non infectious inflammation of the uvea (uveitis) affecting the back segment of eye. 3. MDE (diabetic macular edema).

The Swiss Agency for Therapeutic Products (Swissmedic), Switzerland's has recalled OZURDEX® (Dexamethasone Intravitreal Implant 0.7mg) due to the quality defect and faulty design of product and identified silicone particle generated from the silicone sleeve component on the needle of the applicator upon actuation of the Ozurdex® unit. This may cause potential risks to patients of obscuration of vision, intraocular inflammation, and/or corneal edema/damage and related consequences.

CDSCO has directed M/s Allergan India Pvt. Ltd., Bangalore to recall all defective lots/batches of OZURDEX® (Dexamethasone Intravitreal Implant 0.7mg) –imported for sale & distribution from the distribution channel up to retail and hospital level, and to stop the import of OZURDEX® (Dexamethasone Intravitreal Implant 0.7mg) registered with this Directorate with immediate effect.

The detail of affected batches imported into the country is as under:

Batch	Mfg Date	Exp Date
E78550	25-05-2016	25-05-2019
E79613	27-10-2016	27-10-2019
E81055	04-05-2017	04-05-2020
E82127	10-10-2017	10-10-2020

E82720	15-01-2018	15-01-2021
E82960	14-02-2018	14-02-2021
E83148	Mar-2018	Feb-2021

ADVERSE EFFECTS

Obscuration of vision, intraocular inflammation, and/or corneal edema/damage as potential risks have been identified. Further, while the potential effect of the injection of the silicone particle into the eye cannot be precisely determined, the European Medicines Agency (EMA) has concluded that due to the uncertainty, the potential risks outweigh the benefits of OZURDEX treatment for all batches known to contain the silicone particle.

ACTION BY

- Patients should talk with your health care professional if you have any question or concern.
- Health care professionals should stop treatment with OZURDEX® (Dexamethasone Intravitreal Implant 0.7mg) immediately, and are advised to consider alternative treatments.
- Distributors/Retailer should return all the above mentioned defective lots/batches of OZURDEX® (Dexamethasone Intravitreal Implant 0.7mg) immediately.

CONTACTS

- Central Dugs Standard Control Organisation, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, FDA Bhawan, Kotla Road, New Delhi-110002
  - Tel: 91-11-23236975/23236971
  - Fax: 91-11-23236973
  - Email: dci@nic.in
- M/s Allergan India Pvt. Ltd., Level 6 & 7, Prestige Obelisk No 3, Kasturba Road Bangalore-560001
  - Desk:+91.80.40707216
  - Fax: +91.80.40707007
  - Email: S_Thirumalaivelu@allergan.com
- M/s Allergan Pharmaceuticals Ireland, Castlebar Road Westport, Co. Mayo, Westport, County Mayo, (Ireland)
  - Tel: 353-9825222
  - Fax: 3539825791
  - Email: odonnell_pat@allergan.com