# Medicine Quality Alert: Class II Recall of Diprofos Injection (Betamethasone Dipropionate and Betamethasone Sodium Phosphate), 7mg/ml 2ml AMP MEA

Organon South Africa (Pty) Ltd is recalling batches; ***W005050, W012878, W015902, W020203, W025759, W030457*** & ***W032602*** of Diprofos Injection due to the use of a potentially corroded component in the manufacturing of the products which creates the potential for stainless steel particulates in the formulations.

From: Pharmacy and Poisons Board
Published: 06 February 2023

**Recall Reference Number:** REC/2023/001
**Recall Classification:** Class II
**Recall Level:** Retail/Facility level
**Manufacturer:** Schering Plough Labo N.V., Belgium
**Company Name:** Organon South Africa (Pty) Ltd
**Product name:** Diprofos Injection
**Active Pharmaceutical Ingredient:** 6.43 mg Betamethasone dipropionate equivalent to 5 mg Betamethasone and 2.63 mg Betamethasone sodium phosphate equivalent to 2 mg Betamethasone per ml of solution
**Affected Counties:** All

**Affected Batches**

| | Batch Number | Date Of Expiry | Pack Size |
|---|---|---|---|
| 1. | W005050 | 24.05.2023 | 2ml |
| 2. | W012878 | 02.09.2023 | 2ml |
| 3. | W015902 | 09.09.2023 | 2ml |
| 4. | W020203 | 20.10.2023 | 2ml |
| 5. | W025759 | 18.11.2023 | 2ml |
| 6. | W030457 | 30.12.2023 | 2ml |
| 7. | W032602 | 13.03.2024 | 2ml |

**Brief description of the problem**
Organon South Africa (Pty) Ltd is recalling batches ***W005050, W012878, W015902, W020203, W025759, W030457*** & ***W032602*** of Diprofos Injection due to the use of a potentially corroded component in the manufacturing of the product which creates the potential for stainless steel particulates in the formulations.

**Action for healthcare professionals**

Quarantine all remaining stock and stop further distribution, sale, issuing, and use of the affected batches immediately. You will be contacted by Imperial Managed Solutions to arrange for the return of the product.

**Action for patients and caregivers**
No further action is required by patients as this product is usually administered by healthcare professionals in a hospital setting, and the recall is a Retail/Hospital Pharmacy and Wholesaler/Distributor level recall.

**Further Information**
For stock inquiries please contact Imperial Managed Solutions by email at Quality.healthcare@imperiallogistics.com or via telephone at +254 719 059 178.

You are advised to promptly report any cases of adverse reactions and suspected substandard/falsified products to the nearest healthcare facility or through the following channels:

- https://pv.pharmacyboardkenya.org/users/mpublic
- USSD code at *271#
- Email pv@ppb.go.ke or pms@ppb.go.ke
- Telephone No. 0795743049

For any further information please contact the post-marketing surveillance unit at the Pharmacy and Poisons Board by email: pms@ppb.go.ke