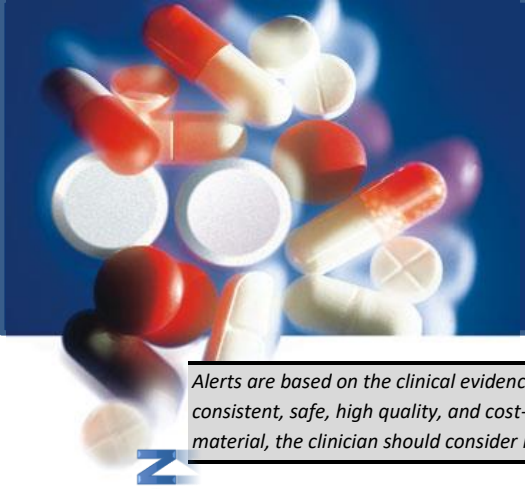

Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost-effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

PBM-2021-23 **May 12, 2021**

ITEM: **Cequa (cyclosporine ophthalmic solution) 0.09% Recall**

SPECIFIC INCIDENT(S): Sun Pharma is voluntarily recalling affected lots due to laboratory results that indicate a lower than expected assay and elevated levels of particulate matter.

GENERAL INFORMATION:

- Cequa ophthalmic solution is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).
- Affected product started shipping August 26, 2020 and is listed below.

Description	Lot #	Exp Date	NDC	UPC	Econo #
CEQUA OPHTHA SOL 0.09% UDV 60	10009	03/31/2022	47335050696	34733550696	3564275
	10006	01/31/2022			

- This alert is an extension of the product sequestration actions in **Product Recall Office (PRO) Log # 16169** (available at the NCPS VA Recalls desktop application).
- Providers should continue to report any adverse reactions with the use of Cequa (cyclosporine ophthalmic solution) 0.09% by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm , or by mail).

ACTIONS:

PROVIDER NOTIFICATION:

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., **Primary Care Providers, Ophthalmologists, and Pharmacy staff, including contract providers**, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).

PATIENT NOTIFICATION:

Chief of Pharmacy: Within 10 business days of issue (due 5/26/2021):

- Determine whether the affected product(s) was dispensed to any patient(s) for home use. CMOP data will be provided by CMOP representatives to Pharmacy Chiefs.
- If an affected lot(s) was dispensed to patient(s) for home administration, then:
  - Identify the patient(s).

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

- Contact the patient(s) who may have received the affected product(s) for home use by letter (or other means).
  - A sample letter can be found at: https://dvagov.sharepoint.com/:w:/r/sites/VHAPBM/Formulary/_layouts/15/Doc.aspx?sourcedoc=%7BB49A9262-448D-4BA9-BD67-46D201C8D379%7D&file=ASA%20Recall%20Patient%20Letter%20Template.doc&action=default&mobileredirect=true.
  - This template can be altered according to site-specific needs.
- Provide patient(s) who have received the affected product with a replacement product and instructions on the following:
  - Advise patients with affected lot number(s) on how to obtain replacement.
  - Patients with unused product should return it for replacement.
  - Patients should discontinue use of the affected product until they obtain replacement product. Local sites will need to work with patients to get them what is needed for their care in the most expedient way.
  - When the correct product is received, patients should begin using the new product.

- Communicate to PBM/VAMedSAFE that all impacted patients have been contacted via the NCPS VA Recalls desktop application.

SOURCE: McKesson

REFERENCE(S): McKesson Urgent Drug Recall. 21-060. 05/07/2021.

ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at VHAPBMPatientLevelrecalls@va.gov.