Central Drugs Standard Control Organization

Directorate General of Health Services
Government of India
(Medical Device Division)

Food & Drugs Administration Bhavan,
Kotla Road, New Delhi.

File No: 31-719-MD/2009-DC (Re.Reg.01) **Date:**

07 APR 2017

MEDICAL DEVICE ALERT

DEVICE

CE Half Day infusor 5.0 ml per h

The details of product are tabulated as below:

Name of Product	Batch No	Date of Mfg	Date of Expiry	Import License No	Imported by	Mfg by
CE Half Day Infusor 5.0 ml per h	16D016	15-04-2016	01-04-2021	MD-719-1274	M/s Baxter (India) Pvt.Ltd.,Plot No.70, A-26, Rama Road, Industrial Area, New Delhi-110015	M/s Baxter Healthcare Corporation, 17511 Armstrong Avenue, Irvine, CA 92614, USA
	16A017	18-01-2016	01-01-2021			
	14M013	11-11-2014	01-11-2019			

* All the above batches of CE Half Day Infusor 5.0 ml per h imported during November 2014 to April 2016, imported with shelf life of 5 years.

BACKGROUND

CE Half Day Infusor 5.0 ml per h is intended for patients requiring slow, continuous, intravenous, intra-arterial, epidural or subcutaneous administration or medications. Approval was granted with a shelf life of 3 years based on the documents submitted by the Indian agent/manufacturer.

PROBLEM

M/s Baxter (India) Pvt.Ltd.,Plot No.70, A-26, Rama Road, Industrial Area, New Delhi-110015 has imported the said product with a shelf life of 5 years; whereas approved shelf life is 3 years by CDSCO.

ACTION BY

- Medical Directors/Healthcare professionals

- Distributors and the Users
- Staff involved in the management of patients.

ADVERSE EFFECTS

Patients and Healthcare professionals are advised to report adverse events suspected to be associated with the use of CE Half Day Infusor 5.0 ml per h to the manufacturer, Importer and CDSCO.

CONTACTS

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