Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Market Withdrawal: Calcium Chloride Intravenous Infusion 10% w/v – 10mL (Prefilled Syringe)

Contact:
Consumer:
1-877-598-5705

Notice to health care providers: please check inventory and crash boxes and remove Calcium Chloride Intravenous Infusion subject to market withdrawal.

FOR IMMEDIATE RELEASE – July 13, 2015 – In April 2015, Mylan Institutional conducted a voluntary market withdrawal of 14 lots of Calcium Chloride Intravenous Infusion 10%w/v, packaged in 10 mL prefilled syringes (listed below). In June 2015, Mylan Institutional issued a second notification of the market withdrawal. We have recently become aware that some units of this drug may still be on the market. Please check your inventory and crash boxes, quarantine and discontinue distribution and use of these lots.

This market withdrawal was initiated as a precautionary measure due to the receipt of customer complaints citing difficulties in administration of the drug as a result of incompatibility between the syringe and certain needleless adaptors. The lots involved with this market withdrawal were distributed in the U.S. between March 19, 2014, and February 24, 2015. The Calcium Chloride product is packaged with an Agila and Amneal label. Amneal is a marketing partner with Agila for Calcium Chloride Intravenous Infusion 10%w/v, 10 mL prefilled syringes.

Calcium Chloride Intravenous Infusion 10%w/v is used as part of the resuscitation procedure following a cardiac arrest and for the treatment of low calcium levels. It is

also used for arrhythmias associated with hypocalcaemia, hyperkalaemia or hypomagnesaemia. Because of the use of Calcium Chloride Intravenous Infusion prefilled syringes in emergency situations, and its use as a lifesaving drug, difficulty in the administration of the drug could create a potential risk by prohibiting or delaying the administration of the medication.

PRODUCT

NDC	Name and Strength	Size	Lot #	Expires
53150-697-01	Calcium Chloride Intravenous Infusion 10%w/v	10 mL	7006979	April 2016
53150-697-01	Calcium Chloride Intravenous Infusion 10%w/v	10 mL	7006980	April 2016
53150-697-01	Calcium Chloride Intravenous Infusion 10%w/v	10 mL	7006981	April 2016
>53150-697-01	Calcium Chloride Intravenous Infusion 10%w/v	10 mL	7006990	April 2016
53150-697-01	Calcium Chloride Intravenous Infusion 10%w/v	10 mL	7007007	May 2016
53150-697-01	Calcium Chloride Intravenous Infusion 10%w/v	10 mL	7007008	May 2016
53150-697-01	Calcium Chloride Intravenous Infusion 10%w/v	10 mL	7007009	May 2016
53150-697-01	Calcium Chloride Intravenous Infusion 10%w/v	10 mL	7007010	May 2016
53150-697-01	Calcium Chloride Intravenous Infusion 10%w/v	10 mL	7007063	June 2016
53150-697-01	Calcium Chloride Intravenous Infusion 10%w/v	10 mL	7007064	June 2016
53150-697-01	Calcium Chloride Intravenous Infusion 10%w/v	10 mL	7007065	June 2016
53150-697-01	Calcium Chloride Intravenous Infusion 10%w/v	10 mL	7007066	June 2016
53150-697-01	Calcium Chloride Intravenous Infusion 10%w/v	10 mL	7007109	July 2016
53150-697-01	Calcium Chloride Intravenous Infusion 10%w/v	10 mL	7007118	July 2016

ACTION

1. Immediately examine your inventory and crash boxes, quarantine and discontinue distribution and use of these lots.
2. If you have the affected product, please contact Stericycle at 1-877-598-5705 to obtain the documentation packet for return of product.use
3. In addition, if you have further distributed the affected product, please identify your customers and notify them at once of this market withdrawal. The customer should be instructed to contact Stericycle at 1-877-598-5705 to obtain the documentation packet for return of product.
4. Additionally, Stericyle will notify your retail level customers that received the affected lots. Provide a list of customers via Microsoft Excel file to mylan5322@stericycle.com within 10 business days.

OTHER

This market withdrawal extends to the pharmacy/clinic level. Credit/check will be

issued for return of withdrawn product only.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: http://www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form http://www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This market withdrawal is being conducted with the knowledge of the Food and Drug Administration. For questions regarding the market withdrawal, please call Stericycle at 1-877-598-5705, Monday- Friday 8am-5pm EST. Any other product returned that is not involved with this market withdrawal will be destroyed and credit will not be issued. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.

Please see attached syringe label.

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RSS Feed for FDA Recalls Information [what's this?]

Photo: Product Label

Recalled Product Photos Are Also Available on FDA's Flickr Photostream.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

Contact FDA