



**URGENT: Edex® (alprostadil for Injection) 10mcg 2 pack carton
Lot 207386
PRODUCT RECALL**

24 February 2017

Dear Patient:

This is to inform you of a Product Recall involving the following:

Edex® 10mcg 2 pack carton (NDC 52244-010-02)	Expiration Date
Lot 207386	May 2019

See enclosed product label for ease in identifying the affected product. Please note that this Product Recall **ONLY** impacts the Edex® (alprostadil for Injection) 10mcg 2 pack carton (NDC 52244-010-02), Lot 207386, Expiration Date: May 2019.

This product recall was voluntarily initiated by Endo Pharmaceuticals Inc. due to the detection of a defect in the crimp caps used in the manufacture of this product lot. This defect has the potential to lead to a loss of container closure integrity, which could impact the product's sterility assurance.

The administration of non-sterile Edex (alprostadil for Injection) may lead to serious adverse events such as infections (both localized at the site of injection and systemically). The signs of infection at the injection site may include redness, warmth, pain, swelling, and pus. Systemic signs of infection may also include fever, sweating, generalized feeling of extreme tiredness, weakness, and shaking chills.

You should seek medical attention if you experience any of the symptoms listed above.

Endo began shipping this product on December 13, 2016 and shipments continued through February 13, 2017.

Examine any unused Edex (alprostadil for Injection) that you have been prescribed and immediately discontinue use of any product bearing the lot number 207386. Return any unused product with lot number 207386 by following the instructions below:

Instructions:

Please contact Inmar at 1-844-529-1586 Monday through Friday (9am to 5pm EST) or email Edex@inmar.com for the following :

- ***Product Return***
 - ***Upon contacting Inmar and indicating you have unused product, please expect Return Authorization labels and Shipping instructions.***
- ***Product Reimbursement***
 - ***Upon contacting Inmar, please be prepared to share proof of purchase.***
 - ***Proof of purchase can be sent to Edex@inmar.com or 635 Vine St. Winston Salem, NC 27101-Attention Recall Department, Edex Recall.***

If you have any questions regarding this recall, please call 1-800-462-ENDO (3636), between the hours of 8:00 a.m. to 8:00 p.m. EST Monday through Thursday and 8:00 a.m. to 6:00 p.m. EST on Friday.

This Product Recall is being made with the knowledge of the United States Food and Drug Administration (FDA).

Sincerely,

Christian Schell
Recall Coordinator
Endo Pharmaceuticals, Inc.
1400 Atwater Drive
Malvern, Pennsylvania 19355
United States