

Follow-On Biologics Workshop

Intro to Naming Discussion:

Neal Hannan

Attorney,

Federal Trade Commission



Should Adverse Event Reports Rely on Drug Name Only?

ENOXAPARIN SODIUM

INJECTABLE;INTRAVENOUS, SUBCUTANEOUS; 300mg/3mL (100mg/mL) – Vials

Drug Name	Active Ingredients	TE Code	Company	Labeler	NDC Codes
ENOXAPARIN SODIUM	ENOXAPARIN SODIUM	AB	SANDOZ INC	SANDOZ	0781-3122-93
LOVENOX	ENOXAPARIN SODIUM	AB	SANOFI AVENTIS US	SANOFI	0075-0626-04 0075-0626-03 0075-8030-01
LOVENOX	ENOXAPARIN SODIUM	AB	SANOFI AVENTIS US	WINTHROP (AUTHORIZED GEN.)	0955-1016-01

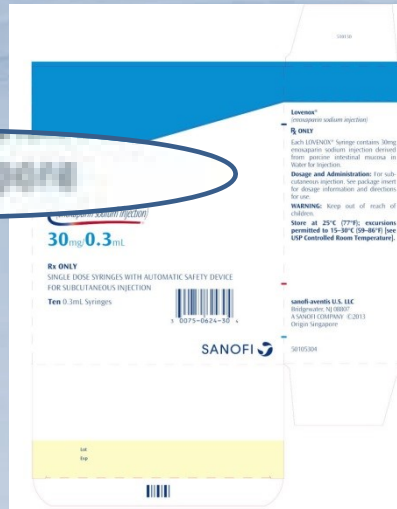
INJECTABLE;SUBCUTANEOUS; 30mg/0.3mL (100mg/mL) - Pre-Filled Syringes

Drug Name	Active Ingredients	TE Code	FDA Applicant	Labeler	NDC Codes
LOVENOX (PRESERVATIVE FREE)	ENOXAPARIN SODIUM	AP	SANOFI AVENTIS US	SANOFI-AVENTIS U.S. LLC	0075-0624-31 0075-0624-30 0075-8013-10
LOVENOX (PRESERVATIVE FREE)	ENOXAPARIN SODIUM	AP	SANOFI AVENTIS US	CARDINAL HEALTH	55154-4024-5 55154-4037-5
ENOXAPARIN SODIUM (PRESERVATIVE FREE)	ENOXAPARIN SODIUM	AP	SANOFI AVENTIS US	WINTHROP (AUTHORIZED GEN.)	0955-1003-10
ENOXAPARIN SODIUM (PRESERVATIVE FREE)	ENOXAPARIN SODIUM	AP	AMPHASTAR PHARM	WATSON PHARMA, INC.	62037-839-20
ENOXAPARIN SODIUM (PRESERVATIVE FREE)	ENOXAPARIN SODIUM	AP	SANDOZ	SANDOZ	0781-3119-63

Even for Branded Drugs, Are The Names Sufficient?



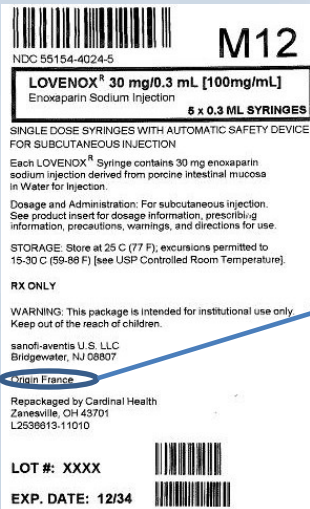
NDC
0075-0624-31



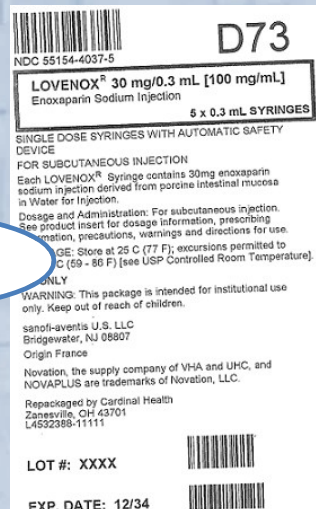
NDC
0075-0624-30



NDC
0075-8013-10



NDC
55154-4024-5



NDC
55154-4037-5

Is The Name Sufficient for Identifying a Biologic With Many Different NDC Codes?

NOT FOR SALE
NDC 0074-9374-71
2 Single-Use
Pre-filled Syringes

For Use In
Pediatric
Patients 15 kg
to < 30 kg

NDC 0074-9374-02
2 Single-Use
Pre-filled Syringes

For Use In
Pediatric
Patients 15 kg
to < 30 kg

HUMIRA[®] adalimumab

20 mg/0.4 mL
Syringe

FOR SUBCUTANEOUS USE ONLY

Rx only

Medication Guide for patient enclosed.
Needle Covers for Syringe Contains Dry Natural Rubber.
Carton contains 2 dose trays, 2 alcohol preps, 1 package insert, 1 Medication Guide and Instructions for Use.
Each dose tray contains 1 single-use pre-filled syringe with 27 gauge 1/2 inch length fixed needle.
The entire carton is to be dispensed as a unit.
Return to pharmacy if dose tray seal is broken or missing.
Do not accept if seals on top and bottom of carton are broken or missing.

abbvie

Pre-Filled Syringes
(Pediatric and Adult Doses)

NDC 0074-4339-06
**Crohn's Disease/Ulcerative Colitis
Starter Package**

NDC 0074-4339-07
Psoriasis Starter Package

NDC 0074-4339-71

NOT FOR SALE

4 Single-Use
Prefilled Pens

40 mg
FOR SUBCUTANEOUS USE ONLY

2 Single-Use
Prefilled Pens

HUMIRA[®] PEN (adalimumab)

40 mg / 0.8 mL
FOR SUBCUTANEOUS USE ONLY

Medication Guide for patient enclosed.
Needle Cover for Syringe Contains Dry Natural Rubber.
Carton contains 2 dose trays (each containing 1 single-use prefilled pen with 27 gauge 1/2 inch length fixed needle), 2 alcohol preps, 1 Package Insert, 1 Medication Guide and Instructions for Use.
The entire carton is to be dispensed as a unit.
Do not accept if seal is broken or missing.
Return to pharmacy if dose tray seal is broken or missing.
www.HUMIRA.com

abbvie

Medication Guide for patient enclosed.
Needle Cover for Syringe Contains Dry Natural Rubber.
Carton contains 2 dose trays (each containing 1 single-use prefilled pen with 27 gauge 1/2 inch length fixed needle), 2 alcohol preps, 1 package insert, 1 Medication Guide and Instructions for Use.
The entire carton is to be dispensed as a unit.
Do not accept if seals on top and bottom of carton are broken or missing.
Return to physician if dose tray seal is broken or missing.

Rx only

abbvie

Pre-Filled Pens
(including Crohn's Disease and Psoriasis Packages)

Do not accept if seal on top of carton is broken or missing.
One 40 mg Vial
NDC 0074-3797-01

40 mg/
0.8 mL

Humira[®] Adalimumab

40 mg/0.8 mL
For Subcutaneous Use Only
Single-Use Vial

Discard Unused Portion
For Institutional Use Only

ATTENTION PHYSICIAN:
Each patient is required to receive the enclosed Medication Guide

Rx only

abbvie

Vials

Adverse Event Reports Can Capture NDC Codes

U.S. Department of Health and Human Services
MEDWATCH
 The FDA Safety Information and Adverse Event Reporting Program

Form Approved OMB No. 0910-0043, Expires 03/31/15
 See FDA Submission website

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

Page 1 of 3

A. PATIENT INFORMATION

1. Patient Identifier
 2. Age at Time of Event or Date of Birth
 3. Sex
 4. Height

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

1. Adverse Event
 2. Date of Onset or Date of Report

6. Lot #
 #1
 #2

7. Expiration Date
 #1
 #2

9. NDC # or Unique ID

U.S. Department of Health and Human Services
MEDWATCH
 Form Approved OMB No. 0910-0043, Expires 03/31/15
 See OMB E.O. 12812 for details

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 #1
 #2

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 #1
 #2

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D. SUSPECT MEDICAL DEVICE

1. Brand Name
 2. Common Device Name
 3. Manufacturer Name, CDE and SIB

FDA 3500 - Voluntary Reporting For Medical Professionals

FDA 3500A - Mandatory Reporting For User-Facilities, Importers, Distributors, and Manufacturers

