URGENT VOLUNTARY RECALL: Hospital Level, June 18, 2024

Dodex® Injectable, Cyanocobalamin Injection, USP 1000 mcg/mL

Accord Healthcare, Inc. ("Accord Healthcare") is voluntarily recalling **multiple lots** of Dodex® Injectable, Cyanocobalamin Injection, USP 1000 mcg/mL, at the Hospital Level.

This recall is being initiated because out of specification results were observed during shelf-life testing of Dodex® Injectable, Cyanocobalamin Injection, USP 1000 mcg/mL at 24 months. The out of specification results were observed on the assay conducted on lot R2200476 of Dodex® Injectable, Cyanocobalamin Injection USP 1000 mcg/mL. The assay content of Cyanocobalamin Injection for this lot was observed to be 94.8%, which is outside of the specification range of 95.0% to 115.0 % of label claim. This means that the observed level of active ingredient in the product was below the approved specification when tested at 24 months, presenting a risk that the injection may deliver a subtherapeutic dosage of the active ingredient. A subtherapeutic dosage may result in longer treatment duration or recovery time for patients that are being treated for vitamin B12 deficiency. An impact assessment on other manufactured batches was conducted and in an abundance of caution, Accord Healthcare is voluntarily recalling all unexpired lots of Dodex® Injectable, Cyanocobalamin Injection, USP 1000 mcg/mL that have been released into the US market.

Please examine your inventory of Accord Healthcare's Dodex® Injectable Cyanocobalamin Injection, USP 1000 mcg/mL for the below listed lots carefully.

The product label for recalled products should have the following details. Please refer to the enclosed product labels included with this recall letter.

Item description	NDC #	Lot #	Mfg. Date	Exp. Date
Dodex® Injectable Cyanocobalamin Injection, USP 1000 mcg/mL	16729-533-08	R2200834	07/2022	06/2024
		R2200835	07/2022	06/2024
		R2200841	07/2022	06/2024
		R2200958	07/2022	06/2024
		R2201044	08/2022	07/2024
		R2201045	08/2022	07/2024
		R2201046	08/2022	07/2024
		R2201047	08/2022	07/2024
		R2201095	08/2022	07/2024
		R2201142	08/2022	07/2024
		R2201143	08/2022	07/2024
		R2201144	08/2022	07/2024
		M2215870	11/2022	10/2024
		M2215918	11/2022	10/2024

Hospitals - Please perform the following activities:

- Examine your inventory immediately for listed lots of Dodex® Injectable Cyanocobalamin Injection, USP 1000 mcg/mL.
- Immediately discontinue distribution of the recalled lots of Accord Healthcare's Dodex® Injectable, Cyanocobalamin Injection, USP 1000 mcg/mL.
- Promptly complete the attached recall stock response form and reply even if you have **NO** Product to return.
- If you do have Product to return, complete the attached recall stock response form, quarantine the stock and follow the instructions given on recall stock response form.
- If you have further distributed these lots to other retailers, please immediately contact your customers, advise them of the recall and have them return their outstanding recalled stock to you. Return this stock as per the instructions on the attached recall stock response form.

Your assistance is appreciated and necessary to prevent any potential health risk to the consumer.

Please complete and return the attached recall stock response form as soon as possible, but no later than five business days from receipt of this letter.

Accord is working with Inmar Inc. to complete this recall. This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is much appreciated.

Completed Recall Stock Response form should be mailed, emailed, or sent via FAX to INMAR,
Attn: Recall Coordinator, One West Fourth Street, Suite 500, Winston-Salem, NC 27101.
INMAR Email: rxrecalls@inmar.com. FAX: 817-868-5362.

INMAR will send you a Return Goods Authorization and shipping label. Appropriate credit for the returned product plus handling and shipping expenses will be issued to you upon receipt of the recalled product with the completed Return Goods Authorization. All recalled products returned without a Return Goods Authorization may delay the issuance of your credit.

We appreciate your assistance in this matter.

Sincerely,

Sabita Nair, RAC, ASQ-CPGP
Vice President – Regulatory Affairs
Accord Healthcare, Inc.
8041 Arco Corporate Drive, Suite 200
Raleigh, NC 27617
USA

Unvarnished area for pasting

accord

NDC 16729-**533**-08 **Sterile**

Dodex® Injectable
Cyanocobalamin Injection, USP

1,000 mcg/mL

For Intramuscular or Subcutaneous Use Only

Contains Benzyl Alcohol as a Preservative

25 x 1 mL Multiple-Dose Vials

Rx only

accord

NDC 16729-**533**-08 **Sterile**

Dodex® Injectable
Cyanocobalamin
Injection, USP

1,000 mcg/mL

For Intramuscular or Subcutaneous Use Only

Contains Benzyl Alcohol as a Preservative

Rx only

25 x 1 mL Multiple-Dose Vials

Manufactured for:
Accord Healthcare, Inc.,
Durham, NC 27703.

Manufactured by:
Intas Pharmaceuticals Limited,
Pharmez, Ahmedabad-382 213, INDIA.
Mfg. Lic. No.: G/28/1336

75 1977 0 729177

Varnish free area
for overcoding
40 x 40 mm

accord

NDC 16729-**533**-08 **Sterile**

Dodex® Injectable
Cyanocobalamin Injection, USP

1,000 mcg/mL

For Intramuscular or Subcutaneous Use Only

Contains Benzyl Alcohol as a Preservative

25 x 1 mL Multiple-Dose Vials

Rx only

Each mL contains:
Active Ingredient: Cyanocobalamin 1,000 mcg

Inactive Ingredients: Sodium chloride 4 mg; benzyl alcohol 15 mg; sodium acetate 0.41 mg; water for injection q.s.; pH adjusted with glacial acetic acid to a range of 4.5 to 7.0.

Contains no more than 200 mcg/L of aluminum.

For Intramuscular or Subcutaneous Use Only

Directions for Use: See Package Insert.

Store at 20°C to 25°C (68° to 77°F). [See USP Controlled Room Temperature].

WARNING: Protect from light.

INC5942_V1

accord

NDC 16729-**533**-08 **Sterile**

Dodex® Injectable
Cyanocobalamin
Injection, USP

1,000 mcg/mL

For Intramuscular or Subcutaneous Use Only

Contains Benzyl Alcohol as a Preservative

Rx only

25 x 1 mL Multiple-Dose Vials

Unvarnished area for pasting

accord

NDC 16729-**533**-08 Sterile

Dodex® Injectable
Cyanocobalamin Injection, USP

1,000 mcg/mL

For Intramuscular or Subcutaneous Use Only

Contains Benzyl Alcohol as a Preservative

25 x 1 mL Multiple-Dose Vials Rx only

Manufactured for:
Accord Healthcare, Inc.,
Durham, NC 27703.

Manufactured by:
Intas Pharmaceuticals Limited,
Ahmedabad-382 210, INDIA.
Mfg. Lic. No.: G/1026

Varnish free area
for overcoding
40 x 40 mm

10 11666 0
6000612

accord Sterile

NDC 16729-533-08

Dodex® Injectable
Cyanocobalamin Injection, USP

1,000 mcg/mL

For Intramuscular or Subcutaneous Use Only

Contains Benzyl Alcohol as a Preservative

25 x 1 mL Multiple-Dose Vials Rx only

accord

NDC 16729-**533**-08 Sterile

Dodex® Injectable
Cyanocobalamin Injection, USP

1,000 mcg/mL

For Intramuscular or Subcutaneous Use Only

Contains Benzyl Alcohol as a Preservative

25 x 1 mL Multiple-Dose Vials Rx only

Each mL contains:
Active Ingredient: Cyanocobalamin 1,000 mcg

Inactive Ingredients: Sodium chloride 4 mg; benzyl alcohol 15 mg; sodium acetate 0.41 mg; water for injection q.s.; pH adjusted with glacial acetic acid to a range of 4.5 to 7.0.

Contains no more than 200 mcg/L of aluminum.

For Intramuscular or Subcutaneous Use Only

Directions for Use: See Package Insert.

Store at 20°C to 25°C (68° to 77°F). [See USP Controlled Room Temperature].

WARNING: Protect from light.

INC5501_V1

accord Sterile

NDC 16729-533-08

Dodex® Injectable
Cyanocobalamin Injection, USP

1,000 mcg/mL

For Intramuscular or Subcutaneous Use Only

Contains Benzyl Alcohol as a Preservative

25 x 1 mL Multiple-Dose Vials Rx only

RECALL RESPONSE FORM

Product Recall Date: June 18, 2024 **Voluntary Recall: Hospital Level**

Item description	NDC	Lot	Quantity Returning (In Packs/vials/units)
Dodex® Injectable Cyanocobalamin Injection, USP 1000 mcg/mL	16729-533-08	R2200834	
		R2200835	
		R2200841	
		R2200958	
		R2201044	
		R2201045	
		R2201046	
		R2201047	
		R2201095	
		R2201142	
		R2201143	
		R2201144	
		M2215870	
		M2215918	

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Customer Name _____ DEA # * _____

**DEA # is required, if not provided the processing of your form will be delayed.*

Address _____

City _____ State _____

Zip _____

Contact Name (please print) _____ Telephone # _____

Contact Signature _____ Date _____

If you did not purchase the product directly from the Manufacturer, please complete the following section.

Purchased from: Name _____ DEA # _____

Address _____

City _____ State _____

Zip _____

Please check all appropriate boxes:

- ☐ I have read and understand the recall instructions provided in the letter.
- ☐ I have checked my stock and have quarantined inventory consisting of _____Packs/vials/units.

Any adverse events associated with recalled product?

☐Yes ☐ NO If yes, please explain: _____

Please describe your business: _____

I have checked my stock and:

_____Do not have any stock of recalled **items**.

OR

_____Have quarantined and listed in the box above the quantity of bottles/units of **Dodex® Injectable Cyanocobalamin Injection, USP 1000 mcg/mL** and will be returning them to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar will issue return authorization label(s).

Please indicate the number of box labels needed:_____

Please fax this form to 1-817-868-5362 or E-mail at: rxrecalls@inmar.com. Questions - 877-885-1936.