



Athenex Pharmaceutical Division, LLC. Unit-of-Use Change and Barcode Updates

Dear Valued Partner/Healthcare Provider:

PLEASE FORWARD THIS UPDATE TO THE SERIALIZATION OR INFORMATICS LEAD AT YOUR COMPANY

This letter outlines our plans for communicating the Unit-of-Use NDC changes and barcode updates for our products. The barcode updates are being made to facilitate compliance with the DSCSA and serialized data exchange.

Please note the following:

Per FDA expectations, Athenex Pharmaceutical Division, LLC. will be **using a new NDC on the Unit-of-Use when it is sold in a multi-pack** (unit of sale greater than one). This is driving the following changes:

- 1) Existing NDC numbers will be updated on the Unit-of-Use to differentiate them from the multi-pack cartons.
- 2) The Unit-of-Use barcode will be updated to reflect the new NDC.
- 3) Products sold in single-cartons will not be impacted by this change.
- 4) **The Unit-of-Sale NDC will not change. This is the NDC that is listed in the package insert and that is used when ordering the product.**

This transition will be phased in based on current manufacturing timelines over the next 24 months. Product specific changes are referenced in the attached chart (Attachment A). Products with these changes will soon be released to our distribution centers. This means you may receive product with the changes described above in the near future. The existing NDC labeled products will remain in the supply chain until inventory is depleted. Our distribution centers have been made aware of the new NDCs so either NDC can be referenced until all labeling has been updated to reflect this change.

Please communicate these changes, as appropriate, to your customers or trading partners. You may find the list at <http://www.athenexpharma.com/products>.

For any questions related to topics in this letter, please contact: 1-847-886-4379

We appreciate your support during this transition phase. We look forward to continuing to serve you and your patients.

Sincerely,

Tom Moutvic
VP Regulatory Affairs

ATTACHMENT A

| Product Description | Unit of Sale NDC | Unit of Sale GTIN | Unit of Use NDC | Unit of Use GTIN |
|---|------------------|-------------------|-----------------|------------------|
| AMPICILLIN FOR INJECTION, USP 250 MG / 10 VIALS | 70860-112-15 | 20370860112156 | 70860-112-41 | 00370860112411 |
| AMPICILLIN FOR INJECTION, USP 500 MG / 10 VIALS | 70860-113-15 | 20370860113153 | 70860-113-41 | 00370860113418 |
| AMPICILLIN FOR INJECTION, USP 1 GRAM / 10 VIALS | 70860-114-15 | 20370860114150 | 70860-114-41 | 00370860114415 |
| AMPICILLIN FOR INJECTION, USP 2 GRAMS / 10 VIALS | 70860-115-26 | 20370860115263 | 70860-115-41 | 00370860115412 |
| AZITHROMYCIN FOR INJECTION, USP 500 MG / 10 VIALS | 70860-100-10 | 20370860100108 | 70860-100-41 | 00370860100418 |
| DEXMEDETOMIDINE HCL INJECTION 200 MCG / 2 ML 10 VIALS | 70860-605-02 | 20370860605023 | 70860-605-41 | 00370860605418 |
| DEXMEDETOMIDINE HCL INJECTION 200 MCG / 2 ML 25 VIALS | 70860-605-03 | 20370860605030 | 70860-605-41 | 00370860605418 |
| ETOMIDATE INJECTION, USP 20 MG / 10 ML 10 VIALS | 70860-652-10 | 20370860652102 | 70860-652-41 | 00370860652412 |
| ETOMIDATE INJECTION, USP 40 MG / 20 ML 10 VIALS | 70860-652-20 | 20370860652201 | 70860-652-42 | 00370860652429 |
| KETOROLAC TROMETHAMINE INJECTION, USP 15 MG / 1 ML 10 VIALS | 70860-700-01 | 20370860700018 | 70860-700-41 | 00370860700410 |
| KETOROLAC TROMETHAMINE INJECTION, USP 15 MG / 1 ML 25 VIALS | 70860-700-02 | 20370860700025 | 70860-700-41 | 00370860700410 |
| KETOROLAC TROMETHAMINE INJECTION, USP 30 MG / 1 ML 10 VIALS | 70860-701-01 | 20370860701015 | 70860-701-41 | 00370860701417 |
| KETOROLAC TROMETHAMINE INJECTION, USP 30 MG / 1 ML 25 VIALS | 70860-701-03 | 20370860701039 | 70860-701-41 | 00370860701417 |
| KETOROLAC TROMETHAMINE INJECTION, USP 60 MG / 2 ML 10 VIALS | 70860-701-02 | 20370860701022 | 70860-701-42 | 00370860701424 |
| KETOROLAC TROMETHAMINE INJECTION, USP 60 MG / 2 ML 25 VIALS | 70860-701-04 | 20370860701046 | 70860-701-42 | 00370860701424 |
| LEVETIRACETAM IN 0.82% SODIUM CHLORIDE INJECTION 500 MG / 100 ML 10 BAGS | 70860-602-82 | 20370860602824 | 70860-602-41 | 00370860602417 |
| LEVETIRACETAM IN 0.75% SODIUM CHLORIDE INJECTION 1000 MG / 100 ML 10 BAGS | 70860-603-82 | 20370860603821 | 70860-603-41 | 00370860603414 |
| LEVETIRACETAM IN 0.54% SODIUM CHLORIDE INJECTION 1500 MG / 100 ML 10 BAGS | 70860-604-82 | 20370860604828 | 70860-604-41 | 00370860604411 |
| METOPROLOL TARTRATE INJECTION, USP 5 MG / 5 ML 10 VIALS | 70860-300-05 | 20370860300058 | 70860-300-41 | 00370860300412 |
| MIDAZOLAM INJECTION, USP 2 MG / 2 ML 25 VIALS | 70860-600-02 | 20370860600028 | 70860-600-41 | 00370860600413 |
| MIDAZOLAM INJECTION, USP 25 MG / 5 ML 10 VIALS | 70860-601-05 | 20370860601056 | 70860-601-41 | 00370860601410 |
| MIDAZOLAM INJECTION, USP 50 MG / 10 ML 10 VIALS | 70860-601-10 | 20370860601100 | 70860-601-42 | 00370860601427 |
| NAFCILLIN FOR INJECTION, USP 1 GRAM / 10 VIALS | 70860-116-26 | 20370860116260 | 70860-116-41 | 00370860116419 |
| NAFCILLIN FOR INJECTION, USP 2 GRAMS / 10 VIALS | 70860-117-26 | 20370860117267 | 70860-117-41 | 00370860117416 |
| ONDANSETRON INJECTION, USP 4 MG / 2 ML 25 VIALS | 70860-776-02 | 20370860776020 | 70860-776-41 | 00370860776415 |
| POLYMYXIN B FOR INJECTION, USP 500000 UNITS 10 VIALS | 70860-103-10 | 20370860103109 | 70860-103-41 | 00370860103419 |
| ROCURONIUM BROMIDE INJECTION 50 MG / 5 ML 10 VIALS | 70860-651-05 | 20370860651051 | 70860-651-41 | 00370860651415 |
| ROCURONIUM BROMIDE INJECTION 100 MG / 10 ML 10 VIALS | 70860-651-10 | 20370860651105 | 70860-651-42 | 00370860651422 |
| TERBUTALINE SULFATE INJECTION, USP 1 MG / 1 ML 10 VIALS | 70860-801-01 | 20370860801012 | 70860-801-41 | 00370860801414 |
| TRANEXAMIC ACID INJECTION 1000 MG / 10 ML 10 VIALS | 70860-400-10 | 20370860400109 | 70860-400-41 | 00370860400419 |
| VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP 500 MG 10 VIALS | 70860-104-10 | 20370860104106 | 70860-104-41 | 00370860104416 |
| VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP 1 GRAM 10 VIALS | 70860-105-20 | 20370860105202 | 70860-105-41 | 00370860105413 |