

**LYOPHILIZED PEGASPARGASE- pegaspargase injection, powder, lyophilized, for solution
Baxalta US Inc.**

LYOPHILIZED PEGASPARGASE

PRINCIPAL DISPLAY PANEL - Shipping Label

Master Label

Description:

SHIPPER LABEL Lyophilized Pegaspargase for _____

Item Code:

SL30521XXX ¹

User Group:

Materials Management

New [X] Revised []

Reason for Master Label:

- Per ISS-_____, under CSWO # _____ added new shipper label info for Lyophilized Pegaspargase _____ to the Weber label database table.
- Label master template will pull product specific information from access database securely from the Weber workstation.

Weber Archive Name:

Shipper Label.____

Created by/Date:

Approved by/Date:

¹ Shipper Labels are site-created components revised by alpha sequence on the label and Master Label document. In

SAP the templates are listed by base item code only.

LYOPHILIZED PEGASPARGASE

Code: 305-21-

Exp. Date: F251-0019-01

Lot #: XXXXX

U/M: Vial

Qty: 60

SL30521

Exelead, Inc.

Indianapolis, IN 46268, USA

999

Master Label

Description:	SHIPPER LABEL Lyophilized Pegaspargase for _____
Item Code:	SL30521XXX ¹
User Group:	Materials Management
New [X] Revised []	Reason for Master Label: <ul style="list-style-type: none"> • Per ISS-_____, under CSWO # _____ added new shipper label info for Lyophilized Pegaspargase _____ to the Weber label database table. • Label master template will pull product specific information from access database securely from the Weber workstation.
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LYOPHILIZED PEGASPARGASE

Code: <u>305-21-</u> Exp. Date: <u>F251-0019-01</u>	
Lot #: <u>XXXXX</u>	
U/M: <u>Vial</u> Qty: <u>60</u>	SL30521
Exelead, Inc. Indianapolis, IN 46268, USA	
	999

LYOPHILIZED PEGASPARGASE

pegaspargase injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0944-3922
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PEGASPARGASE (UNII: 7D96IR0PPM) (PEGASPARGASE - UNII:7D96IR0PPM)	PEGASPARGASE	750 U in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0944-3922-02	60 in 1 CARTON	02/07/2018	
1	NDC:0944-3922-01	5 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
EXPORT ONLY		02/07/2018	

Labeler - Baxalta US Inc. (079887619)

Establishment

Name	Address	ID/FEI	Business Operations
Exelead, Inc		961822389	MANUFACTURE(0944-3922) , PACK(0944-3922) , LABEL(0944-3922)

Revised: 5/2018

Baxalta US Inc.