

# **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014	Introduction Type: New Item						Fir	nal Version		Date:		
PRODUCT INFORMATION							SPECIAL HAN	NDLING AND S	TORAGE REQUI	REMENTS*		
Company Name: AuroMedics Pharma LLC Application: ANDA						NDA	a. Temperature – Indicate the USP temperature range for this product.					
Application Number for	or NDA/ANDA/BLA, Me	d Device:	207160				I. F	Freezer – betw	een -25 and -10	C (-13° – 14° F)		
DUNS:							11.	Cold – betwee	n 2 and 8 C (36	° – 46° F)		
Rx Product/Proprietary N	lame:	Levetiracetam ir	n 0.82% Sodium Chloride i	njection for intra	venous Infusion only 500mg/100mL			en 8 and 15 C (4	,			
NDC:	55150-246-47 UPC: 355150246472				355150246472		IV.	. Controlled Ro	om – between 2	20 and 25 C (68°	– 77° F)	
CVX Code:				MVX Code:				allows for exc	ursions betweer	n 15 and 30 C (59	° – 86° F)	
Description:	Levetiracetam in 0.82	% Sodium Chloric	de injection for intravenous	Infusion only 50	0mg/100mL(5mg/mL)					e 40 C (>104° F)		
		1					YES VI.		rature Range Re			-
Active ingredients:								· · ·		d storage: At or b	elow 25°C	
URL for Additional Produ	uct Information:	www.auromedic	rs com				VI	I. No Requirem	ient			
Address:		www.adromedic		Address 2:					•	•		
City:	6 Wheeling Road Dayton		State:	NJ	Zip: 08810		b. Contact for t Name:	Steve Lucas	xcursion quest	lions:		
Key Contact:	Dayton		Email:	145				732-823-4122				
Phone Number:	888-238-7880		Fax:	732-355-9449	)				to customers c	n ice?	No	
		FOR	GENERIC DRUG PRODU	стя					to customers c		No	-
I. Orange Book Rating:	AP		II. Brand Name:	Keppra			7					_
III. Generic Equivalent fo		levetiracetam	II. Drand Name.	Керріа			c. Special regu	lations for pro	oduct in certair	states?	No	
			IN SECURITY ACT (DSC		ION			•	s for this produc		No	_
D							Opecial return	is requirement			NO	_
Does supplier meet DSC			Yes									
Is product exempt from I	DSCSA?	No	_				d. Store produ	ict (unit of sal	e) upright?		No	_
If yes, select exemptio							Protect proc	duct (unit of s	ale) from light?	?	No	_
Other exemption - Write	te in:								_			
				al product purc	hased direct from mfr?		e. Shelf life:	24	Months			-
Is product sold by manuf		stributor?	No				e. Shelf life:		Months fe at launch (if	different):		Months
		stributor? e?	No No	If yes, attach	hased direct from mfr?		e. Shelf life:	Initial shelf li	fe at launch (if	,		Months
Is product sold by manual Are any waivers granted	for product ID/barcod	stributor? e?	No	If yes, attach	documentation from FDA		e. Shelf life:	Initial shelf li	fe at launch (if PACKING INF	ORMATION		Months
Is product sold by manual Are any waivers granted Is the Product		stributor? e? ADDITIONAL P		If yes, attach I ORDER INFOF	documentation from FDA		e. Shelf life:	Initial shelf li ITEM AND Dim	fe at launch (if PACKING INF ensions (US m	ORMATION	Volume	Months
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Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control?	for product ID/barcod	stributor? e? ADDITIONAL P 	No No PRODUCT INFORMATION Unit of Sale Bottle	If yes, attach ORDER INFOR What is the N 10 No's of sir	documentation from FDA RMATION IDC selling unit? ngle use flexible containers in one	Item:		Initial shelf li ITEM AND Dim	fe at launch (if PACKING INF ensions (US m	ORMATION		
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Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	for product ID/barcod	stributor? e? ADDITIONAL P No No No No	No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube	If yes, attach ORDER INFOR What is the N 10 No's of sin case pack. Th	documentation from FDA RMATION IDC selling unit? ngle use flexible containers in one the Case pack NDC No. is 55150- . 1 Box of 10 Vials)	Box/ Carton:	Weight Lbs.	Initial shelf li ITEM AND Dim Depth 11.42 (1 Triple	fe at launch (if PACKING INF nensions (US m Height 0.5905 (1 Triple	ORMATION Ismts.) Width: 8.27 (1 Triple Laminated		# Pieces: 1 Triple Laminated Case (10
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	for product ID/barcod	stributor? e? ADDITIONAL P No No No No	No No PRODUCT INFORMATION Unit of Sale Box/Carton Ampule Glass Tube Vial Liquid Sgl	If yes, attach ORDER INFOR What is the N 10 No's of sir case pack. Th (Write-in, e.g Minimum ord	Adocumentation from FDA	Box/	Weight Lbs.	Initial shelf li ITEM AND Dim Depth 11.42 (1	ensions (US m Height 0.5905 (1 Triple 7.0866	ORMATION Ismts.) Width: 8.27 (1 Triple		# Pieces: 1 Triple Laminated Case (10 Triple
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# **Standard Pharmaceutical Product Information (Page 2)**

	signated Drop Ship Only Products, Please Use Page 3 AL HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply):	
a. Cytotoxic? No	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No	_
Carcinogen	-
Reproductive Toxicant	
Both	
Warning appears on label	Hazardous Waste Identification
c. Contact Hazard? No	EPA Hazardous Waste Code:
d. Does this product require special clean-up instructions? No	_
(If yes, attach SDS with special instructions.)	
e. Does the product contain DEHP? No	
Is this product regulated for shipment by the DOT?	(if yes, answer a-d below and provide SDS)
	a. DOT Hazard Class
Is this a reportable quantity?	b. UN/ID Number
RQ Threshold:	c. Packing Group
Is this a marine pollutant?	d. Inhalation Hazard?
Is this product shipped utilizing an authorized DOT exception or Special Permit?	
(if yes, identify method below)	
Limited Quantity	ADDITIONAL PRODUCT INFORMATION - Serialization
Consumer Commodity, ORM-D	Level How? GTIN-14
Small Quantity (49 CFR 173.4)	Serialized? Item 2D Linear RFID NA
Special Permit; DOT-SP	If not, when? Box/Carton 2D Linear RFID NA
Special Provision (listed in Column 7 of 49 CFR 172.101);	Items aggregated to case? Case 2D Linear RFID 50355150246477
SP#	Pallet 2D Linear RFID 770355150246471
51#	
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS
Passenger	Is there a REMS on this product?
Cargo	If Yes, is it managed with a pharmacy registry?
Passenger & Cargo	Website URL:
ADD'L STORAGE INFORMATION	Comments / Details: (For example, iPledge program?)
Please check as appropriate for this product.	
Organic Inorganic	
Antineoplastic Steroid/Androgen	
Corrosive Oxidizer	
Aerosol Class; Identify NFPA Storage Level:	RETURN INSTRUCTIONS
	Contact tel. # if product received damaged:
	Is product returnable for credit:
Listed Chemical (List I or II) (Indicate or Write-in below):	URL/Link to returns policy:
	Special regulations or returns requirements for this product in certain states?
Pseudoephedrine	If so, which states? Other requirements? Comments?
Phenylpropanolamine	
lodine (≥2.2%)	
Other:	J L
CLASS OF TRADE RESTRICTION:	ADDITIONAL INFORMATION
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	If Unit Dose NDC, indicate NDC here:
Restricted to retail pharmacy only:	MISCELLANEOUS NOTES and/or Image of Product Barcode:
Restricted to hospital, clinics, and physician offices only:	
Restricted from US territories? (explain in comments)	
Comments:	



# **Standard Pharmaceutical Product Information (Page 3)**

FOR DESIGNAT	ED DROP	SHIP PRODUCT	ONLY - if not a	designated	drop ship, d	o not com	plet	e.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax Fax Number:	Purchase order daily receipt cut off time by supplier         Cut off time:
c. Fax Fax Number:	Shipping lead time of PO: Hours Days
d. Phone only Phone No.:	
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:
Minimum Order Quantity:	Ships for second day receipt:
Supplier's Customer Service Number: Contracted 3PL company / contact #: Name:	Ships regular ground for 3-10 days receipt:
Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday
Comments:	Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
Class of Trade Restriction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:
Restricted to retail pharmacy only:	PO Receipt Cut off time:
Restricted to hospital, clinics, and physician offices only:	Order receipt method: Phone: Phone #:
Restricted from US territories? (explain in comments)	Fax: Fax #:
Comments:	EDI:
	Overnight Fees apply:
	Other fees apply:
REMS or Registry Restrictions	Return Instructions
REMS:	Contact # if product is received damaged:
REMS Program Manager Name: Phone:	Is product returnable for credit:
Supplier Manages REMS registry exclusively: Wholesale distributor support:	URL/Link to returns policy: Special regulations or returns requirements for this product in certain states?
Provider Name:	If so, which states? Other requirements? Comments?
Site Enrollment Number assigned by Supplier:	n do, when dates : other requirements : comments :
DEA #:	
PCPDP #:	
NPI#:	
Comments:	
Registry:	ADDITIONAL INFORMATION
Registry Program Contact Name: Phone:	Is product order for scheduled patient procedure?
Comments	Is product order for restocking purposes?
Other Data Information Required to Process PO:	Miscellaneous Notes:
Patient Procedure Date:	
Physician Name:	
Physician/Clinic Phone #	
Physician State License # Physician/Clinic DEA #:	
Physician/Clinic DEA #: Physician/Clinic Specialty:	



# **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014	Introduction Type: New Item						Fi	nal Version		Date:			
PRODUCT INFORMATION							SPECIAL HANDLING AND STORAGE REQUIREMENTS*						
Company Name:	Company Name: AuroMedics Pharma LLC Application: ANDA						a. Temperature	e – Indicate the	e USP tempera	ture range for th	is product.		
Application Number for	or NDA/ANDA/BLA, Me	d Device:	207160		••		I. I.	Freezer – betw	een -25 and -10	C (-13° – 14° F)			
DUNS:							II.	Cold - betwee	n 2 and 8 C (36	° – 46° F)			
Rx Product/Proprietary N						venous Infusion only 1000mg/100mL(10mg/mL)			III. Cool – between 8 and 15 C (46° – 59° F)				
NDC:	55150-247-47			UPC:	355150247479		IV			20 and 25 C (68° -	,		
CVX Code:				MVX Code:						n 15 and 30 C (59	° – 86° F)		
Description:	Levetiracetam in 0.75	% Sodium Chlorid	de injection for intravenous	Infusion only 10	00mg/100mL(10mg/mL)					e 40 C (>104° F)			
Active ingredients:							YES VI		rature Range Re	equirement d storage: At or be	Now 25°C	1	
Active ingredients.								I. No Requirem		a storage. At or be	510W 25 0		
URL for Additional Produ	uct Information:	www.auromedic	cs.com										
Address:	6 Wheeling Road			Address 2:			b. Contact for	temperature e	xcursion quest	tions:			
City:	Dayton		State:	NJ	<b>Zip:</b> 08810		Name:	Steve Lucas					
Key Contact:			Email:					732-823-4122					
Phone Number:	888-238-7880		Fax:	732-355-9449					to customers c		No	_	
		FOR	GENERIC DRUG PRODUC	-			is this produc	ct to be shipped	to customers c	on dry ice?	No	-	
I. Orange Book Rating:	AP		II. Brand Name:	Keppra									
III. Generic Equivalent fo		levetiracetam					c. Special regu	lations for pro	oduct in certair	n states?	No	_	
	DRU	G SUPPLY CHA	IN SECURITY ACT (DSCS	SA) INFORMATI	ON		Special return	ns requirement	s for this produc	xt?	No	_	
Does supplier meet DSC	SA definition of manu	facturer?	Yes										
Is product exempt from I	DSCSA?	No					d. Store produ	uct (unit of sal	e) upright?		No		
If yes, select exemptio	n:		_				Protect pro	duct (unit of s	ale) from light?	?	No	_	
Other exemption - Write	te in:							•	, -			_	
· · · · · · · · · · · · · · · · · · ·									Mantha				
					hased direct from mfr?		e. Shelf life:	24	Months				
Is product sold by manuf		stributor?	No				e. Shelf life:		fe at launch (if	different):		Months	
		stributor? e?	No No	If yes, attach	hased direct from mfr?		e. Shelf life:	Initial shelf li	fe at launch (if			Months	
Is product sold by manuf		stributor? e?	No	If yes, attach	documentation from FDA		e. Shelf life:	Initial shelf li	fe at launch (if PACKING INF	ORMATION		Months	
Is product sold by manual Are any waivers granted Is the Product		stributor? e? ADDITIONAL F	No No PRODUCT INFORMATION	If yes, attach ORDER INFOF	documentation from FDA		e. Shelf life:	Initial shelf li ITEM AND Dim	fe at launch (if PACKING INF eensions (US m	ORMATION	Volume	Months	
Is product sold by manuf Are any waivers granted Is the Product Legend Device?	for product ID/barcod	stributor? e? ADDITIONAL F	No No PRODUCT INFORMATION	If yes, attach ORDER INFOF What is the N	documentation from FDA RMATION IDC selling unit?			Initial shelf li	fe at launch (if PACKING INF	ORMATION	Volume (Cube)	-	
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control?	for product ID/barcod	stributor? e? ADDITIONAL F 	No No PRODUCT INFORMATION Unit of Sale Bottle	If yes, attach ORDER INFOR What is the N 10 No's of sir	documentation from FDA RMATION IDC selling unit? agle use flexible containers in one	Item.		Initial shelf li ITEM AND Dim	fe at launch (if PACKING INF eensions (US m	ORMATION		-	
Is product sold by manuf Are any waivers granted Is the Product Legend Device?	for product ID/barcod	stributor? e? ADDITIONAL F	No No PRODUCT INFORMATION	If yes, attach ORDER INFOR What is the N 10 No's of sin case pack. Th	documentation from FDA RMATION IDC selling unit?	Item.		Initial shelf li ITEM AND Dim	fe at launch (if PACKING INF eensions (US m	ORMATION		-	
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?	for product ID/barcod	stributor? e? ADDITIONAL F 	No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton	If yes, attach ORDER INFOR What is the N 10 No's of sin case pack. Th	documentation from FDA RMATION IDC selling unit? Igle use flexible containers in one te Case pack NDC No. is 55150-	item:	Weight Lbs.	Initial shelf li ITEM AND Dim Depth	PACKING INF PACKING INF ensions (US m Height	ORMATION Ismts.) Width:		# Pieces:	
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	for product ID/barcod	stributor? e? ADDITIONAL F No No No No	No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube	If yes, attach ORDER INFOR What is the N 10 No's of sin case pack. Th	documentation from FDA MATION IDC selling unit? Igle use flexible containers in one le Case pack NDC No. is 55150- . 1 Box of 10 Vials)	Box/	Weight Lbs.	Initial shelf li ITEM AND Dim Depth 11.42 (1	fe at launch (if PACKING INF Iensions (US m Height 0.5905 (1	ORMATION Ismts.) Width: 8.27 (1 Triple		# Pieces: 1 Triple Laminated Case (10	
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	for product ID/barcod	stributor? e? ADDITIONAL F No No No No	No No PRODUCT INFORMATION Unit of Sale Box/Carton Ampule Glass Tube Vial Liquid Sgl	If yes, attach ORDER INFOR What is the N 10 No's of sir case pack. Th (Write-in, e.g Minimum ord	documentation from FDA RMATION IDC selling unit? Igle use flexible containers in one the Case pack NDC No. is 55150- . 1 Box of 10 Vials) Ider quantity? Yes	Box/ Carton Case:	Weight Lbs. 0.30823 (1 Triple 4.276 375 077 (Eor	Initial shelf Ii ITEM AND Dim Depth 11.42 (1 Triple 12.5984	fe at launch (if PACKING INF tensions (US m Height 0.5905 (1 Triple 7.0866	ORMATION Ismts.) Width: 8.27 (1 Triple Laminated 8.66141		# Pieces: 1 Triple Laminated Case (10 Triple	
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co	for product ID/barcod	stributor? e? ADDITIONAL F No No No No No	No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi	If yes, attach ORDER INFOR What is the N 10 No's of sir case pack. Th (Write-in, e.g Minimum ord	documentation from FDA MATION IDC selling unit? Igle use flexible containers in one le Case pack NDC No. is 55150- . 1 Box of 10 Vials)	Box/ Carton	Weight Lbs. 0.30823 (1 Triple 4.276 375 077 (Eor	Initial shelf li ITEM AND Dim Depth 11.42 (1 Triple	fe at launch (if PACKING INF tensions (US m Height 0.5905 (1 Triple	ORMATION Ismts.) Width: 8.27 (1 Triple Laminated		# Pieces: 1 Triple Laminated Case (10	
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	for product ID/barcod	stributor? e? ADDITIONAL F No No No No	No No PRODUCT INFORMATION Unit of Sale Box/Carton Ampule Glass Tube Vial Liquid Sgl	If yes, attach ORDER INFOF What is the N 10 No's of sir case pack. Tr (Write-in, e.g Minimum orc If Yes, how n	documentation from FDA RMATION IDC selling unit? Igle use flexible containers in one the Case pack NDC No. is 55150 . 1 Box of 10 Vials) der quantity? Yes hany of which package type?	Box/ Carton Case: Pallet:	Weight Lbs. 0.30823 (1 Triple 4.276 375.077 (For	Initial shelf Ii ITEM AND Dim Depth 11.42 (1 Triple 12.5984	fe at launch (if PACKING INF mensions (US m Height 0.5905 (1 Triple 7.0866 41.42 (For	ORMATION Ismts.) Width: 8.27 (1 Triple Laminated 8.66141		# Pieces: 1 Triple Laminated Case (10 Triple For Sea (80	
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co	for product ID/barcod	stributor? e? ADDITIONAL F No No No No No	No No No PRODUCT INFORMATION Unit of Sale Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Liquid Multi Vial Power Sql Vial Power Multi X Other: Write In	If yes, attach ORDER INFOF What is the N 10 No's of sir case pack. Th (Write-in, e.g Minimum orc If Yes, how n 10	documentation from FDA RMATION IDC selling unit? Ingle use flexible containers in one	Box/ Carton Case:	Weight Lbs. 0.30823 (1 Triple 4.276 375.077 (For Sea)	Initial shelf Ii ITEM AND Dim Depth 11.42 (1 Triple 12.5984	fe at launch (if PACKING INF Height 0.5905 (1 Triple 7.0866 41.42 (For Sea)	ORMATION Ismts.) Width: 8.27 (1 Triple Laminated 8.66141		# Pieces: 1 Triple Laminated Case (10 Triple For Sea (80	
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Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning?	for product ID/barcod	stributor? e? ADDITIONAL F No No No No No	No No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Powder Sql Vial Powder Sql Vial Power Multi X Other: Write In SD infusion bag PHARMACY ORDER	If yes, attach ORDER INFOR What is the N 10 No's of sir case pack. Th (Write-in, e.g Minimum orc If Yes, how n 10 1 1 1 1 / BILL UNIT	documentation from FDA	- Casten Pallet: UPC:	Weight Lbs. 0.30823 (1 Triple 4.276 375.077 (For Sea) Case: Carton:	Initial shelf Ii ITEM AND Dim Depth 11.42 (1 Triple 12.5984 48 35515024747	fe at launch (if PACKING INF Height 0.5905 (1 Triple 7.0866 41.42 (For Sea)	ORMATION Ismts.) Width: 8.27 (1 Triple Laminated 8.66141 40	(Cube)	# Pieces: 1 Triple Laminated Case (10 Triple For Sea (80 Shippers or	
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Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Cc Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning? Is it reverse numbered? WHOLE Vendor #:	for product ID/barcod	stributor? e? ADDITIONAL F No No No No No	No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Sgl Vial Liquid Multi Vial Power Multi Vial Power Multi X Other: Write In SD infusion bag PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. 1)	If yes, attach ORDER INFOR What is the N 10 No's of sir case pack. Th (Write-in, e.g Minimum orce If Yes, how n 10 1 1 1 / BILL UNIT her? Vial)	documentation from FDA  RMATION  IDC selling unit?  Igle use flexible containers in one Ince Case pack NDC No. is 55150- I Box of 10 Vials)  Ider quantity? Yes  Inany of which package type? Each Inner/Carton/Pack Case  Other Product Inform Size/Strength/Form:	- Casten Pallet: UPC:	Weight Lbs.	Initial shelf li ITEM AND Dim Depth 11.42 (1 Triple 12.5984 48 3555150247477 t Per Unit of	ensions (US m Height 0.5905 (1 Triple 7.0866 41.42 (For Sea) 9 COST INFC Invoice Co	ORMATION Ismts.) Width: 8.27 (1 Triple Laminated 8.66141 40	(Cube)	# Pieces: 1 Triple Laminated Case (10 Triple For Sea (80 Shippers or Cise Tax Per	
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# **Standard Pharmaceutical Product Information (Page 2)**

MATERIA	ignated Drop Ship Only Products, Please Use Page 3 IL HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply):	
a. Cytotoxic? No	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No	
Carcinogen	
Reproductive Toxicant	
Both	
Warning appears on label	Hazardous Waste Identification
c. Contact Hazard? No	EPA Hazardous Waste Code:
d. Does this product require special clean-up instructions? No	
(If yes, attach SDS with special instructions.)	
e. Does the product contain DEHP? No	
Is this product regulated for shipment by the DOT?	(if yes, answer a-d below and provide SDS)
	a. DOT Hazard Class
Is this a reportable quantity?	b. UN/ID Number
RQ Threshold:	c. Packing Group
Is this a marine pollutant?	d. Inhalation Hazard?
Is this a manne poliutant? Is this product shipped utilizing an authorized DOT exception or Special Permit?	
(if yes, identify method below)	
Limited Quantity	ADDITIONAL PRODUCT INFORMATION - Serialization
Consumer Commodity, ORM-D	Level How? GTIN-14
Small Quantity (49 CFR 173.4)	Serialized? Item 2D Linear RFID NA
Special Permit; DOT-SP	If not, when? Box/Carton 2D Linear RFID NA
Special Provision (listed in Column 7 of 49 CFR 172.101);	Items aggregated to case? Case 2D Linear RFID 50355150247474
SP#	Pallet 2D Linear RFID 70355150247478
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS
Passenger	Is there a REMS on this product?
Cargo	If Yes, is it managed with a pharmacy registry?
Passenger & Cargo	Website URL:
ADD'L STORAGE INFORMATION	Comments / Details: (For example, iPledge program?)
Disease sharely an engranding for this and us!	
Please check as appropriate for this product.	
Please check as appropriate for this product.	
Organic Inorganic	
Organic Inorganic Antineoplastic Steroid/Androgen	
Organic Inorganic	
Organic Inorganic Antineoplastic Steroid/Androgen Corrosive Oxidizer	RETURN INSTRUCTIONS
Organic Inorganic Antineoplastic Steroid/Androgen	
Organic Inorganic Antineoplastic Steroid/Androgen Corrosive Oxidizer	Contact tel. # if product received damaged:
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:	Contact tel. # if product received damaged:       Is product returnable for credit:
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:	Contact tel. # if product received damaged:         Is product returnable for credit:         URL/Link to returns policy:
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:	Contact tel. # if product received damaged:         Is product returnable for credit:         URL/Link to returns policy:         Special regulations or returns requirements for this product in certain states?
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:         Listed Chemical (List I or II) (Indicate or Write-in below):         Ephedrine         Pseudoephedrine	Contact tel. # if product received damaged:         Is product returnable for credit:         URL/Link to returns policy:
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:	Contact tel. # if product received damaged:         Is product returnable for credit:         URL/Link to returns policy:         Special regulations or returns requirements for this product in certain states?
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:	Contact tel. # if product received damaged:         Is product returnable for credit:         URL/Link to returns policy:         Special regulations or returns requirements for this product in certain states?
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:	Contact tel. # if product received damaged:         Is product returnable for credit:         URL/Link to returns policy:         Special regulations or returns requirements for this product in certain states?
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?  ADDITIONAL INFORMATION
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:	Contact tel. # if product received damaged:         Is product returnable for credit:         URL/Link to returns policy:         Special regulations or returns requirements for this product in certain states?         If so, which states? Other requirements? Comments?         ADDITIONAL INFORMATION         If Unit Dose NDC, indicate NDC here:
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?  ADDITIONAL INFORMATION
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:	Contact tel. # if product received damaged:         Is product returnable for credit:         URL/Link to returns policy:         Special regulations or returns requirements for this product in certain states?         If so, which states? Other requirements? Comments?         ADDITIONAL INFORMATION         If Unit Dose NDC, indicate NDC here:
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?  ADDITIONAL INFORMATION If Unit Dose NDC, indicate NDC here:
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:	Contact tel. # if product received damaged:         Is product returnable for credit:         URL/Link to returns policy:         Special regulations or returns requirements for this product in certain states?         If so, which states? Other requirements? Comments?         ADDITIONAL INFORMATION         If Unit Dose NDC, indicate NDC here:
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:	Contact tel. # if product received damaged:         Is product returnable for credit:         URL/Link to returns policy:         Special regulations or returns requirements for this product in certain states?         If so, which states? Other requirements? Comments?         ADDITIONAL INFORMATION         If Unit Dose NDC, indicate NDC here:
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:	Contact tel. # if product received damaged:         Is product returnable for credit:         URL/Link to returns policy:         Special regulations or returns requirements for this product in certain states?         If so, which states? Other requirements? Comments?         ADDITIONAL INFORMATION         If Unit Dose NDC, indicate NDC here:
Organic       Inorganic         Antineoplastic       Steroid/Androgen         Corrosive       Oxidizer         Aerosol Class; Identify NFPA Storage Level:	Contact tel. # if product received damaged:         Is product returnable for credit:         URL/Link to returns policy:         Special regulations or returns requirements for this product in certain states?         If so, which states? Other requirements? Comments?         ADDITIONAL INFORMATION         If Unit Dose NDC, indicate NDC here:



# **Standard Pharmaceutical Product Information (Page 3)**

FOR DESIGNAT	ED DROP	SHIP PRODUCT	ONLY - if not a	designated	drop ship, d	o not com	plet	e.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax Fax Number:	Purchase order daily receipt cut off time by supplier         Cut off time:
c. Fax Fax Number:	Shipping lead time of PO: Hours Days
d. Phone only Phone No.:	
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:
Minimum Order Quantity:	Ships for second day receipt:
Supplier's Customer Service Number: Contracted 3PL company / contact #: Name:	Ships regular ground for 3-10 days receipt:
Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday
Comments:	Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
Class of Trade Restriction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:
Restricted to retail pharmacy only:	PO Receipt Cut off time:
Restricted to hospital, clinics, and physician offices only:	Order receipt method: Phone: Phone #:
Restricted from US territories? (explain in comments)	Fax: Fax #:
Comments:	EDI:
	Overnight Fees apply:
	Other fees apply:
REMS or Registry Restrictions	Return Instructions
REMS:	Contact # if product is received damaged:
REMS Program Manager Name: Phone:	Is product returnable for credit:
Supplier Manages REMS registry exclusively: Wholesale distributor support:	URL/Link to returns policy: Special regulations or returns requirements for this product in certain states?
Provider Name:	If so, which states? Other requirements? Comments?
Site Enrollment Number assigned by Supplier:	n do, when dates : other requirements : comments :
DEA #:	
PCPDP #:	
NPI#:	
Comments:	
Registry:	ADDITIONAL INFORMATION
Registry Program Contact Name: Phone:	Is product order for scheduled patient procedure?
Comments	Is product order for restocking purposes?
Other Data Information Required to Process PO:	Miscellaneous Notes:
Patient Procedure Date:	
Physician Name:	
Physician/Clinic Phone #	
Physician State License # Physician/Clinic DEA #:	
Physician/Clinic DEA #: Physician/Clinic Specialty:	



# **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014	Introduction Type: New Item						Fir	nal Version		Date:		
PRODUCT INFORMATION							SPECIAL HAN	NDLING AND S	TORAGE REQUI	REMENTS*		
Company Name: AuroMedics Pharma LLC Application: ANDA						DA	a. Temperature – Indicate the USP temperature range for this product.					
Application Number fo	or NDA/ANDA/BLA, Me	ed Device:	207160		••		1.1	Freezer – betw	een -25 and -10	C (-13° – 14° F)		
DUNS:							<u> </u>	Cold – betwee	n 2 and 8 C (36	° – 46° F)		
Rx Product/Proprietary N	Name:	Levetiracetam in 0.54% Sodium Chloride injection for intrave			venous Infusion only 1500mg/100mL	III.	. Cool – betwee	en 8 and 15 C (4	6° – 59° F)			
NDC:	55150-248-47 UPC: 355150248476						IV			20 and 25 C (68° ·	,	
CVX Code:				MVX Code:				allows for exc	ursions betweer	15 and 30 C (59	° – 86° F)	
Description:	Levetiracetam in 0.54	% Sodium Chlori	de injection for intravenous	Infusion only 15	i00mg/100mL (15mg/mL)					e 40 C (>104° F)		
A		1					YES VI		rature Range Re		-1 05%	-
Active ingredients:								(write in) I. No Requirem		storage: At or be	25°C	
URL for Additional Produ	uct Information:	www.auromedic	cs.com					I. No Requirem	ient			
Address:	6 Wheeling Road			Address 2:			b. Contact for t	temperature e	xcursion quest	ions:		
City:	Dayton		State:	NJ	<b>Zip:</b> 08810		Name:	Steve Lucas	xeursion quest			
Key Contact:			Email:		•		Number:	732-823-4122				
Phone Number:	888-238-7880		Fax:	732-355-9449	9		Is this produc	ct to be shipped	to customers o	n ice?	No	
		FOR	GENERIC DRUG PRODU	CTS			Is this produc	ct to be shipped	to customers o	n dry ice?	No	_
I. Orange Book Rating:	AP		II. Brand Name:	Keppra								
III. Generic Equivalent fo	or Brand:	levetiracetam					c. Special regu	lations for pro	oduct in certair	states?	No	=
	DRU	IG SUPPLY CHA	IN SECURITY ACT (DSC	SA) INFORMAT	ION		Special return	ns requirement	s for this produc	:t?	No	_
Does supplier meet DSC	SA definition of manu	facturer?	Yes									_
Is product exempt from I	DSCSA?	No					d. Store produ	uct (unit of sal	e) upright?		No	
If yes, select exemptio							-		ale) from light?	<b>)</b>	No	-
Other exemption - Write							Protect prot		ale) nom light	I	INO	-
								-				
					hased direct from mfr?		e Shelf life	24	Months			
	facturer's exclusive di	No stributor?	If Yes, was origina No	al product purc	hased direct from mfr?		e. Shelf life:	24 Initial shelf li	Months fe at launch (if	different):		Months
		stributor?			hased direct from mfr?		e. Shelf life:		Months fe at launch (if	different):		Months
Is product sold by manuf		stributor? le?	No	If yes, attach			e. Shelf life:	Initial shelf li		-		Months
Is product sold by manuf		stributor? le?	No No	If yes, attach	documentation from FDA			Initial shelf li ITEM AND	fe at launch (if	ORMATION	Volume	-
Is product sold by manuf Are any waivers granted Is the Product Legend Device?	for product ID/barcod	stributor? le?	No No	If yes, attach ORDER INFOR What is the N	n documentation from FDA RMATION NDC selling unit?		e. Shelf life: Weight Lbs.	Initial shelf li ITEM AND	fe at launch (if PACKING INF	ORMATION	Volume (Cube)	Months
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control?	for product ID/barcod	stributor? le? ADDITIONAL F 	No No PRODUCT INFORMATION Unit of Sale Bottle	If yes, attach ORDER INFOR What is the N 10 No's of sir	a documentation from FDA RMATION NDC selling unit? ngle use flexible containers in one	Item:		Initial shelf li ITEM AND Dim	fe at launch (if PACKING INF eensions (US m	ORMATION smts.)		-
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable?	for product ID/barcod	stributor? ADDITIONAL F 	No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton	If yes, attach ORDER INFOR What is the N 10 No's of sin case pack. Th	a documentation from FDA RMATION NDC selling unit? ngle use flexible containers in one ne Case pack NDC No. is 55150-		Weight Lbs.	Initial shelf li ITEM AND Dim Depth	PACKING INF PACKING INF ensions (US m Height	ORMATION Ismts.) Width:		# Pieces:
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed?	for product ID/barcod	stributor? le? ADDITIONAL F No No No No	No           No           PRODUCT INFORMATION           Unit of Sale           Bottle           Box/Carton           Ampule	If yes, attach ORDER INFOR What is the N 10 No's of sin case pack. Th	a documentation from FDA RMATION NDC selling unit? ngle use flexible containers in one	Box/	Weight Lbs.	Initial shelf li ITEM AND Dim Depth 11.42 (1	fe at launch (if PACKING INF Iensions (US m Height 0.5905 (1	ORMATION Ismts.) Width: 8.27 (1 Triple		# Pieces:
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable?	for product ID/barcod	stributor? ADDITIONAL F 	No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton	If yes, attach ORDER INFOR What is the N 10 No's of sir case pack. Th (Write-in, e.g	A documentation from FDA RMATION VDC selling unit? Ingle use flexible containers in one he Case pack NDC No. is 55150- 1 Box of 10 Vials)	Box/ Carton:	Weight Lbs.	Initial shelf li ITEM AND Dim Depth 11.42 (1 Triple	fe at launch (if PACKING INF eensions (US m Height 0.5905 (1 Triple	ORMATION smts.) Width: 8.27 (1 Triple Laminated		# Pieces:
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	for product ID/barcod	stributor? le? ADDITIONAL F No No No No	No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass	If yes, attach ORDER INFOR What is the N 10 No's of sir case pack. Th (Write-in, e.g	a documentation from FDA RMATION VDC selling unit? Ingle use flexible containers in one the Case pack NDC No. is 55150- I. 1 Box of 10 Vials)	Box/	Weight Lbs.           0.30823 (1 Triple           4.276	Initial shelf li ITEM AND Dim Depth 11.42 (1	fe at launch (if PACKING INF tensions (US m Height 0.5905 (1 Triple 7.0866	ORMATION Ismts.) Width: 8.27 (1 Triple		# Pieces: 1 Triple Laminated Case (10 Triple
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co	Direct Ship Item	stributor? le? ADDITIONAL F No No No No No	No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi	If yes, attach ORDER INFOP What is the N 10 No's of sin case pack. Th (Write-in, e.g Minimum ord If Yes, how n	A documentation from FDA  RMATION  NDC selling unit?  ngle use flexible containers in one ne Case pack NDC No. is 55150- j. 1 Box of 10 Vials)  der quantity? Yes  nany of which package type?	Box/ Carton:	Weight Lbs. 0.30823 (1 Triple 4.276 375.077 (For	Initial shelf li ITEM AND Dim Depth 11.42 (1 Triple	fe at launch (if PACKING INF nensions (US m Height 0.5905 (1 Triple 7.0866 41.42 (For	ORMATION smts.) Width: 8.27 (1 Triple Laminated		# Pieces: 1 Triple Laminated Case (10 Triple For Sea (80
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item	stributor? le? ADDITIONAL F No No No No	No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	If yes, attach ORDER INFOF What is the N 10 No's of sin case pack. Th (Write-in, e.g Minimum ord If Yes, how n 10	A documentation from FDA  RMATION  NDC selling unit?  Ingle use flexible containers in one Ine Case pack NDC No. is 55150- I. 1 Box of 10 Vials)  der quantity?  Yes  nany of which package type? Each	Box/ Carton: Case:	Weight Lbs.           0.30823 (1 Triple           4.276           375.077 (For Sea)	Initial shelf Ii ITEM AND Dim Depth 11.42 (1 Triple 12.5984	fe at launch (if PACKING INF tensions (US m Height 0.5905 (1 Triple 7.0866	ORMATION smts.) Width: 8.27 (1 Triple Laminated 8.66141		# Pieces: 1 Triple Laminated Case (10 Triple
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoti Controlled Substance Co Hazardous Material/Cyto	Direct Ship Item	stributor? le? ADDITIONAL F No No No No No	No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Liquid Multi Vial Powder Sql Vial Power Multi	If yes, attach ORDER INFOP What is the N 10 No's of sin case pack. Th (Write-in, e.g Minimum ord If Yes, how n	A documentation from FDA  RMATION  NDC selling unit?  Ingle use flexible containers in one Ine Case pack NDC No. is 55150- I. 1 Box of 10 Vials)  der quantity?  Yes  nany of which package type? Each Inner/Carton/Pack	Box/ Carton: Case:	Weight Lbs.           0.30823 (1 Triple           4.276           375.077 (For Sea)           Case:	Initial shelf Ii ITEM AND Dim Depth 11.42 (1 Triple 12.5984 48	fe at launch (if PACKING INF tensions (US m Height 0.5905 (1 Triple 7.0866 41.42 (For Sea)	ORMATION smts.) Width: 8.27 (1 Triple Laminated 8.66141		# Pieces: 1 Triple Laminated Case (10 Triple For Sea (80
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoti Controlled Substance Co Hazardous Material/Cyto Is Item	for product ID/barcod	stributor? le? ADDITIONAL F No No No No No	No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	If yes, attach ORDER INFOR What is the N 10 No's of sin case pack. Th (Write-in, e.g Minimum ord If Yes, how n 10 1	A documentation from FDA  RMATION  NDC selling unit?  Ingle use flexible containers in one Ine Case pack NDC No. is 55150- I. 1 Box of 10 Vials)  der quantity?  Yes  nany of which package type? Each	Box/ Carton: Case: Pallet:	Weight Lbs.           0.30823 (1 Triple           4.276           375.077 (For Sea)	Initial shelf Ii ITEM AND Dim Depth 11.42 (1 Triple 12.5984	fe at launch (if PACKING INF tensions (US m Height 0.5905 (1 Triple 7.0866 41.42 (For Sea)	ORMATION smts.) Width: 8.27 (1 Triple Laminated 8.66141		# Pieces: 1 Triple Laminated Case (10 Triple For Sea (80
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoti Controlled Substance Co Hazardous Material/Cyto	for product ID/barcod	stributor? le? ADDITIONAL F No No No No No	No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi X Other: Write In	If yes, attach ORDER INFOR What is the N 10 No's of sir case pack. TH (Write-in, e.g Minimum ord If Yes, how m 10 1 1	A documentation from FDA  RMATION  NDC selling unit?  Ingle use flexible containers in one Ine Case pack NDC No. is 55150- I. 1 Box of 10 Vials)  der quantity?  Yes  nany of which package type? Each Inner/Carton/Pack	Box/ Carton: Case: Pallet: UPC:	Weight Lbs.           0.30823 (1 Triple           4.276           375.077 (For Sea)           Case:	Initial shelf Ii ITEM AND Dim Depth 11.42 (1 Triple 12.5984 48	fe at launch (if PACKING INF tensions (US m Height 0.5905 (1 Triple 7.0866 41.42 (For Sea)	ORMATION smts.) Width: 8.27 (1 Triple Laminated 8.66141 40		# Pieces: 1 Triple Laminated Case (10 Triple For Sea (80
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co	for product ID/barcod	stributor? le? ADDITIONAL F No No No No No	No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi X Other: Write In SD infusion bag	If yes, attach ORDER INFOR What is the N 10 No's of sir case pack. TH (Write-in, e.g Minimum ord If Yes, how m 10 1 1 1 1 / BILL UNIT	A documentation from FDA   RMATION  NDC selling unit?  Ingle use flexible containers in one Ine Case pack NDC No. is 55150- I. 1 Box of 10 Vials)  der quantity?  Yes  nany of which package type? Each Inner/Carton/Pack Case	Box/ Carton: Case: Pallet: UPC:	Weight Lbs.           0.30823 (1 Triple           4.276           375.077 (For Sea)           Case:	Initial shelf Ii ITEM AND Dim Depth 11.42 (1 Triple 12.5984 48 35515024847	fe at launch (if PACKING INF mensions (US m Height 0.5905 (1 Triple 7.0866 41.42 (For Sea) 6 COST INFO	ORMATION smts.) Width: 8.27 (1 Triple Laminated 8.66141 40	(Cube)	# Pieces: 1 Triple Laminated Case (10 Triple For Sea (80
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning?	for product ID/barcod	stributor? le? ADDITIONAL F No No No No No	No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Powder Sql Vial Powder Sql Vial Power Multi X Other: Write In SD infusion bag PHARMACY ORDER	If yes, attach ORDER INFOR What is the N 10 No's of sir case pack. TH (Write-in, e.g Minimum ord If Yes, how m 10 1 1 1 1 / BILL UNIT	A documentation from FDA   RMATION  NDC selling unit?  Ingle use flexible containers in one Ine Case pack NDC No. is 55150- Ingle use flexible containers in one Ingle use flexible containers in on	Box/ Carton: Case: Pallet: UPC:	Weight Lbs.           0.30823 (1 Triple           4.276           375.077 (For Sea)           Case: Carton:	Initial shelf Ii ITEM AND Dim Depth 11.42 (1 Triple 12.5984 48 35515024847 t Per Unit of	fe at launch (if PACKING INF mensions (US m Height 0.5905 (1 Triple 7.0866 41.42 (For Sea) 6 COST INFO	ORMATION smts.) Width: 8.27 (1 Triple Laminated 8.66141 40	(Cube)	# Pieces: 1 Triple Laminated Case (10 Triple For Sea (80 Shippers or
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Cc Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning? Is it reverse numbered?	for product ID/barcod	stributor? le? ADDITIONAL F No No No No No	No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Powder Sql Vial Powder Sql Vial Power Multi X Other: Write In SD infusion bag PHARMACY ORDER	If yes, attach ORDER INFOR What is the N 10 No's of sir case pack. Th (Write-in, e.g Minimum ord If Yes, how m 10 1 1 / BILL UNIT mer?	A documentation from FDA   RMATION  NDC selling unit?  Ingle use flexible containers in one Ine Case pack NDC No. is 55150- Ingle use flexible containers in one Ingle use flexible containers in on	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 0.30823 (1 Triple 4.276 375.077 (For Sea) Case: Carton: Regular Cost	Initial shelf Ii ITEM AND Dim Depth 11.42 (1 Triple 12.5984 48 35515024847 t Per Unit of	fe at launch (if PACKING INF mensions (US m Height 0.5905 (1 Triple 7.0866 41.42 (For Sea) 6 COST INFO	ORMATION smts.) Width: 8.27 (1 Triple Laminated 8.66141 40	(Cube)	# Pieces: 1 Triple Laminated Case (10 Triple For Sea (80 Shippers or Shippers or
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# **Standard Pharmaceutical Product Information (Page 2)**

	signated Drop Ship Only Products, Please Use Page 3 AL HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply):	
a. Cytotoxic? No	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No	_
Carcinogen	-
Reproductive Toxicant	
Both	
Warning appears on label	Hazardous Waste Identification
c. Contact Hazard? No	EPA Hazardous Waste Code:
d. Does this product require special clean-up instructions? No	_
(If yes, attach SDS with special instructions.)	
e. Does the product contain DEHP? No	
Is this product regulated for shipment by the DOT?	(if yes, answer a-d below and provide SDS)
	a. DOT Hazard Class
Is this a reportable quantity?	b. UN/ID Number
RQ Threshold:	c. Packing Group
Is this a marine pollutant?	d. Inhalation Hazard?
Is this product shipped utilizing an authorized DOT exception or Special Permit?	
(if yes, identify method below)	
Limited Quantity	ADDITIONAL PRODUCT INFORMATION - Serialization
Consumer Commodity, ORM-D	Level How? GTIN-14
Small Quantity (49 CFR 173.4)	Serialized? Item 2D Linear RFID NA
Special Permit; DOT-SP	If not, when? Box/Carton 2D Linear RFID NA
Special Provision (listed in Column 7 of 49 CFR 172.101);	Items aggregated to case? Case 2D Linear RFID 50355150248471
SP#	Pallet 2D Linear RFID 770355150248475
51#	
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS
Passenger	Is there a REMS on this product?
Cargo	If Yes, is it managed with a pharmacy registry?
Passenger & Cargo	Website URL:
ADD'L STORAGE INFORMATION	Comments / Details: (For example, iPledge program?)
Please check as appropriate for this product.	
Organic Inorganic	
Antineoplastic Steroid/Androgen	
Corrosive Oxidizer	
Aerosol Class; Identify NFPA Storage Level:	RETURN INSTRUCTIONS
	Contact tel. # if product received damaged:
	Is product returnable for credit:
Listed Chemical (List I or II) (Indicate or Write-in below):	URL/Link to returns policy:
	Special regulations or returns requirements for this product in certain states?
	If so, which states? Other requirements? Comments?
Pseudoephedrine	i so, which states? Other requirements?
Phenylpropanolamine	
lodine (≥2.2%)	
Other:	
CLASS OF TRADE RESTRICTION:	ADDITIONAL INFORMATION
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	If Unit Dose NDC, indicate NDC here:
Restricted to retail pharmacy only:	MISCELLANEOUS NOTES and/or Image of Product Barcode:
Restricted to hospital, clinics, and physician offices only:	
Restricted from US territories? (explain in comments)	
Comments:	



# **Standard Pharmaceutical Product Information (Page 3)**

FOR DESIGNAT	ED DROP	SHIP PRODUCT	ONLY - if not a	designated	drop ship, d	o not com	plet	e.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax Fax Number:	Purchase order daily receipt cut off time by supplier         Cut off time:
c. Fax Fax Number:	Shipping lead time of PO: Hours Days
d. Phone only Phone No.:	
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:
Minimum Order Quantity:	Ships for second day receipt:
Supplier's Customer Service Number: Contracted 3PL company / contact #: Name:	Ships regular ground for 3-10 days receipt:
Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday
Comments:	Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
Class of Trade Restriction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:
Restricted to retail pharmacy only:	PO Receipt Cut off time:
Restricted to hospital, clinics, and physician offices only:	Order receipt method: Phone: Phone #:
Restricted from US territories? (explain in comments)	Fax: Fax #:
Comments:	EDI:
	Overnight Fees apply:
	Other fees apply:
REMS or Registry Restrictions	Return Instructions
REMS:	Contact # if product is received damaged:
REMS Program Manager Name: Phone:	Is product returnable for credit:
Supplier Manages REMS registry exclusively: Wholesale distributor support:	URL/Link to returns policy: Special regulations or returns requirements for this product in certain states?
Provider Name:	If so, which states? Other requirements? Comments?
Site Enrollment Number assigned by Supplier:	n do, when dates : other requirements : comments :
DEA #:	
PCPDP #:	
NPI#:	
Comments:	
Registry:	ADDITIONAL INFORMATION
Registry Program Contact Name: Phone:	Is product order for scheduled patient procedure?
Comments	Is product order for restocking purposes?
Other Data Information Required to Process PO:	Miscellaneous Notes:
Patient Procedure Date:	
Physician Name:	
Physician/Clinic Phone #	
Physician State License # Physician/Clinic DEA #:	
Physician/Clinic DEA #: Physician/Clinic Specialty:	