

# Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2020				Introduction Type:	New Item		Final Version			Date:	2/17	7/21
		PRODUCT INFORMATI	ION				SPECIAL HANI	DLING AND STOR	AGE REQUIR	EMENTS*		
Company Name: Application Number for NDA/ANI	PD-Rx Pharmaceuticals, In		a. Temperature – Indicate the USP temperature range for this product.  Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)									
DUNS:	156893695	(	ANDA090382			-	er Temperature Range F		Excursions			
Proprietary Name (If Applicable)		Losartan Potassium				1	(write in)	requirement	EXCUISIONS	permitted to	39 and 60 F	
Selling Unit NDC: UDI	72789-0164-90	Unit of Use NDC: CVX Code:		UPC: MVX Code:		Note	es					
Description:	Losartan Potassium 50mg Vendor Item# 333307	g 90 Tab					nis product to be shippe his product to be shippe				No No	-
Active Ingredient(s):		n Potassium				11	perature excursion que		.,			•
URL for Additional Product Inform		/dailymed.nlm.nih.gov/dailymed/d	lrugInfo.cfm?setid=372b		1b664fbecba9	Nam			Ben Silva			
Address:	727 N. Ann Arbor Address 2:									405-942-3040		
City: Key Contact:	Oklahoma City         State:         OK         Zip:           73127           Jack McCall         Email:           ilm@pdrx.com						up E-mail:					
Phone Number:	405-942-3040							states?			No	
Product Therapeutic Classificatio	n:						cial returns requirement		?		*Yes	•
						_	•	•			-	•
	ADDITIONAL PR	ODUCT INFORMATION		PRODUCT DESCR	RIPTION INFORMATION	d. Store product (u	nit of sale) upright?				Yes	
The product is?		Is the Product	Drop-Ship Only				ect product (unit of sa	le) from light?			Yes	
a legend device?	No	Is the Product	Neither	Size:	10mm	e. Shelf life:	al abalf life of larmab	/:£ d:££====4\.			18-24	Months
if yes, enter class # a product kit?	No	Orphan Drug Status			50mg	Initia	al shelf life at launch	(IT different):				Months
if yes, list NDCs of	140	FDA Approval Status		Strength:	Johng			ORDER INFORM	ATION			
component parts				Dosage Form:	Tablet							
reverse numbered?	No No						of Sale		What is the	NDC selling	unit?	
co-licensed? latex-free?	Yes	Allergens Present			Round (Round, Biconvex)		Bottle Box/Carton		1 Bottle	g. 1 Box of	10 Viale)	
preservative-free?	No No			Product Shape:	Round (Round, Biconvex)		Ampule		(vviite-iii, e.	g. I box of	10 viais)	
correctional institution block?				Product Color:	White		Glass		Minimum or	der quantity	y?	Yes
opioid?	No	_		Product Color.			Tube				'-	
Cannabinoid?  If Unit Dose, is item bar coded to	No No	Country of Origin	India	Product Imprint:	12		Vial Liquid Sgl		1636			· · · · · · · · · · · · · · · · · · ·
hospital scanning?	unit dose for	Is this product covered	inder the				Vial Liquid Multi Vial Powder Sal			many or wn Each	ich package	type?
If Unit Dose, indicate NDC here:		Trade Agreements Act (					Vial Power Multi		24	Inner/Cartor	n/Pack	
		Trade / tareements / tet t					Other: Write In		1	Case		
		FOR GENERIC DRUG PRO	DUCTS									
							BU	ADMACK ORDER	DILL LINET			
			_ L Au		thorized Generic, other	PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating: II. Generic Equivalent to What Bra	AB Cozaar			sectio	n fields are not applicable	Rec. sell unit to cu	Istomer? Bottle	1	Rx billing u	nit to pharm Each	acy:	
II. Generic Equivalent to what Bra	diu:					(Write-in, e.g. 1 Via		j		Gram		
	DR	UG SUPPLY CHAIN SECURITY ACT (D	SCSA) INFORMATION			(**************************************	,			Milliliter		
Does supplier meet DSCSA defini	tion of manufacturer?	No	GLN:				ITEM	I AND PACKING IN	JEORMATION			
Is product exempt from DSCSA?	tion of managed of .	No					***	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				
If yes, select exemption: Other exemption - Write in:				'-			Weight Lbs.	Dimensi Depth	ons (US msm Width	its.) Height	Volume	# Pieces:
Is product repackaged?		Yes	If Yes was ori	ginal product purchased	Yes	Item/Each:					(Cube)	
Is product sold by manufacturer's	exclusive distributor?	No	direct from mf			Tterri Lucii.	0.08	1.5	1.5	4	9	1
Has FDA granted waiver/exception	n/exemption for product?	No		locumentation from FDA.		Box/Carton/Bundle	1					
		GTIN AND HIBCC PRODUCT IN	FORMATION			Inner Pack:						
		GTIN AND HIBCC PRODUCT IN	FURMATION			Case:	1.92	6.62	9.62	4	254.7376	24
Saleable Unit of Measure	Quantit	y HIBCC	GTIN	N-14	Unit of Use GTIN-14	Pallet:	476.6	48	40	48	92160	5520
X Item/Each	1		0037	2789164908			4/0.0	40	40	40	92160	5520
Box/Carton/Bundle/Inner Pack	04		500	70700404000			OOST INFORMATION			MUOL FOAL	ED HOE ON	V.
X Case X Pallet	24 5520			72789164903 72789164904			COST INFORMATION			WHOLESALI	ER USE ONL	r:-
A Fallet	3320	,	0037	2703104304		Regular Cost			Vendor #:			
						Invoice Cost (WAC)	) (\$)	\$9.17	Whsl. Code			
						11	0.4.7.04		Fineline Cod	de:		
						As of date:	2/17/21					
		Attach copy of SAFETY DA	TA SHEET (SDS) or non-ha	zard letter PACKAGE ING	SERT, LABEL AND PHOTO O	E BBUDITCE BACKAGIA	JG and BARCODE		1			
*Please provide any additional in	formation on page 2	Attach copy of SAFETT DA	IN OTHEET (SDS) OF HOLL HA		gnated Drop Ship Only	Sian	no and DAROUDE.					



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#### For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? No	SDS Hazard Classification  Organic Corrosive Oxidizer Steroid/Androgen Contact Hazard						
c. Contact Hazard?  d. Does this product require special clean-up instructions?  (If yes, attach SDS with special instructions.)  e. Does the product contain DEHP?  No  Is this product regulated for shipment by DOT?	Aerosol Class; Identify NFPA Storage Level:  Is the product a NIOSH hazardous drug?  If yes, indicate which:						
(if yes, answer a-e below and provide SDS)  a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?  No	Hazardous Waste Identification  EPA Hazardous Waste Code:  Waste Characteristics						
Is this product regulated for shipment by IATA?  (if yes, answer a-e below and provide SDS)  a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?  No	REMS or REGISTRY RESTRICTIONS  Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:  Med Guide Required  No						
Is the product restricted for air shipment? If so, indicate restriction:  Passenger Cargo Passenger & Cargo Is this a reportable quantity? No	Limited Distribution Requirement Comments / Details: (For example, iPledge program?)  REMS:  No						
RQ Threshold:  Is this a marine pollutant? No  Is this product shipped utilizing an authorized DOT exception or Special Permit?  No (if yes, identify method below)  Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	REMS Program Manager Name:  Supplier Manages REMS registry exclusively:  Wholesale distributor support:  Provider Name:  Site Enrollment Number assigned by Supplier:  Comments  Phone:  DEA #:  PCPDP#:  NPI #:						
SP# ADD'L STORAGE INFORMATION	Registry: No Registry Program Contact Name: Phone: Comments						
Is the Product  Controlled Substance?  Controlled Substance Code  Controlled by State(s)?  ARCOS Reportable?  Schedule No.  No  If yes, indicate which:  Is it a scheduled listed chemical product?:  No  CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS  Contact tel. # if product received damaged: 405-942-3040  Is product returnable for credit: No  URL/Link to returns policy: http://nebula.wsimg.com/2d4c27185448acd27ec3cb2ba470ced7?AccessKeyId=65CD						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  No Restricted from US territories? (explain in comments)  No Comments:	67080D5ABADB075D&disposition=0&alloworigin=1						
MISCELLANEOUS NOTES and/or Image of Product Barcode:							



## **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

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### FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing					
Purchase orders may be accepted by:  a. EDI  Yes  THE DATE OF THE	Purchase order daily receipt cut off time by supplier Cut off time:  5:00pm Central					
b. Autofax Yes Fax Number: 405-942-5471 c. Fax Yes Fax Number: 405-942-5471 d. Phone only Yes Phone No.: 405-942-3040	Shipping lead time of PO: Hours 2-5 Days					
e. Supplier Web Site only Minimum Order Quantity: 24 Supplier's Customer Service Number: Contracted 3PL company / contact #:  Value Site Address:  Units  Value Site Address:  Va	Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:  No Yes					
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order: Yes	Overnight receipt available: Yes					
Drop Ship service fee billed with each order: No	PO Receipt cut off time: 12:00pm Central					
Drop Ship miscellaneous fees billed:  Comments: Freight is charged to orders from Hawaii and Alaska. There are no freight charges for domestic customers on orders over \$200.00	Days of week overnight is available:					
	Priority Overnight receipt available: Yes					
Class of Trade Restriction:	PO Receipt Cut off time: 12:00pm CST					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No Comments:	Saturday Overnight receipt available:					
Other Data Information Required to Process PO:	Return Instructions					
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:  Miscellaneous Notes:	Contact # if product is received damaged:  Is product returnable for credit:  URL/Link to returns policy:  http://nebula.wsimg.com/2d4c27185448acd27e  c2cb2b4770cd724cccck/ovld=65C06708005ABA  Special regulations or returns requirements for this product in certain states?  No  If so, which states? Other requirements? Comments?					
	ADDITIONAL INFORMATION					
	Is product order for scheduled patient procedure?  Is product order for restocking purposes?  No Yes					