



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

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

Version 2021

Introduction Type:

New Item

Final Version

Date:

9/3/2026

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: MSN Pharmaceuticals Inc Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 220865 Medical Device Class, if applicable: DUNS: 079229051 Proprietary Name (If Applicable) and Established Name: Tapentadol Tablets 50 mg_100's Selling Unit NDC: 72205-369-91 UDI Description: Pink film-coated round shaped, biconvex tablets debossed with "25" on one side and "T" on other side, free from physical defects. Active Ingredient(s): Tapentadol Hydrochloride URL for Additional Product Information: Address: 20 Duke Road City: Piscataway Key Contact: Phone Number: 908-360-1500 Product Therapeutic Classification:				Application: ANDA Other Temperature Range Requirement (write in): NA Notes: NA Is this product to be shipped to customers on ice? No Is this product to be shipped to customers on dry ice? No b. Contact for temperature excursion questions: Name: Number: Group E-mail: c. Special regulations for product in any states? Special returns requirements for this product? d. Store product (unit of sale) upright? Protect product (unit of sale) from light? e. Shelf life: Initial shelf life at launch (if different):			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is? a legend device? No if yes, enter class # a product kit? No if yes, list NDCs of component parts reverse numbered? No co-licensed? No latex-free? Yes preservative-free? Yes correctional institution block? No opioid? Yes Cannabinoid? No If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here: 72205-369-91		Is the Product... Direct-Ship Only Is the Product... Neither Orphan Drug Status FDA Approval Status Allergens Present No Country of Origin USA Is this product covered under the Trade Agreements Act (TAA)? Yes		Size: 100's Strength: 50 mg Dosage Form: Tablets Product Shape: Product Color: Product Imprint:			
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: Nucynta Authorized Generic *If Authorized Generic, other section fields are not applicable							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? Yes Is product exempt from DSCSA? No If yes, select exemption: Other exemption - Write in: Is product repackaged? No Is product sold by manufacturer's exclusive distributor? No Has FDA granted waiver/exemption/exemption for product? No If yes, attach documentation from FDA.		GLN: 8904159670843 GCP: 89041596 If yes, was original product purchased direct from mfr? Provide source manufacturer for repackaged product					
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure Yes Item/Each NA Box/ Carton/Bundle/Inner Pack Yes Case Yes Pallet		Saleable Quantity 1 Bottle of 100 Tablets 24 bottles in case 4032 bottles in pallet					
HIBCC		GTIN-14 00372205369917 NA 30372205369918 50372205369912					
Unit of Use GTIN-14 00372205369917							
ORDER INFORMATION							
Unit of Sale x Bottle Box/ Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sgl Vial Powder Multi Other: Write In		What is the NDC selling unit? 1 Bottle of 100 Tablets (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? Yes If Yes, how many of which package type? 24 Each Inner/ Carton/ Pack Case					
PHARMACY ORDER / BILL UNIT							
Rec. sell unit to customer? (Write-in, e.g. 1 Vial)		Rx billing unit to pharmacy: x Each Gram Milliliter					
ITEM AND PACKING INFORMATION							
Item/Each:		Weight Lbs.	Dimensions (US msmts.)	Volume (Cube)	Saleable # Pieces		
		0.102	Depth Width Height	52	1		
Box/ Carton/ Bundle/ Inner Pack:		NA	NA	NA	NA		
Case:		3.44	10.03 7.08 4.92	349.38101	24		
Pallet:		618.09	47.24 39.37 40.35	90053.3	4,032		
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost Invoice Cost (WAC) (\$) As of date: 9/3/2026		Vendor #: Whsl. Code #: Fineline Code:					

*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING AND BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:



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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION			
Is this product (check all that apply):			
a. Cytotoxic?	☐	No	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?			
Is the product a CA Prop 65 carcinogen?	☐	No	
Is the product a CA Prop 65 reproductive toxicant?	☐	No	
Does the product label bear a CA Prop 65 warning?	☐	No	
c. Contact Hazard?	☐	No	
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	☐	No	
e. Does the product contain DEHP?	☐	No	
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)		☐	No
a. UN/Identification Number			
b. Proper Shipping Name			
c. DOT Hazard Class			
d. Packing Group			
e. Inhalation Hazard?	☐	No	
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)		☐	No
a. UN/Identification Number			
b. Proper Shipping Name			
c. DOT Hazard Class			
d. Packing Group			
e. Inhalation Hazard?	☐	No	
Is the product restricted for air shipment? If so, indicate restriction:		☐	No
☐ Passenger			
☐ Cargo			
☐ Passenger & Cargo			
Is this a reportable quantity?	☐	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);			
SP#			
ADD'L STORAGE INFORMATION			
Is the Product...			
Controlled Substance?	☐	Yes	Controlled Substance Code 9780
Controlled by State(s)?	☐	Yes	Listed Chemical (List I or II) ☐ No
ARCOS Reportable?	☐	Yes	If yes, indicate which:
Schedule No.		2	Is it a scheduled listed chemical product? ☐ No
CLASS OF TRADE RESTRICTION:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		☐	Yes
Restricted to retail pharmacy only:		☐	No
Restricted to hospital, clinics, and physician offices only:		☐	No
Restricted from US territories? (explain in comments)		☐	No
Comments:			
MISCELLANEOUS NOTES and/or Image of Product Barcode:			

SDS Hazard Classification	
☐ Organic	☐ Corrosive
☐ Inorganic	☐ Oxidizer
☐ Steroid/Androgen	☐ Contact Hazard
Does the product have an Aerosol class? If yes, identify No	
NFPA Storage Level:	
NFPA Storage Level:	
Is the product a NIOSH hazardous drug? ☐ No	
If yes, indicate which:	

Hazardous Waste Identification	
EPA Hazardous Waste Code:	Waste Characteristics

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? ☐ Yes	
If Yes, is it managed with a pharmacy registry? ☐ No	
Website URL: https://www.opioidanalgesicrems.com/home.html	
Med Guide Required ☐ Yes	
Limited Distribution Requirement ☐ No	
Comments / Details: (For example, iPledge program?) Covered under FDA Opioid Analgesic REMS Program	
REMS:	
☐ No	
REMS Program Manager Name:	Phone:
Supplier Manages REMS registry exclusively:	
Wholesale distributor support:	
Provider Name:	DEA #:
Site Enrollment Number assigned by Supplier:	NCPDP#:
	NPI #:
Comments	
Registry: ☐ No	
Registry Program Contact Name:	Phone:
Comments	

RETURN INSTRUCTIONS	
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? ☐ No	
If so, which states? Other requirements? Comments?	

Release DATE



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

Version 2021

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 b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone: Fax Number: Fax Number: Phone No.: Site Address:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday Priority Overnight receipt available: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: Overnight Fees apply: Other fees apply:
Class of Trade Restriction:	
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) Comments:	
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:	Contact # if product is 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?
Miscellaneous Notes:	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?