Mallinckrodt Pharmaceuticals

Addiction Treatment Product Catalog

NDC# 47781	PI	MG	Product Description	Size	Reference Listed Drug	TEE* Rating	Product Image
Buprenorphine and Naloxone Sublingual Film for Sublingual or Buccal Use Ⓒ III							
355-03	●	●	Buprenorphine and Naloxone Sublingual Film (2 mg/0.5 mg)	30 films per box	Suboxone® Sublingual Film	AB	
356-03	●	●	Buprenorphine and Naloxone Sublingual Film (4 mg/1 mg)	30 films per box	Suboxone® Sublingual Film	AB	
357-03	●	●	Buprenorphine and Naloxone Sublingual Film (8 mg/2 mg)	30 films per box	Suboxone® Sublingual Film	AB	
358-03	●	●	Buprenorphine and Naloxone Sublingual Film (12 mg/3 mg)	30 films per box	Suboxone® Sublingual Film	AB	

NDC# 0406	PI	MG	Product Description	Size	Reference Listed Drug	TEE* Rating	Product Image
Buprenorphine and Naloxone Sublingual Tablets, USP Ⓒ III							
8005-03	●	●	Buprenorphine and Naloxone Sublingual Tablets, USP (2 mg/0.5 mg)	30s	Suboxone®	AB	
8020-03	●	●	Buprenorphine and Naloxone Sublingual Tablets, USP (8 mg/2 mg)	30s	Suboxone®	AB	

This product is subject to a Risk Evaluation and Mitigation Strategy (REMS). Refer to the following website for complete information on the REMS program: https://www.btodrems.com/SitePages/Welcome.aspx.

Methadone Hydrochloride Dispersible Tablets (methadone hydrochloride for oral suspension, USP) Ⓒ II							
0540-34	●		Methadose™ Dispersible Tablets, USP (methadone hydrochloride tablets for oral suspension, USP) (40 mg)	100s	Diskets®	AA	
2540-01	●		Methadone Hydrochloride Tablets, USP (methadone hydrochloride tablets for oral suspension, USP) (dispersible, orange flavored) (40 mg)	100s	Diskets®	AA	
Methadone Hydrochloride Powder, USP Ⓒ II							
1510-56			Methadone Hydrochloride Powder, USP	50 gm	NA	NA	NA
1510-57			Methadone Hydrochloride Powder, USP	100 gm	NA	NA	NA

NDC# 0406	PI	MG	Product Description	Size	Reference Listed Drug	TEE* Rating	Product Image

Methadone Hydrochloride Tablets, USP C II

5755-01	●	●	Methadone Hydrochloride Tablets, USP (5 mg)	100s	Dolophine®	AA
5755-62	●	●	Methadone Hydrochloride Tablets, USP (5 mg) Unit Dose Packaging (ten 2x5 blister cards)	100 U.D.	Dolophine®	AA
5771-01	●	●	Methadone Hydrochloride Tablets, USP (10 mg)	100s	Dolophine®	AA
5771-62	●	●	Methadone Hydrochloride Tablets, USP (10 mg) Unit Dose Packaging (ten 2x5 blister cards)	100 U.D.	Dolophine®	AA

This product is subject to a Risk Evaluation and Mitigation Strategy (REMS). Refer to the following website for complete information on the REMS program: https://opioidanalgesicrems.com/home.html.

Methadone Hydrochloride Oral Concentrate, USP C II AND Methadose™ Oral Concentrate (methadone hydrochloride oral concentrate, USP) C II

4123-03	●		Methadone Hydrochloride Oral Concentrate, USP (raspberry flavored) (10 mg/mL)	30 mL	NA	AA
4123-10	●		Methadone Hydrochloride Oral Concentrate, USP (raspberry flavored) (10 mg/mL)	1000 mL	NA	AA
0527-10	●		Methadose™ Oral Concentrate (methadone hydrochloride oral concentrate, USP) (10 mg/mL)	1000 mL	NA	AA
8725-10	●		Methadose™ Sugar-Free Oral Concentrate (methadone hydrochloride oral concentrate, USP) (dye-free, sugar-free, unflavored) (10 mg/mL)	1000 mL	NA	AA

Methadone Hydrochloride Oral Solution, USP C II

6225-05	●	●	Methadone Hydrochloride Oral Solution, USP (raspberry flavored) (5 mg/5 mL)	500 mL	NA	AA
6221-05	●	●	Methadone Hydrochloride Oral Solution, USP (raspberry flavored) (10 mg/5 mL)	500 mL	NA	AA

This product is subject to a Risk Evaluation and Mitigation Strategy (REMS). Refer to the following website for complete information on the REMS program: https://opioidanalgesicrems.com/home.html.

Naltrexone Hydrochloride Tablets, USP

1170-03	●		Naltrexone Hydrochloride Tablets, USP (50 mg)	30s	ReVia™	AB
1170-01	●		Naltrexone Hydrochloride Tablets, USP (50 mg)	100s	ReVia™	AB

PI Click ● to view Full Prescribing Information

MG Click ● to view Medication Guide

Color/Shape can be found in the Alphabetical Product Listing starting on Page 4.
* Definitions are available on Page 15.

NDC# 47781	Product Description	Color/Shape	Size	Case Quantity	DEA Schedule	TEE* Rating	Reference Listed Drug
355-03	Buprenorphine and Naloxone Sublingual Film for Sublingual or Buccal Use **(2 mg/0.5 mg)**	white imprint/ orange film	30 films per box	24	C	AB	Suboxone® Sublingual Film
356-03	Buprenorphine and Naloxone Sublingual Film for Sublingual or Buccal Use **(4 mg/1 mg)**	white imprint/ orange film	30 films per box	24	C	AB	Suboxone® Sublingual Film
357-03	Buprenorphine and Naloxone Sublingual Film for Sublingual or Buccal Use **(8 mg/2 mg)**	white imprint/ orange film	30 films per box	24	C	AB	Suboxone® Sublingual Film
358-03	Buprenorphine and Naloxone Sublingual Film for Sublingual or Buccal Use **(12 mg/3 mg)**	white imprint/ orange film	30 films per box	24	C	AB	Suboxone® Sublingual Film

NDC# 0406	Product Description	Color/Shape	Size	Case Quantity	DEA Schedule	TEE* Rating	Reference Listed Drug
8005-03	Buprenorphine and Naloxone Sublingual Tablets, USP **(2 mg/0.5 mg)**	orange/hexagon	30s	12	C	AB	Suboxone®
8020-03	Buprenorphine and Naloxone Sublingual Tablets, USP **(8 mg/2 mg)**	orange/hexagon	30s	12	C	AB	Suboxone®
4123-03	Methadone Hydrochloride Oral Concentrate, USP (raspberry flavored) **(10 mg/mL)**	red, raspberry flavored liquid	30 mL	6	C	AA	NA
4123-10	Methadone Hydrochloride Oral Concentrate, USP (raspberry flavored) **(10 mg/mL)**	red, raspberry flavored liquid	1000 mL	4	C	AA	NA
6225-05	Methadone Hydrochloride Oral Solution, USP (raspberry flavored) **(5 mg/5 mL)**	orange-colored , raspberry solution	500 mL	12	C	AA	NA
6221-05	Methadone Hydrochloride Oral Solution, USP (raspberry flavored) **(10 mg/5 mL)**	orange-colored, raspberry solution	500 mL	12	C	AA	NA
1510-56	Methadone Hydrochloride Powder, USP	white powder	50 gm	1	C	NA	NA
1510-57	Methadone Hydrochloride Powder, USP	white powder	100 gm	1	C	NA	NA
5755-01	Methadone Hydrochloride Tablets, USP **(5 mg)**	white/rectangle	100s	12	C	AA	Dolophine®
5771-01	Methadone Hydrochloride Tablets, USP **(10 mg)**	white/rectangle	100s	12	C	AA	Dolophine®
5755-62	Methadone Hydrochloride Tablets, USP **(5 mg)** Unit Dose Packaging (ten 2x5 blister cards)	white/rectangle	100 U.D.	24	C	AA	Dolophine®
5771-62	Methadone Hydrochloride Tablets, USP **(10 mg)** Unit Dose Packaging (ten 2x5 blister cards)	white/rectangle	100 U.D.	24	C	AA	Dolophine®
2540-01	Methadone Hydrochloride Tablets, USP (methadone hydrochloride tablets for oral suspension, USP) (dispersible, orange flavored) **(40 mg)**	speckled orange/ rounded rectangular	100s	6	C	AA	Diskets®
0540-34	Methadose™ Dispersible Tablets, USP (methadone hydrochloride tablets for oral suspension, USP) **(40 mg)**	white/round	100s	6	C	AA	Diskets®
0527-10	Methadose™ Oral Concentrate (methadone hydrochloride oral concentrate, USP) **(10 mg/mL)**	red, cherry flavored liquid	1000 mL	4	C	AA	NA
8725-10	Methadose™ Sugar-Free Oral Concentrate (methadone hydrochloride oral concentrate, USP) (dye-free, sugar-free, unflavored) **(10 mg/mL)**	colorless, unflavored liquid	1000 mL	4	C	AA	NA

* Definitions are available on Page 15.

NDC# 0406	Product Description	Color/Shape	Size	Case Quantity	DEA Schedule	TEE* Rating	Reference Listed Drug
1170-03	Naltrexone Hydrochloride Tablets, USP **(50 mg)**	yellow/film-coated/ cap-shape	30s	12	NA	AB	ReVia™
1170-01	Naltrexone Hydrochloride Tablets, USP **(50 mg)**	yellow/film-coated/ cap-shape	100s	12	NA	AB	ReVia™

* Definitions are available on Page 15.

Controlled Substance Ordering System (CSOS)

Mallinckrodt's secure electronic ordering system for controlled substances.

- This program utilizes DEA-issued digital certificate technology.
- How does it work?
  - Customer applies for a digital certificate issued by the DEA.
  - Once the digital certificate has been received, Mallinckrodt will perform set up to allow access to the online CSOS ordering system.
  - Customer logs onto **https://222.mallinckrodt.com** to select items and submit their order.
  - The order is electronically transmitted to Mallinckrodt's EDI system.
  - Confirmation E-mail is sent to customer verifying order has been received.

Getting started

- Contact Mallinckrodt for instructions and links to apply for your DEA digital certificate.
  - Call Mallinckrodt Customer Service at 800.325.8888.
- Complete and submit your application to the DEA. Once approved by the DEA, download the digital certificate.
- When all documentation has been received, contact Mallinckrodt to gain access to the **https://222.mallinckrodt.com** website.
- Mallinckrodt will assist you in setting up your account and provide training for use of the system.
- You are now ready to begin using the Controlled Substance Ordering System.

What are the benefits of using the CSOS software?

- Provides customers ordering freedom, faster turnaround time, more accurate orders, lower transaction cost and enhanced accounting practices.
- A simple, cost effective way to eliminate paper 222s and ensure DEA compliance.
- Provides "one stop shopping" for placing orders and attaching digital signature.
- Assists in DEA requirements by providing ability to track receipt of product and confirm completion of order.

Note:

If you are ordering Buprenorphine/Naloxone products along with CII products, you may order together on a CSOS e222 form.

Controlled Substance Ordering System (CSOS) (Continued)

What is involved in obtaining a DEA digital certificate and password?

› Access a digital certificate application at **www.deaecom.gov**.

› Determine the correct application status.

- Registrant – Individual who is authorized to sign DEA applications.
- Coordinator - Individual who serves as the Local Registration Authority. There can be two coordinators for each DEA registration.
- Power of Attorney – Individual (other than Registrant) who has been granted power of attorney to sign Schedule I and II controlled substance orders.

› Submit application and import certificate once approval has been granted.

How many digital certificate applications do I need?

› The DEA requires one digital certificate per applicant per DEA number.

- If an owner has 3 clinics and 2 people placing orders per location, this is a total of 6 digital certificate applications.
- If one person places orders for 3 clinics, that person would need 3 separate digital certificate applications.

How are the user ID and password generated?

› The login will be your DEA number.

› A temporary password will be supplied by email, and the user will have the ability to update the password at any time.

› Once the primary customer is set up, he/she can create logins for additional users under their DEA account.

How long should records be kept for orders that are placed online?

It is recommended that you retain your transaction records from **https://222.mallinckrodt.com** for at least two years as per the DEA requirement.

Customer Service

Order Information

Our highly responsive customer service department can assist you in placing your orders by phone, mail and EDI. For assistance with preparing your DEA order form, please see previous page. Please note that all Mallinckrodt products are shipped in case quantities only. Minimum order amount is $200.00.

Customer Service

Toll Free No.: *800.325.8888*

Mailing Address:
SpecGx LLC
Attn: Dosage Pharmaceuticals - Customer Service
345 Marshall Avenue, Suite 201
Webster Groves, MO 63119
dpharma@mnk.com

Customer Service Hours:
Monday through Friday, 7:30 am to 4:30 pm Central Time

Customer Support Services are available to assist you with billing, credit, returns and shipment schedule inquiries and procedures.

Concealed Shipment Damages/Losses

Damage/Loss claims must be documented upon delivery and reported directly to Mallinckrodt Customer Service at 800.325.8888 within 5 days of purchase. DEA recommends that all customers open and inventory all shipments as soon as possible. Failure to report these damages/losses in a timely manner significantly impairs Mallinckrodt's ability to properly investigate the cause of the damage or loss. Any damage or loss reported to Mallinckrodt after 5 days of purchase will not be eligible for credit.

Sales And Marketing Support

Our sales and marketing support services are committed to providing you information and answering your inquiries on:

- Product Information ***(genericsmedinfo@mnk.com)***
- Bids and Contract Administration ***(pharma.contracts@mnk.com)***
- EDI ***(EDI.support@mnk.com)***
- Conventions and Trade Shows

Toll Free No.: *800.325.8888*

Mailing Address:
SpecGx LLC
385 Marshall Avenue
Webster Groves, MO 63119

To demonstrate our commitment to the services you deserve, Mallinckrodt has installed an automated charge back and rebate system to increase our transaction efficiency and supplier performance with our trading partners. In addition, Mallinckrodt has EDI capabilities and invites our customers to call and establish electronic transaction processing.

Shipments And Warehouse Facility

Our distribution center is located in our pharmaceuticals manufacturing and packaging facility at 172 Railroad Ave., Hobart, NY, 13788 and ships products five days a week, Monday through Friday. Products ship to Addiction Treatment clinics Monday through Thursday.

DEA Order Form 222 Preparation

Our customer service representatives are available to assist you in filling out and mailing your DEA 222 Order Forms to purchase Schedule II products.

Instructions from DEA for completing the DEA 222 Form can be found on the back of the form.

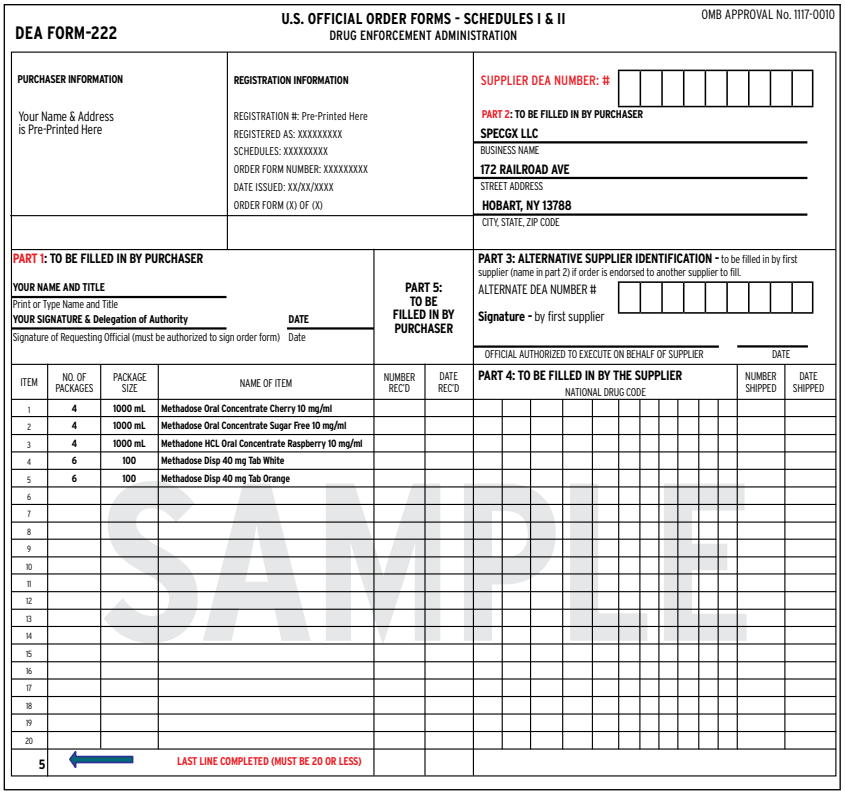
The following information is provided to aid you in accurately completing and sending your DEA 222 Order Form to SpecGx LLC.

1. Complete Part 1 for your order. Please note:
   a. The form may only be signed by a person with the legal authority to do so.
   b. DO NOT forget to fill in the number of the last line completed at the bottom of Part 1.
2. Complete Part 2 using our name, address and our DEA number:

   SpecGx LLC
   172 Railroad Ave.
   Hobart, NY 13788

3. DO NOT complete Part 3 or Part 4 of the form.
4. Keep a photocopy of the form you send to us. You will need it to complete Part 5 after you have received the order from us and to retain that copy for your records.
5. DO NOT alter your Purchaser or Registration Information that is pre-printed at the top of the form. If your name or address has changed, contact DEA to order new forms using the phone number or web address on the back of the DEA 222 Form.
6. FEDERAL REGULATIONS DO NOT ALLOW SUPPLIERS TO ACCEPT DEA 222 ORDER FORMS CONTAINING CORRECTIONS, ALTERATIONS OR WRITE-OVERS. If a mistake is made while completing a form, you must VOID the form and issue a new one.
7. Mail the completed form to:

   SpecGx LLC
   Attn: Dosage Pharmaceuticals - Customer Service
   345 Marshall Avenue
   Webster Groves, MO 63119



DEA FORM-222 — **U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II** — DRUG ENFORCEMENT ADMINISTRATION — OMB APPROVAL No. 1117-0010

PURCHASER INFORMATION
Your Name & Address is Pre-Printed Here

REGISTRATION INFORMATION
REGISTRATION #: Pre-Printed Here
REGISTERED AS: XXXXXXXXX
SCHEDULES: XXXXXXXXX
ORDER FORM NUMBER: XXXXXXXXX
DATE ISSUED: XX/XX/XXXX
ORDER FORM (X) OF (X)

SUPPLIER DEA NUMBER: #

PART 2: TO BE FILLED IN BY PURCHASER
SPECGX LLC — BUSINESS NAME
172 RAILROAD AVE — STREET ADDRESS
HOBART, NY 13788 — CITY, STATE, ZIP CODE

PART 1: TO BE FILLED IN BY PURCHASER
YOUR NAME AND TITLE
Print or Type Name and Title
YOUR SIGNATURE & Delegation of Authority — DATE
Signature of Requesting Official (must be authorized to sign order form) — Date

PART 5: TO BE FILLED IN BY PURCHASER

PART 3: ALTERNATIVE SUPPLIER IDENTIFICATION - to be filled in by first supplier (name in part 2) if order is endorsed to another supplier to fill.
ALTERNATE DEA NUMBER #
Signature - by first supplier
OFFICIAL AUTHORIZED TO EXECUTE ON BEHALF OF SUPPLIER — DATE

ITEM	NO. OF PACKAGES	PACKAGE SIZE	NAME OF ITEM	NUMBER REC'D	DATE REC'D	PART 4: TO BE FILLED IN BY THE SUPPLIER — NATIONAL DRUG CODE	NUMBER SHIPPED	DATE SHIPPED
1	4	1000 mL	Methadose Oral Concentrate Cherry 10 mg/ml					
2	4	1000 mL	Methadose Oral Concentrate Sugar Free 10 mg/ml					
3	4	1000 mL	Methadone HCL Oral Concentrate Raspberry 10 mg/ml					
4	6	100	Methadose Disp 40 mg Tab White					
5	6	100	Methadose Disp 40 mg Tab Orange					
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
5			LAST LINE COMPLETED (MUST BE 20 OR LESS)					

Returned Goods Policy

Applicable to Pharmaceutical Products Sold by SpecGx LLC
(Effective September 3, 2024)

SCOPE

This SpecGx LLC ("**SpecGx**") Returned Goods Policy ("**Policy**") applies to all finished dosage pharmaceutical products sold by SpecGx through direct or indirect arrangements (collectively referred to herein as "Product(s)"). SpecGx will only accept the return of Products for consideration of credit or refund under the conditions and limitations set forth in this Policy and any applicable supply agreement, invoice, purchase order, or applicable law. This Policy supersedes all previous policies relating to the return of Products and may be modified by SpecGx at any time.

GENERAL TERMS

SpecGx's customer service department and distribution center (together, "**Distribution Center**") manages returns for certain damaged Products or erroneous shipments as more fully described below. SpecGx has designated PharmaLink ("**Return Agent**") as its third party returns processor to manage the return and destruction of certain short-dated, near expiry, or expired Products, also as more fully described below. As used herein, the party returning any Product is sometimes referred to as a "**customer**" or "**you**."

SpecGx will only process and consider for credit or refund Products returned directly to its Distribution Center or the Return Agent, as applicable, and reserves the right to deny credit or refunds for returns sent to any other party. Additionally, SpecGx shall be the sole determinator of whether Products qualify for credit or refund and SpecGx's determination of the physical count of any returned Products is final.

Returns will not be processed unless and until you request and the Distribution Center or the Return Agent, as applicable, issues a return authorization ("**RA**"). However, issuance of an RA by the Distribution Center or the Return Agent, as applicable, does not guarantee credit will be issued. Credit issuance is dependent upon confirmed receipt and review of the Product. By returning Products or other goods, you authorize the Distribution Center or the Return Agent to destroy, at their discretion and without credit or other recourse to you, any returned Products or goods. Any Products or other goods returned to the Distribution Center or the Return Agent without an RA or otherwise in violation of the terms of this Policy may be destroyed or returned to you at their discretion, and in such case credit will not be issued.

All transportation and insurance fees are to be prepaid by you, except when an error occurs due to the actions of SpecGx (see Damages and Erroneous Shipments section below). SpecGx will not reimburse fees due to processing third party returns, destruction charges, shipping costs, or administrative fees.

DAMAGED AND ERRONEOUS SHIPMENTS (RETURNS MANAGED BY THE DISTRIBUTION CENTER)

For direct customers only, Products shipped in error by SpecGx, Products damaged in transit, or Products containing concealed damages must be reported to Customer Service as soon as reasonably possible and in any event within five (5) days of receipt and these Products must be returned to the Distribution Center within ten (10) days of receipt. Additionally, any Product shortages must be reported by direct customers to Customer Service immediately. You must note visible damage or shortages on the Bill of Lading or receiving document. Where loss, shortage, breakage, leakage, or other damage has occurred in transit, you agree to cooperate fully with SpecGx in its efforts to establish a claim against the transportation company. For example, if requested by SpecGx, you must provide photographs of damaged Products for investigation purposes. A restocking fee of twenty percent (20%) of the credit may be charged for items ordered in error by you or for overstock Products, as determined by SpecGx in its discretion.

For return instructions for damaged or erroneous shipments, contact SpecGx Customer Service at 800-325-8888, or via E-mail *Dpharma@mnk.com*.

Returned Goods Policy (Continued)

NEAR EXPIRY OR EXPIRED PRODUCTS (RETURNS MANAGED BY THE RETURN AGENT)

Returns will only be accepted by the Return Agent for credit for Products as specified below:

1. Six (6) months prior to expiration date (sometimes referred to as "**near expiry**") with a valid legible SpecGx Serial number, lot number, and expiry date.
2. Up to twelve (12) months after expiration date (sometimes referred to as "**expired**"), with a valid legible SpecGx Serial number, lot number, and expiry date.
3. Product must be in its original container.

INITIATION OF RETURNS FOR NEAR EXPIRY OR EXPIRED PRODUCTS (RETURNS MANAGED BY THE RETURN AGENT)

All "near expiry" or expired Product must be returned to the Return Agent at the below address and in accordance with the following procedures to be eligible for credit:

PharmaLink
Receiving Department PLI- SGX
8285 Bryan Dairy Road, #160
Largo, FL 33777

An RA and the accompanying return label can be obtained from the Return Agent as follows:

1. Access the Return Agent's website at ***https://www.PharmaLinkinc.com*** and select Manufacturer RA at the top of the webpage.
    a. First Time users need to create a New User login.

2. Select "Start a new return" and choose SpecGx from the Manufacturer dropdown menu.
    a. Create Inventory: Allows you to enter an inventory of items in the shipment.
    b. Upload Debit memo: Allows you to upload an inventory of items in the shipment.

3. The following information must be supplied, or the RA Request will be declined, and Product will not be eligible for credit:
    a. NDC Number, Product Description, Lot/Batch #, Quantity, Customer's Reference Number
    b. Authorized Servicing Wholesaler
    c. Debit Memo Number, Date, and Amount requested.
    d. Expiration Date (in the event the package expiration date is stated in month/year format, expiration date will default to the last day of the month)
    e. Returning Facility details including
        i. Facility Name, Address, City, State, and Zip code
        ii. Facility DEA Number
        iii. Facility State License

4. The RA label must be attached to the outside of the return shipment package.

5. Additional information must be provided to SpecGx or the Return Agent if requested.

All returns must be received by the Return Agent no later than sixty (60) days after RA label issuance, with the RA label attached on the exterior of the box, together with a copy of the customer's debit memo for such return(s) enclosed in the shipment. Product returned that does not meet the criteria listed above will be quarantined by the Return Agent. If the above information cannot be obtained by the end of the business day, the Return Agent will not accept return of the Product at its facility and it will be sent back to you.

For assistance returning "near expiry" or expired Products to the Return Agent, contact *CustomerSolutions@pharmalinkinc.com*

Returned Goods Policy (Continued)

CONDITIONS FOR CREDIT FOR ANY RETURNS

1. A valid RA number must accompany all Product returns for proper credit. RA numbers for damaged or erroneous shipments are valid for ten (10) days from issuance and RA numbers for near expiry or expired Product are valid for sixty (60) days from issuance. Expired RA numbers will be considered invalid, and no credit will be issued.
2. All near expiry or expired Products must be returned to the Return Agent within sixty (60) days of the issuance of the RA to receive credit.
3. Products destroyed by customers or agents of customers will not receive credit.
4. For returns of multiple Products with different RA numbers, each Product should be in a separate box with its corresponding RA number. If multiple Products with different RA numbers are packed into one box, each Product must be bagged separately.
5. Only Products should be in the box.
6. Product must be in its original container.
7. Customers will only be eligible for partial return credits when required by applicable state law or per the terms of an applicable written agreement.
8. Product must be returned by the customer who purchased the Product from SpecGx, end customer, or authorized 3rd party. Proof of purchase may be required for credit issuance.
9. Credit will only be issued to direct accounts in good standing. Credits and checks remaining open after one hundred eighty (180) days from issue date of check or credit memo will be reversed.
10. Contracted Products will be issued credit based on the lowest eligible purchase price within the past twenty-four (24) month timeframe.
11. Non-contracted brand Products will be valued on a weighted average selling price for the lot number returned.
12. In all other circumstances, credit will be issued at the lowest price offered by SpecGx within the past twenty-four (24) month timeframe.

NON-RETURNABLE ITEMS

- Product not purchased directly from SpecGx or an authorized distributor
- Except as otherwise expressly provided in this Policy, Products damaged due to insurable causes or acts of force majeure, or Products that have been damaged or deteriorated due to improper handling or storage by customer
- Products involved in salvage, bankruptcy, or insolvency proceedings
- Private label, repackaged Products, or Products not in the original container
- Any Products sold on a non-returnable basis, including, but not limited to, Product sold short-dated
- Any Products donated without charge to customer
- Products purchased or distributed in violation of federal, state or local laws, rules, or regulations
- Products with labels removed or altered
- Products that have been outside the United States and its territories
- Any Product designated as samples or free goods
- Products past one year of the expiry date
- Products discontinued for more than 12 months
- Product for which proof of purchase cannot be verified
- Products returned outside of this Policy will not receive credit
- Products returned without an RA

For questions on this Policy, contact *Expired.Returns@mnk.com*.

Mallinckrodt Methadone Products Shipment, Delivery and Accountability FAQ

How quickly will Mallinckrodt ship product ordered by OTP customers?

Mallinckrodt offers free shipping to OTP customers on the following schedule provided the order, DEA 222 Form or CSOS transaction is received by 11:00 AM CST.

Order Received by SpecGx LLC Customer Service by 11:00 AM CST	Monday	Tuesday	Wednesday	Thursday	Friday
Order Shipped	Tuesday	Wednesday	Thursday	Monday	Monday
Order Delivered	Wednesday	Thursday	Friday	Tuesday	Tuesday

**Holidays may impact timing. Any change to the schedule will be communicated in advance.*

Any order requiring same day shipment must be received by 11:00 AM CST. Additional fees may apply to any orders that do not meet the one (1) business day lead time requirement.

What are the criteria for Mallinckrodt acceptance of a DEA 222 Form?

Title *21 C.F.R. §1305.15 (https://www.ecfr.gov/current/title-21/chapter-II/part-1305/subpart-B/section-1305.15)* sets forth the regulatory requirements for DEA 222 forms. DEA 222 forms received by Mallinckrodt containing corrections or alterations will be returned to the customer.

What are the delivery signature requirements for Methadose Liquid and Methadone HCl Tablets?

Title *21 C.F.R. §1301.74(h) (https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.74)* sets forth the regulatory requirements for acceptance of delivery by a narcotic treatment program.

How is the delivery signature requirement information maintained?

It is the customer's responsibility to notify Mallinckrodt, in writing, of a change to the list of employees authorized to accept OTP deliveries. Please contact Mallinckrodt Pharmaceuticals Dosage Products Customer Service by E-mail *dpharma@mnk.com* to verify or update your list of employees authorized to accept OTP deliveries.

Which carrier does Mallinckrodt use for OTP delivery service?

Mallinckrodt uses FedEx Priority Alert Overnight service for OTP shipments in order to obtain delivery signatures and for other unique OTP requirements such as delivery appointments.

How does the FedEx Priority Alert Overnight system function?

FedEx Priority Alert Overnight service assigns one unique FedEx tracking number to each individual outer carton (package) being shipped. Shipments consisting of two or more packages are assigned two or more FedEx tracking numbers, one tracking number for each package.

Mallinckrodt Methadone Products Shipment, Delivery and Accountability FAQ (Continued)

As an OTP accepting shipment of Mallinckrodt product, what do I do about "partial" FedEx deliveries?

As noted above, FedEx tracks each package separately within the FedEx Priority Alert Overnight system. The FedEx delivery person may not have knowledge of other packages/tracking numbers expected by the OTP.

Title ***21 C.F.R. §1301.74(e) (https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.74)*** directs that the registrant employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses. The FedEx delivery person should not be made aware of the contents or number of packages expected for delivery.

Should the OTP send a "partial" delivery back to the FedEx terminal?

It is not recommended that OTPs refuse "partial" delivery shipments in order to decrease the likelihood of an in-transit loss.

What happens if an OTP accepts a "partial" delivery and the remainder of the OTP order is not delivered?

OTPs may contact Mallinckrodt Pharmaceuticals Dosage Products Customer Service at 1.800.325.8888 or ***dpharma@mnk.com*** for shipment tracking number information.

Who has responsibility for filing DEA106 Theft/Loss Report if the remainder of my order does not arrive?

OTP customers should contact their DEA field office for specific instructions. Additional information is available on the DEA webpage ***www.deadiversion.usdoj.gov***.

Resources

Publications & Manuals
Manuals
Narcotic Treatment Program

In-Transit Loss of Controlled Substances

When all or part of a shipment of controlled substances fails to reach its intended destination, the supplier is responsible to report the in-transit losses of controlled substances to DEA. An OTP is responsible for reporting any losses of controlled substances after a designated staff member has signed for and taken custody of a shipment.

21 CFR 1301.74(c)

Accountability

What happens if pill count or liquid volume varies from the Mallinckrodt label claim?

Fill rate may vary within the packaging operation but must meet target volumes and specifications prior to shipment. Contact Mallinckrodt Corporate Product Monitoring at 1.800.778.7898 or ***pmquality@mnk.com*** to report any issues with fill count or other quality related events.

Mallinckrodt contact if additional information is required:

Customer Service
Telephone: 800.325.8888
E-mail: dpharma@mnk.com.

Definitions

Mallinckrodt is pleased to provide the following product identification guide for our Addiction Treatment products. Although every effort has been made to ensure the accuracy of photographs and content, it is important to note that the product size and color may vary. The information presented is to be used only as a reference guide.

If you have specific requests regarding product identification, please call product Monitoring at 1.800.778.7898 or E-mail ***genericsmedinfo@mnk.com***.

* Therapeutic Equivalence Evaluations (TEE) Rating Glossary

AA Drug products coded as "AA" contain active ingredients and dosage forms that are not regarded as presenting either actual or potential bioequivalence problems.

NOTE: A drug product that has a therapeutic equivalence to another drug product can be expected to have the same clinical effect and safety profile as the prescribed product, and therefore can be substituted.

AB Drug products are coded as AB if they meet bioequivalence requirements.

NR Not rated.

NA Not applicable.

Drug Enforcement Administration (DEA) Schedule Definitions

Schedule II/IIN Controlled Substances (2/2N)

Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.

Schedule III/IIIN Controlled Substances (3/3N)

Substances in this schedule have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.

Mallinckrodt Pharmaceuticals

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