



Mallinckrodt
Pharmaceuticals



**Addiction Treatment
Product Catalog**
June 2015



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NDC #00406	Product Description	Size	Case Quantity	DEA Schedule	TEE Rating*	Tablet Shape/Color
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BUPRENORPHINE and NALOXONE SUBLINGUAL TABLETS**

1923-03	Buprenorphine and Naloxone Sublingual Tablets 2 mg/0.5 mg	30	24	Ⓒ	AB	
1924-03	Buprenorphine and Naloxone Sublingual Tablets 8 mg/2 mg	30	24	Ⓒ	AB	

METHADONE HYDROCHLORIDE TABLETS

5755-01	Methadone Hydrochloride Tablets, USP 5 mg	100	12	Ⓒ	AA	
5771-01	Methadone Hydrochloride Tablets, USP 10 mg	100	12	Ⓒ	AA	
2540-01	Methadone Hydrochloride Tablets, USP 40 mg (Dispersible, Orange Flavored)	100	6	Ⓒ	AA	

METHADOSE™ DISPERSIBLE TABLETS (methadone hydrochloride tablets for oral suspension USP)

0540-34	Methadose™ Dispersible Tablets, 40 mg	100	6	Ⓒ	AA	
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METHADOSE™ ORAL CONCENTRATE (methadone hydrochloride oral concentrate, USP)

0527-10	Methadose™ Oral Concentrate 10 mg per mL	1000 mL	4	Ⓒ	AA	
8725-10	Methadose™ Sugar-Free Oral Concentrate 10 mg per mL (dye-free, sugar-free, unflavored)	1000 mL	4	Ⓒ	AA	

METHADONE HYDROCHLORIDE, USP POWDER

1510-57	Methadone Hydrochloride USP Powder	100 gram Bottle	1	Ⓒ	NA	
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Important Information

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

If you have specific requests regarding product identification, please call Medical Information 800.778.7898.

* Products coded as AA contain active ingredients and dosage forms that are not regarded as presenting either actual or potential bioequivalence problems or drug quality or standard issues.

** DEA 222 Order Form not required for CIII products.



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.



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.

DEA Order Form 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. See below for a completed DEA 222 Order Form example.

The following are instructions for completing your DEA 222 Order Form and mailing to Mallinckrodt.

- Supplier's name and DEA registered address is:
Mallinckrodt LLC
172 Railroad Ave.
Hobart, NY 13788
- Current date
- List items ordered: "No. of Packages," "Size of Package," "Name of Item."
- DO NOT fill in area marked "TO BE FILLED IN BY SUPPLIER."
- Fill in "LAST LINE COMPLETED." This number should represent the number of different items listed in the "NAME OF ITEM" column (not the total number of packages and not necessarily the number of lines completed).
- "SIGNATURE OF PURCHASER" line must be signed by person with legal authority.
- DO NOT alter printed information in "Name and Address of Registrant" section. If your name or address has changed, contact your Regional DEA Office. Shipment can only be made to the address printed on the DEA 222 Order Form.
- 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.
- The DEA 222 Order Form is mailed to the following address:
Mallinckrodt LLC
Attn: Dosage Pharmaceuticals - Customer Service
675 McDonnell Blvd.
Hazelwood, MO 63042

Mail only the BROWN and GREEN copies of the DEA 222 Order Form to Mallinckrodt. For additional instructions for completing these forms, refer to the back of your BLUE "PURCHASER'S" copy.



See Reverse of PURCHASER'S Copy for Instructions			No order form may be issued for Schedule I or II substances unless a completed application form has been received. (21 CFR 1305.04).				OMB APPROVAL No. 1117-0010		
TO: (Name of Supplier) Mallinckrodt LLC			STREET ADDRESS 172 Railroad Avenue						
CITY and STATE Hobart, NY 13788			DATE Today's Date		TO BE FILLED IN BY SUPPLIER SUPPLIERS DEA REGISTRATION No.				
LINE No.	TO BE FILLED IN BY PURCHASER						National Drug Code	Packages Shipped	Date Shipped
	No. of Packages	Size of Package	Name of Item						
1	12	100	Methadone 5 mg Tablets						
2	12	100	Methadone 10 mg Tablets						
3	12	100	Methadose™ 40 mg Tablets						
4	12	100	Methadone HCl - 40 mg Orange Tablets						
5	12	1 Liter	Methadose™ Oral Conc - Cherry						
6	12	1 Liter	Methadose™ Sugar Free						
7	12	100 G	Methadone HCl USP Powder						
8									
9									
10									
6	LAST LINE COMPLETED			(MUST BE 10 OR LESS)		SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT			
Date Issued 01312008		DEA Registration No.		Name and Address of Registrant					
Schedules 2,3,3N,4,5				Your Business Name Your Business Street Address Your City, State, Zip Code					
Registered as a DISTRIBUTOR		No. of this Order Form							
DEA Form-222 (Oct. 1992)		U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II DRUG ENFORCEMENT ADMINISTRATION					75550258		
SUPPLIER'S Copy 1									

Please reference "Mallinckrodt LLC" on DEA Form 222 to ensure efficient processing. (This reference should be made under the "To: (Name of Supplier)" section in the upper left portion of the DEA 222 Form.)



Customer Service

ORDER INFORMATION

Our highly responsive customer service department can assist you in placing your orders by phone, fax, 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 \$300.00.

Customer Service Toll Free No.: 800.325.8888
Fax No.: 314.654.6511
Mailing Address: Mallinckrodt LLC
Attn: Dosage Pharmaceuticals - Customer Service
675 McDonnell Blvd.
Hazelwood, MO 63042

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 10 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 10 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
- Bids and Contract Administration
- EDI
- Conventions and Trade Shows

Toll Free No.: 800.325.8888
Fax No.: 314.654.6580
Mailing Address: Mallinckrodt - Contracts Dept.
675 McDonnell Blvd., Bldg. 301 2-W
Hazelwood, MO 63042

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. This shipping facility is a state-of-the-art distribution center which will enhance our daily shipping efficiency and provide better service for our customers' product orders and scheduling needs.

Our distribution center ships products five days a week, Monday through Friday. Products ship to Addiction Treatment clinics Monday through Thursday.



Return Goods Policy

SHORT DATED AND EXPIRED RETURNABLE ITEMS

- In order to receive credit, Products in original, unopened containers must be returned no earlier than six (6) months prior to the expiration of the Product's shelf life and no later than twelve (12) months after expiration of the Product's shelf life.
- No credit will be given for the return of partial bottles of any Product (unless required by applicable law).
- All Products must be returned in the original, secured package.
- Credits and checks remaining open after six months or 180 days from issue date of check or credit memo will be reversed.

PROCEDURES FOR RETURNING SHORT DATED OR EXPIRED PRODUCTS

Request for Return Authorizations (box labels) can be made by any of the below methods:

1. Accessing the Inmar, Inc. website at <https://CLSNetLink.com> (you will need to upload a PDF copy of your debit memo)
2. E-mail your debit memo to rarequest@inmar.com (Be sure to include NDC#, lot# and expiration dates assigned to each item)
3. Fax your debit memo to Inmar, Inc. at 817.868.5343

Actual returns are to be forwarded to the processing facility at the following location:

Mallinckrodt LLC
C/O Inmar, Inc. - South Dock
4332 Empire Road
Fort Worth, TX 76155

RETURNS THAT REQUIRE PRE-AUTHORIZATION

Products shipped in error or Products damaged in transit must be reported to Mallinckrodt Customer Service at 800.325.8888 within ten (10) days of receipt by the Customer and pre-authorization and instructions relating to the return of those Products must be obtained by Customer from Mallinckrodt Customer Service.

Please reference "Mallinckrodt LLC." on DEA Form 222 to ensure efficient processing. (This reference should be made under the "To: (Name of Supplier)" section in the upper left portion of the DEA 222 Form.)

PRODUCTS THAT ARE NOT RETURNABLE

Notwithstanding any of the foregoing, the following Products will not be accepted for return at Inmar, Inc.:

- Mallinckrodt Imaging and API ;
- Products damaged due to insurable causes or acts of force majeure, or damaged/deteriorated due to improper handling or storage by Customer;
- Any Products sold on a non-returnable basis, including, but not limited to, product sold short-dated;
- Products purchased or distributed contrary to federal, state or local laws;
- Products with labels removed or altered;
- Products that have been outside the United States and United States territories;
- Any items designated as samples or free goods.

VALUATION OF RETURNS (INCLUDING RECALLED PRODUCT)

- Credit will be issued based on lowest eligible purchase price within the past twenty-four month timeframe.
- If eligibility cannot be determined credit will be issued at lowest price.
- Mallinckrodt will only credit Products returned to Inmar Pharmaceutical Services (unless Mallinckrodt Customer Service instructs Customer to return the Products in another manner).
- Third party processing fees are not reimbursable.
- Transportation charges, including insurance, are to be prepaid by Customer, except when Products are shipped in error by Mallinckrodt.
- A restocking fee of 20% of the credit will be charged for items ordered in error or for overstock Products. Mallinckrodt has full authority to determine if Product is of an overstock nature.

For questions on this Return Goods Policy, please contact Returns: 800.833.1717, ext. 47013.



Mallinckrodt Methadose/Methadone Products Shipment, Delivery and Accountability FAQ

How quickly will Mallinckrodt ship product ordered by OTP customers?

Mallinckrodt offers same day shipment to OTP customers Monday through Thursday provided the order, DEA 222 Form or CSOS transaction is received by 12 noon CST.

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

Title [21 C.F.R. §1305.15](http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_15.htm) (http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_15.htm) 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\(h\)](http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_74.htm) (http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_74.htm) 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@mallinckrodt.com to verify or update your list of employees authorized to accept OTP deliveries.

Which carrier does Mallinckrodt use for OTP delivery service?

Mallinckrodt used 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.

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\(e\)](http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_74.htm) (http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_74.htm) 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.



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

How is Mallinckrodt assisting OTPs on tracking “partial” deliveries?

Effective June, 2014, Mallinckrodt will begin sending Advanced Shipping Notices (ASN) by e-mail to OTPs for each shipment. Please contact Mallinckrodt Pharmaceuticals Dosage Products Customer Service at 1.888.325.8888 or dpharma@mallinckrodt.com to update your e-mail address for receipt of ASNs.

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

OTPs may consult the ASN provided by Mallinckrodt to obtain FedEx tracking numbers for the remainder of product ordered or contact Mallinckrodt Pharmaceuticals Dosage Products Customer Service at 1.888.325.8888 or dpharma@mallinckrodt.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

Identification of Discrepancy/Damage to a Shipment

Procedures to be followed when a discrepancy or damage is found by the designated OTP staff at the time of delivery include the following:

When all or part of a shipment disappears, or never reaches its intended destination, the supplier is responsible for reporting any 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 C.F.R. §1301.74(c) (http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_74.htm)

Accountability

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

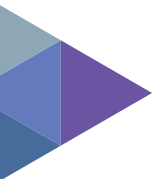
Fill rate may vary within the packaging operation but must meet target volumes and specifications prior to shipment. Contact Mallinckrodt Corporate Product Monitoring at 1.800.778.7898 or pmquality@mallinckrodt.com to report any issues with fill count or other quality related events.

Mallinckrodt contact if additional information is required:

Customer Service

Telephone: 800.325.8888

Email: AT@mallinckrodt.com



NOTES





A Solid Foundation

- Reliable Supply
- Excellent Service
- Customer Support



675 McDonnell Blvd.
Hazelwood, MO 63042

www.mallinckrodt.com