



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version

Date:

| PRODUCT INFORMATION | |
|--|--|
| Company Name: | Zydus Pharmaceuticals USA Inc. |
| Application: | ANDA |
| Application Number for NDA/ANDA/BLA, Med Device: | 91352 |
| Rx Product/Proprietary Name: | Omeprazole Delayed-Release Capsules, USP 40mg, 30 ct |
| NDC: | 68382-500-06 |
| UPC: | 368382500069 |
| CVX Code: | |
| MVX Code: | |
| Description: | Off-white to pale brown free flowing pellets filled in size '1' hard gelatin capsules with amethyst purple colored cap printed with "ZA-11" in black ink & white body printed with "40 mg" in black ink. |
| Active ingredients: | Omeprazole |
| URL for Additional Product Information: | www.zydususa.com |
| Address: | 73 Route 31 North |
| City: | Pennington |
| State: | NJ |
| Zip: | 08534 |
| Key Contact: | |
| Email: | |
| Phone Number: | (609) 730 1900 |
| Fax: | (609) 730 1991 |

| SPECIAL HANDLING AND STORAGE REQUIREMENTS* | |
|--|--|
| a. Temperature – Indicate the USP temperature range for this product. | |
| <input type="checkbox"/> | I. Freezer – between -25 and -10 C (-13° – 14° F) |
| <input type="checkbox"/> | II. Cold – between 2 and 8 C (36° – 46° F) |
| <input type="checkbox"/> | III. Cool – between 8 and 15 C (46° – 59° F) |
| <input checked="" type="checkbox"/> | IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F) |
| <input type="checkbox"/> | V. Avoid Excessive Heat – above 40 C (>104° F) |
| <input type="checkbox"/> | VI. Other Temperature Range Requirement (write in) <input type="text"/> |
| <input type="checkbox"/> | VII. No Requirement |
| b. Contact for temperature excursion questions: | |
| Name: | <input type="text"/> |
| Number: | <input type="text"/> |
| Is this product to be shipped to customers on ice? | <input type="text" value="No"/> |
| Is this product to be shipped to customers on dry ice? | <input type="text" value="No"/> |
| c. Special regulations for product in certain states? | |
| Special returns requirements for this product? | <input type="text" value="No"/> |
| d. Store product (unit of sale) upright? | |
| Protect product (unit of sale) from light? | <input type="text" value="No"/> |
| e. Shelf life: | |
| <input type="text" value="24"/> Months | |
| Initial shelf life at launch (if different): | <input type="text"/> Months |

| FOR GENERIC DRUG PRODUCTS | |
|------------------------------------|--|
| I. Orange Book Rating: | AB |
| II. Brand Name: | Prilosec |
| III. Generic Equivalent for Brand: | Omeprazole Delayed-Release Capsules, USP 40mg, 30 ct |

| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | |
|--|---|
| Does supplier meet DSCSA definition of manufacturer? | <input checked="" type="text" value="Yes"/> |
| DUNS: | 156861945 |
| Is product exempt from DSCSA? | <input type="text" value="No"/> |
| If yes, select exemption: | <input type="text"/> |
| Other exemption - Write in: | <input type="text"/> |
| Is product repackaged? | <input type="text" value="No"/> |
| If Yes, was original product purchased direct from mfr? | <input type="text"/> |
| Is product sold by manufacturer's exclusive distributor? | <input type="text" value="No"/> |
| Are any waivers granted for product ID/barcode? | <input type="text" value="No"/> |
| If yes, attach documentation from FDA | <input type="text"/> |

| ADDITIONAL PRODUCT INFORMATION | |
|---|---------------------------------|
| Is the Product... Direct Ship Item | <input type="text"/> |
| Legend Device? | <input type="text" value="No"/> |
| State Control? | <input type="text" value="No"/> |
| ARCOS reportable? | <input type="text" value="No"/> |
| Co-Licensed? | <input type="text" value="No"/> |
| Controlled Substance? | <input type="text" value="No"/> |
| Schedule No.? | <input type="text"/> |
| (incl. N for non-narcotic) | |
| Controlled Substance Code: | <input type="text"/> |
| Hazardous Material/Cytotoxic Agent? | <input type="text" value="No"/> |
| Is Item... | <input type="text"/> |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | <input type="text"/> |
| Is it reverse numbered? | <input type="text"/> |

| ORDER INFORMATION | |
|---|---|
| Unit of Sale | <input checked="" type="checkbox"/> Bottle |
| | <input type="checkbox"/> Box/Carton |
| | <input type="checkbox"/> Ampule |
| | <input type="checkbox"/> Glass |
| | <input type="checkbox"/> Tube |
| | <input type="checkbox"/> Vial Liquid Sgl |
| | <input type="checkbox"/> Vial Liquid Multi |
| | <input type="checkbox"/> Vial Powder Sgl |
| | <input type="checkbox"/> Vial Power Multi |
| | <input type="checkbox"/> Other: Write In <input type="text"/> |
| What is the NDC selling unit? | Each |
| (Write-in, e.g. 1 Box of 10 Vials) | <input type="text"/> |
| Minimum order quantity? | <input type="text" value="Yes"/> |
| If Yes, how many of which package type? | |
| | <input type="text"/> Each |
| | <input type="text"/> Inner/ Carton/Pack |
| | <input type="text"/> Case |
| | <input type="text" value="1"/> |

| ITEM AND PACKING INFORMATION | | | | | | |
|------------------------------|-------------|------------------------|--------|--------|---------------|-----------|
| Item: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | # Pieces: |
| | | Depth | Height | Width: | | |
| Item: | 37.0 G | | 2.375 | 1.531 | 3.63613 | |
| Box/ Carton: | | | | | 0 | |
| Case: | 3.20LBS | 6.22 | 3.43 | 9.33 | 199.051818 | 24 |
| Pallet: | | 47.24 | 47 | 39.37 | 87412.4236 | |
| UPC: | | | | | | |
| Case: | | | | | | |
| Carton: | | | | | | |

| WHOLESALE USE ONLY: | |
|---------------------|----------------------|
| Vendor #: | <input type="text"/> |
| Whsl. Code #: | <input type="text"/> |
| Fineline Code: | <input type="text"/> |

| PHARMACY ORDER / BILL UNIT | Other Product Information |
|--|------------------------------------|
| Rec. sell unit to customer? | Size/Strength/Form: |
| <input type="text"/> | 30ct/40mg/Capsule |
| (Write-in, e.g. 1 Vial) | |
| Rx billing unit to pharmacy: | Product Shape: |
| <input checked="" type="checkbox"/> Each | Capsule |
| <input type="checkbox"/> Gram | Product Color: |
| <input type="checkbox"/> Milliliter | Amethyst Purple/White to off white |
| | Product Imprint: |
| | ZA 11 40mg |

| COST INFORMATION | | |
|--|-------------------------|-------------------------------------|
| Regular Cost Per Unit of Sale (\$) | Invoice Cost (WAC) (\$) | Federal Excise Tax Per Unit of Sale |
| | \$17.33 | |
| As of date: <input type="text" value="9/10/2014"/> | | |

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

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



Standard Pharmaceutical Product Information (Page 2)

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? No

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

| Hazardous Waste Identification | |
|--------------------------------|--|
| EPA Hazardous Waste Code: | |

Is this product regulated for shipment by the DOT? No

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?
 (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#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

| ADDITIONAL PRODUCT INFORMATION - Serialization | | | | | | |
|--|-------------------------------------|------------|--|--------------------------|--------------------------|-----------------------|
| Serialized? | Yes | Level | How? | RFID | GTIN-14 | |
| | <input checked="" type="checkbox"/> | Item | <input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear | <input type="checkbox"/> | <input type="checkbox"/> | 10368382500066 |
| If not, when? | <input type="text"/> | Box/Carton | <input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear | <input type="checkbox"/> | <input type="checkbox"/> | |
| Items aggregated to case? | <input type="text"/> | Case | <input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear | <input type="checkbox"/> | <input type="checkbox"/> | |
| | | Pallet | <input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear | <input type="checkbox"/> | <input type="checkbox"/> | |

| REMS or REGISTRY RESTRICTIONS | |
|---|----------------------|
| Is there a REMS on this product? | <u>No</u> |
| If Yes, is it managed with a pharmacy registry? | <input type="text"/> |
| Website URL: | <input type="text"/> |
| Comments / Details: (For example, iPledge program?) | |
| <input type="text"/> | |

ADD'L STORAGE INFORMATION

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: | <u>877-993-8779</u> |
| Is product returnable for credit? | <input type="text"/> |
| URL/Link to returns policy: | <u>www.zydususa.com</u> |
| Special regulations or returns requirements for this product in certain states? | <u>No</u> |
| If so, which states? Other requirements? Comments? | <input type="text"/> |

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other:

| CLASS OF TRADE RESTRICTION: | |
|---|----------------------|
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices | <u>Yes</u> |
| Restricted to retail pharmacy only: | <u>No</u> |
| Restricted to hospital, clinics, and physician offices only: | <u>No</u> |
| Restricted from US territories? (explain in comments) | <u>No</u> |
| Comments: | <input type="text"/> |

| ADDITIONAL INFORMATION | |
|--------------------------------------|----------------------|
| If Unit Dose NDC, indicate NDC here: | <input type="text"/> |

| MISCELLANEOUS NOTES and/or Image of Product Barcode: | |
|--|--|
| <input type="text"/> | |



Standard Pharmaceutical Product Information (Page 3)

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 _____ Fax Number: _____ c. Fax _____ Fax Number: _____ d. Phone only _____ Phone No.: _____ e. Supplier Web Site only _____ Site Address: _____ Minimum Order Quantity: _____ Supplier's Customer Service Number: _____ Contracted 3PL company / contact #: _____ Name: _____ Phone: _____ | 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: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> 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: _____ | |
| REMS or Registry Restrictions | Return Instructions |
| REMS: _____ REMS Program Manager Name: _____ Phone: _____ Supplier Manages REMS registry exclusively: _____ Wholesale distributor support: _____ Provider Name: _____ Site Enrollment Number assigned by Supplier: _____ DEA #: _____ PCPDP #: _____ NPI #: _____ Comments: _____ Registry: _____ Registry Program Contact Name: _____ Phone: _____ Comments: _____ | 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? _____ |
| Other Data Information Required to Process PO: | ADDITIONAL INFORMATION |
| Patient Procedure Date: _____ Physician Name: _____ Physician/Clinic Phone #: _____ Physician State License #: _____ Physician/Clinic DEA #: _____ Physician/Clinic Specialty: _____ | Is product order for scheduled patient procedure? _____ Is product order for restocking purposes? _____ Miscellaneous Notes: _____ |



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date:

| PRODUCT INFORMATION | |
|--|--|
| Company Name: | Zydus Pharmaceuticals USA Inc. |
| Application: | ANDA |
| Application Number for NDA/ANDA/BLA, Med Device: | 91352 |
| Rx Product/Proprietary Name: | Omeprazole Delayed-Release Capsules, USP 40mg, 100 ct |
| NDC: | 68382-500-01 |
| UPC: | 368382500014 |
| CVX Code: | |
| MVX Code: | |
| Description: | Off-white to pale brown free flowing pellets filled in size '1' hard gelatin capsules with amethyst purple colored cap printed with "ZA-11" in black ink & white body printed with "40 mg" in black ink. |
| Active ingredients: | Omeprazole |
| URL for Additional Product Information: | www.zydususa.com |
| Address: | 73 Route 31 North |
| City: | Pennington |
| State: | NJ |
| Zip: | 08534 |
| Key Contact: | |
| Email: | |
| Phone Number: | (609) 730 1900 |
| Fax: | (609) 730 1991 |

| SPECIAL HANDLING AND STORAGE REQUIREMENTS* | |
|--|--|
| a. Temperature – Indicate the USP temperature range for this product. | |
| <input type="checkbox"/> | I. Freezer – between -25 and -10 C (-13° – 14° F) |
| <input type="checkbox"/> | II. Cold – between 2 and 8 C (36° – 46° F) |
| <input type="checkbox"/> | III. Cool – between 8 and 15 C (46° – 59° F) |
| <input checked="" type="checkbox"/> | IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F) |
| <input type="checkbox"/> | V. Avoid Excessive Heat – above 40 C (>104° F) |
| <input type="checkbox"/> | VI. Other Temperature Range Requirement (write in) <input type="text"/> |
| <input type="checkbox"/> | VII. No Requirement |
| b. Contact for temperature excursion questions: | |
| Name: | <input type="text"/> |
| Number: | <input type="text"/> |
| Is this product to be shipped to customers on ice? | <input type="text" value="No"/> |
| Is this product to be shipped to customers on dry ice? | <input type="text" value="No"/> |
| c. Special regulations for product in certain states? | |
| Special returns requirements for this product? | <input type="text" value="No"/> |
| d. Store product (unit of sale) upright? | |
| Protect product (unit of sale) from light? | <input type="text" value="No"/> |
| e. Shelf life: | |
| <input type="text" value="24"/> Months | Initial shelf life at launch (if different): <input type="text"/> Months |

| FOR GENERIC DRUG PRODUCTS | |
|------------------------------------|---|
| I. Orange Book Rating: | AB |
| II. Brand Name: | Prilosec |
| III. Generic Equivalent for Brand: | Omeprazole Delayed-Release Capsules, USP 40mg, 100 ct |

| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | |
|--|---|
| Does supplier meet DSCSA definition of manufacturer? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |
| DUNS: | 156861945 |
| Is product exempt from DSCSA? | <input type="checkbox"/> No |
| If yes, select exemption: | <input type="text"/> |
| Other exemption - Write in: | <input type="text"/> |
| Is product repackaged? | <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes |
| If Yes, was original product purchased direct from mfr? | <input type="text"/> |
| Is product sold by manufacturer's exclusive distributor? | <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes |
| Are any waivers granted for product ID/barcode? | <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes |
| If yes, attach documentation from FDA | <input type="text"/> |

| ADDITIONAL PRODUCT INFORMATION | |
|---|-----------------------------|
| Is the Product... Direct Ship Item | <input type="checkbox"/> |
| Legend Device? | <input type="checkbox"/> No |
| State Control? | <input type="checkbox"/> No |
| ARCOS reportable? | <input type="checkbox"/> No |
| Co-Licensed? | <input type="checkbox"/> No |
| Controlled Substance? | <input type="checkbox"/> No |
| Schedule No.? | <input type="text"/> |
| (incl. N for non-narcotic) | |
| Controlled Substance Code: | <input type="text"/> |
| Hazardous Material/Cytotoxic Agent? | <input type="checkbox"/> No |
| Is Item... | <input type="text"/> |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | <input type="text"/> |
| Is it reverse numbered? | <input type="text"/> |

| ITEM AND PACKING INFORMATION | | | | | | |
|------------------------------|-------------|------------------------|--------|--------|---------------|-----------|
| Item: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | # Pieces: |
| | | Depth | Height | Width: | | |
| Item: | 75.0 G | | 3.735 | 2.234 | 8.34399 | |
| Box/ Carton: | | | | | 0 | |
| Case: | 6.30LBS | 8.98 | 5 | 13.46 | 604.354 | 24 |
| Pallet: | | 47.24 | 47 | 39.37 | 87412.4236 | |
| UPC: | Case: | | | | | |
| | Carton: | | | | | |

| WHOLESALE USE ONLY: | |
|---------------------|----------------------|
| Vendor #: | <input type="text"/> |
| Whsl. Code #: | <input type="text"/> |
| Fineline Code: | <input type="text"/> |

| PHARMACY ORDER / BILL UNIT | Other Product Information |
|--|------------------------------------|
| Rec. sell unit to customer? <input type="checkbox"/> | Size/Strength/Form: |
| <input type="text"/> | 100ct/40mg/Capsule |
| (Write-in, e.g. 1 Vial) | Product Shape: |
| Rx billing unit to pharmacy: | Capsule |
| <input checked="" type="checkbox"/> Each | Product Color: |
| <input type="checkbox"/> Gram | Amethyst Purple/White to off white |
| <input type="checkbox"/> Milliliter | Product Imprint: |
| | ZA 11 40mg |

| COST INFORMATION | | |
|--|-------------------------|-------------------------------------|
| Regular Cost Per Unit of Sale (\$) | Invoice Cost (WAC) (\$) | Federal Excise Tax Per Unit of Sale |
| | \$57.76 | |
| As of date: <input type="text" value="9/10/2014"/> | | |

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

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



Standard Pharmaceutical Product Information (Page 2)

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? No

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

| Hazardous Waste Identification | |
|--------------------------------|--|
| EPA Hazardous Waste Code: | |

Is this product regulated for shipment by the DOT? No

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?
 (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#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

| ADDITIONAL PRODUCT INFORMATION - Serialization | | | | | | |
|--|-------------------------------------|-------------|------|--------|--------------------------|----------------|
| Serialized? | Yes | Level | How? | RFID | GTIN-14 | |
| Serialized? | <input checked="" type="checkbox"/> | Item | 2D | Linear | <input type="checkbox"/> | 10368382500011 |
| If not, when? | <input type="text"/> | Box/ Carton | 2D | Linear | <input type="checkbox"/> | |
| Items aggregated to case? | <input type="text"/> | Case | 2D | Linear | <input type="checkbox"/> | |
| | | Pallet | 2D | Linear | <input type="checkbox"/> | |

| REMS or REGISTRY RESTRICTIONS | |
|---|----------------------|
| Is there a REMS on this product? | <u>No</u> |
| If Yes, is it managed with a pharmacy registry? | <input type="text"/> |
| Website URL: | <input type="text"/> |
| Comments / Details: (For example, iPledge program?) | |
| <input type="text"/> | |

ADD'L STORAGE INFORMATION

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: | <u>877-993-8779</u> |
| Is product returnable for credit: | <input type="text"/> |
| URL/Link to returns policy: | <u>www.zydususa.com</u> |
| Special regulations or returns requirements for this product in certain states? | <u>No</u> |
| If so, which states? Other requirements? Comments? | <input type="text"/> |

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other:

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:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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 |
|---|---|
| <p>Purchase orders may be accepted by:</p> <ul style="list-style-type: none">a. EDI <input type="checkbox"/>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/></p> | <p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p> |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing |
| <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p> | <p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> |
| Class of Trade Restriction: | Saturday Overnight receipt available: |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p> | <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p> |
| REMS or Registry Restrictions | Return Instructions |
| <p>REMS: <input type="checkbox"/></p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/></p> <p>Wholesale distributor support: <input type="checkbox"/></p> <p>Provider Name: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/></p> <p>DEA #: <input type="text"/></p> <p>PCPDP #: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments: <input type="text"/></p> <p>Registry: <input type="checkbox"/></p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments: <input type="text"/></p> | <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p> |
| Other Data Information Required to Process PO: | Miscellaneous Notes: |
| <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p> | <p>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p> <p>Miscellaneous Notes:</p> <p><input type="text"/></p> |



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version

Date:

| PRODUCT INFORMATION | |
|--|--|
| Company Name: | Zydus Pharmaceuticals USA Inc. |
| Application: | ANDA |
| Application Number for NDA/ANDA/BLA, Med Device: | 91352 |
| Rx Product/Proprietary Name: | Omeprazole Delayed-Release Capsules, USP 40mg, 1000 ct |
| NDC: | 68382-500-10 |
| UPC: | 368382500106 |
| CVX Code: | |
| MVX Code: | |
| Description: | Off-white to pale brown free flowing pellets filled in size '1' hard gelatin capsules with amethyst purple colored cap printed with "ZA-11" in black ink & white body printed with "40 mg" in black ink. |
| Active ingredients: | Omeprazole |
| URL for Additional Product Information: | www.zydususa.com |
| Address: | 73 Route 31 North |
| City: | Pennington |
| State: | NJ |
| Zip: | 08534 |
| Key Contact: | |
| Email: | |
| Phone Number: | (609) 730 1900 |
| Fax: | (609) 730 1991 |

| SPECIAL HANDLING AND STORAGE REQUIREMENTS* | |
|--|--|
| a. Temperature – Indicate the USP temperature range for this product. | |
| <input type="checkbox"/> | I. Freezer – between -25 and -10 C (-13° – 14° F) |
| <input type="checkbox"/> | II. Cold – between 2 and 8 C (36° – 46° F) |
| <input type="checkbox"/> | III. Cool – between 8 and 15 C (46° – 59° F) |
| <input checked="" type="checkbox"/> | IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F) |
| <input type="checkbox"/> | V. Avoid Excessive Heat – above 40 C (>104° F) |
| <input type="checkbox"/> | VI. Other Temperature Range Requirement (write in) <input type="text"/> |
| <input type="checkbox"/> | VII. No Requirement |
| b. Contact for temperature excursion questions: | |
| Name: | <input type="text"/> |
| Number: | <input type="text"/> |
| Is this product to be shipped to customers on ice? | <input type="text" value="No"/> |
| Is this product to be shipped to customers on dry ice? | <input type="text" value="No"/> |
| c. Special regulations for product in certain states? | |
| Special returns requirements for this product? | <input type="text" value="No"/> |
| d. Store product (unit of sale) upright? | |
| Protect product (unit of sale) from light? | <input type="text" value="No"/> |
| e. Shelf life: | |
| <input type="text" value="24"/> Months | |
| Initial shelf life at launch (if different): | <input type="text"/> Months |

| FOR GENERIC DRUG PRODUCTS | |
|------------------------------------|--|
| I. Orange Book Rating: | AB |
| II. Brand Name: | Prilosec |
| III. Generic Equivalent for Brand: | Omeprazole Delayed-Release Capsules, USP 40mg, 1000 ct |

| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | |
|--|---|
| Does supplier meet DSCSA definition of manufacturer? | <input checked="" type="text" value="Yes"/> |
| DUNS: | 156861945 |
| Is product exempt from DSCSA? | <input type="text" value="No"/> |
| If yes, select exemption: | <input type="text"/> |
| Other exemption - Write in: | <input type="text"/> |
| Is product repackaged? | <input type="text" value="No"/> |
| If Yes, was original product purchased direct from mfr? | <input type="text"/> |
| Is product sold by manufacturer's exclusive distributor? | <input type="text" value="No"/> |
| Are any waivers granted for product ID/barcode? | <input type="text" value="No"/> |
| If yes, attach documentation from FDA | <input type="text"/> |

| ADDITIONAL PRODUCT INFORMATION | |
|---|---------------------------------|
| Is the Product... Direct Ship Item | <input type="text"/> |
| Legend Device? | <input type="text" value="No"/> |
| State Control? | <input type="text" value="No"/> |
| ARCOS reportable? | <input type="text" value="No"/> |
| Co-Licensed? | <input type="text" value="No"/> |
| Controlled Substance? | <input type="text" value="No"/> |
| Schedule No.? | <input type="text"/> |
| (incl. N for non-narcotic) | |
| Controlled Substance Code: | <input type="text"/> |
| Hazardous Material/Cytotoxic Agent? | <input type="text" value="No"/> |
| Is Item... | <input type="text"/> |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | <input type="text"/> |
| Is it reverse numbered? | <input type="text"/> |

| ORDER INFORMATION | |
|---|---|
| Unit of Sale | <input checked="" type="checkbox"/> Bottle |
| | <input type="checkbox"/> Box/Carton |
| | <input type="checkbox"/> Ampule |
| | <input type="checkbox"/> Glass |
| | <input type="checkbox"/> Tube |
| | <input type="checkbox"/> Vial Liquid Sgl |
| | <input type="checkbox"/> Vial Liquid Multi |
| | <input type="checkbox"/> Vial Powder Sgl |
| | <input type="checkbox"/> Vial Powder Multi |
| | <input type="checkbox"/> Other: Write In <input type="text"/> |
| What is the NDC selling unit? | Each |
| (Write-in, e.g. 1 Box of 10 Vials) | |
| Minimum order quantity? | <input type="text" value="Yes"/> |
| If Yes, how many of which package type? | |
| | <input type="text"/> |
| | Each |
| | Inner/ Carton/Pack |
| | Case |
| | <input type="text" value="1"/> |

| ITEM AND PACKING INFORMATION | | | | | | |
|------------------------------|-------------|------------------------|--------|--------|---------------|-----------|
| Item: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | # Pieces: |
| | | Depth | Height | Width: | | |
| Item: | 455.00 G | | 7.984 | 3.937 | 31.433 | |
| Box/ Carton: | | | | | 0 | |
| Case: | 17.3LBS | 11.81 | 9.76 | 15.75 | 1815.4332 | 12 |
| Pallet: | | 47.24 | 47 | 39.37 | 87412.4236 | 32 |
| UPC: | Case: | | | | | |
| | Carton: | | | | | |

| WHOLESALE USE ONLY: | |
|---------------------|----------------------|
| Vendor #: | <input type="text"/> |
| Whsl. Code #: | <input type="text"/> |
| Fineline Code: | <input type="text"/> |

| PHARMACY ORDER / BILL UNIT | Other Product Information |
|--|------------------------------------|
| Rec. sell unit to customer? | Size/Strength/Form: |
| <input type="text"/> | 1000ct/40mg/Capsule |
| (Write-in, e.g. 1 Vial) | |
| Rx billing unit to pharmacy: | Product Shape: |
| <input checked="" type="checkbox"/> Each | Capsule |
| <input type="checkbox"/> Gram | Product Color: |
| <input type="checkbox"/> Milliliter | Amethyst Purple/White to off white |
| | Product Imprint: |
| | ZA 11 40mg |

| COST INFORMATION | | |
|--|-------------------------|-------------------------------------|
| Regular Cost Per Unit of Sale (\$) | Invoice Cost (WAC) (\$) | Federal Excise Tax Per Unit of Sale |
| | \$577.60 | |
| As of date: <input type="text" value="9/10/2014"/> | | |

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

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



Standard Pharmaceutical Product Information (Page 2)

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? No

Carcinogen
 Reproductive Toxicant
 Both
 Warning appears on label

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

| Hazardous Waste Identification | |
|--------------------------------|--|
| EPA Hazardous Waste Code: | |

Is this product regulated for shipment by the DOT? No

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?
 (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#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

Passenger
 Cargo
 Passenger & Cargo

| ADDITIONAL PRODUCT INFORMATION - Serialization | | | | | | |
|--|-------------------------------------|-------------|------|--------|--------------------------|----------------|
| Serialized? | Yes | Level | How? | RFID | GTIN-14 | |
| Serialized? | <input checked="" type="checkbox"/> | Item | 2D | Linear | <input type="checkbox"/> | 10368382500103 |
| If not, when? | <input type="text"/> | Box/ Carton | 2D | Linear | <input type="checkbox"/> | |
| Items aggregated to case? | <input type="text"/> | Case | 2D | Linear | <input type="checkbox"/> | |
| | | Pallet | 2D | Linear | <input type="checkbox"/> | |

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

ADD'L STORAGE INFORMATION

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: 877-993-8779

Is product returnable for credit:

URL/Link to returns policy: www.zydususa.com

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments?

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine
 Pseudoephedrine
 Phenylpropanolamine
 Iodine (≥2.2%)
 Other:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

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:



Standard Pharmaceutical Product Information (Page 3)

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 |
|---|--|
| <p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/></p> | <p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p> |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing |
| <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p> | <p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p> |
| Class of Trade Restriction: | REMS or Registry Restrictions |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p> | <p>REMS: <input type="checkbox"/></p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/></p> <p>Wholesale distributor support: <input type="checkbox"/></p> <p>Provider Name: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/></p> <p>DEA #: <input type="text"/></p> <p>PCPDP #: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p> <p>Registry: <input type="checkbox"/></p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p> |
| Other Data Information Required to Process PO: | Return Instructions |
| <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p> | <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 50px;" type="text"/></p> |
| Miscellaneous Notes: | ADDITIONAL INFORMATION |
| <p><input style="width: 100%; height: 100px;" type="text"/></p> | <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p> |