ISOTRETINOIN- isotretinoin capsule
Zydus Lifesciences Limited

SPL MEDGUIDE

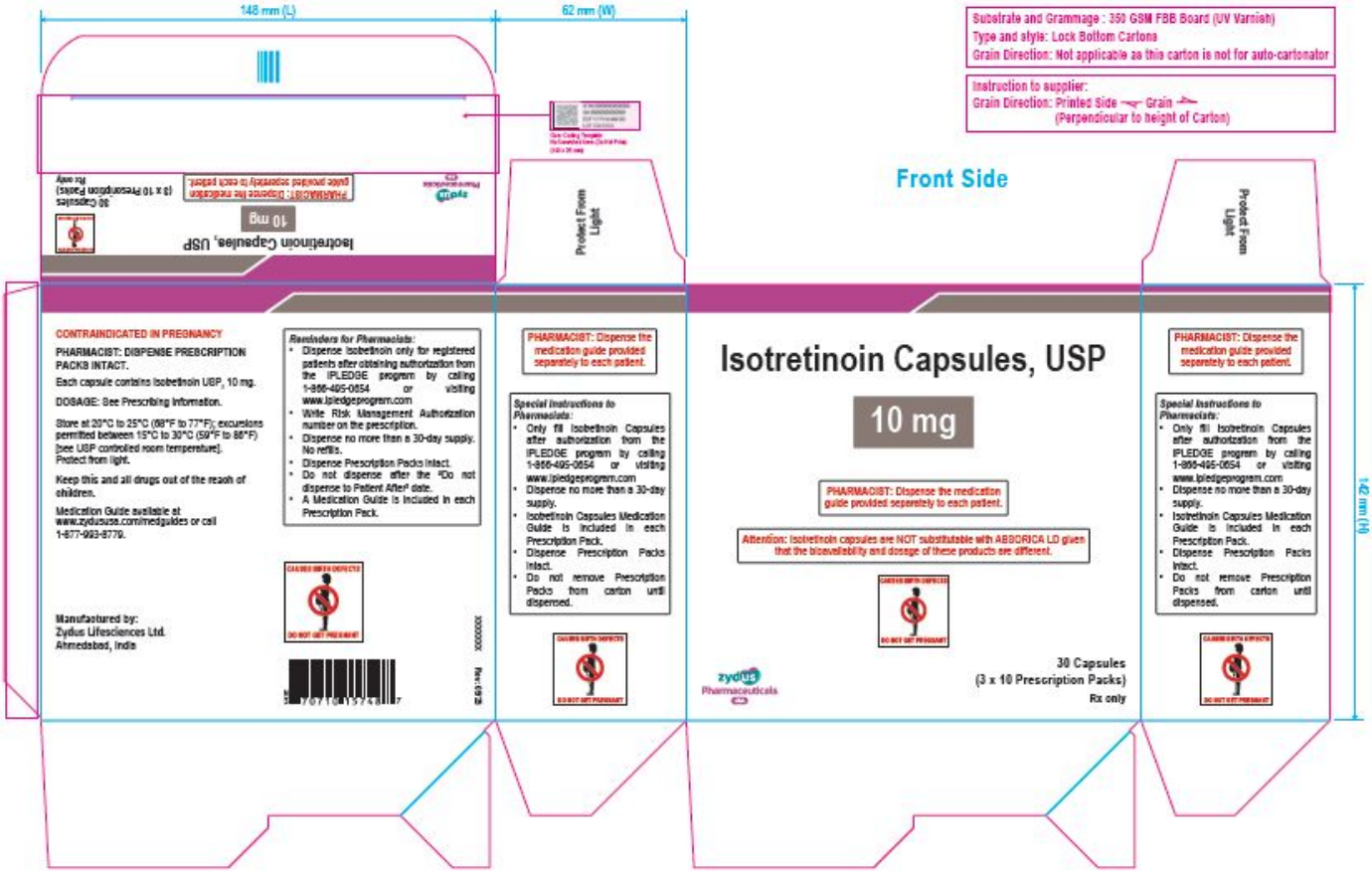
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

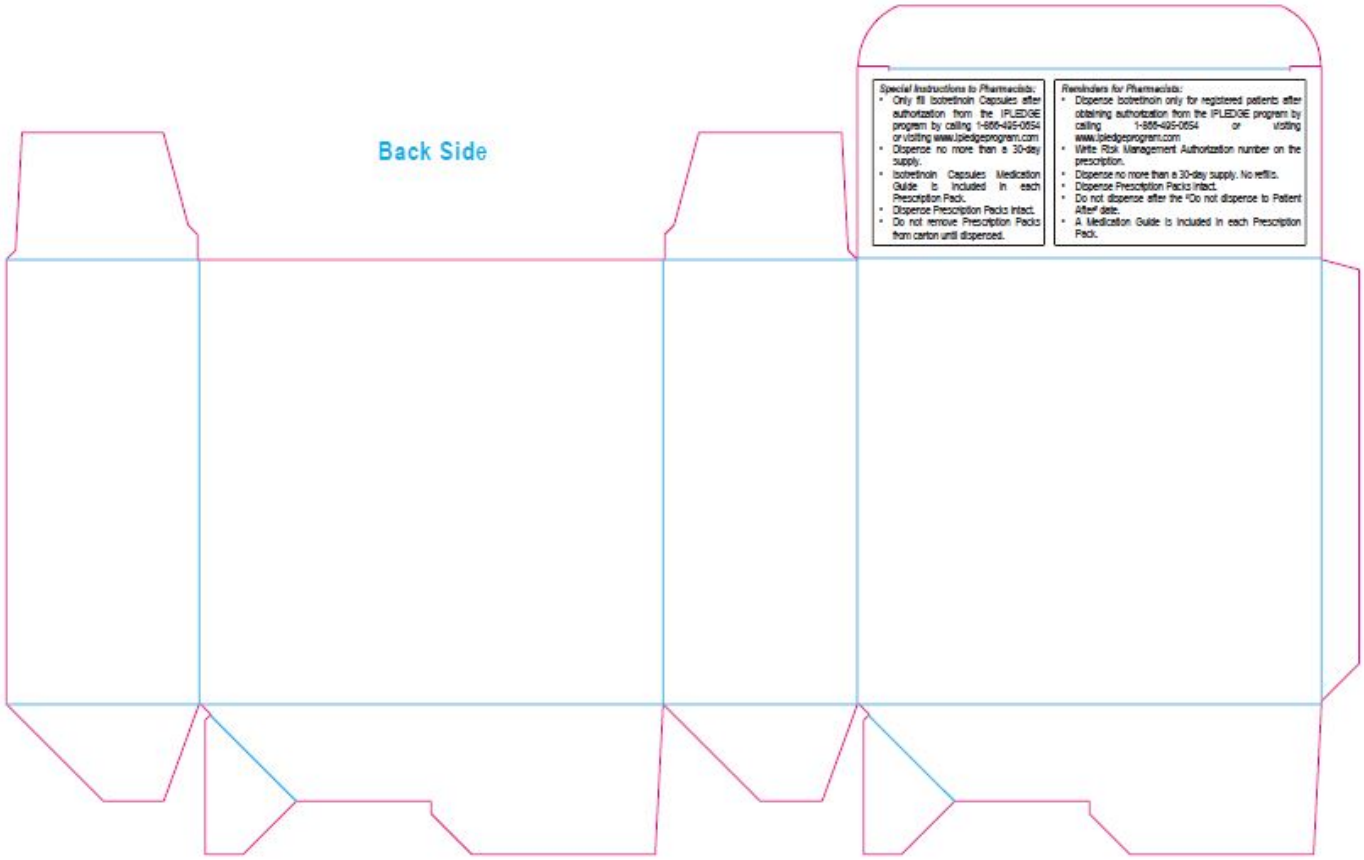
NDC 70771-1662-8

Isotretinoin Capsules USP, 10 mg

30 Capsules

Rx only



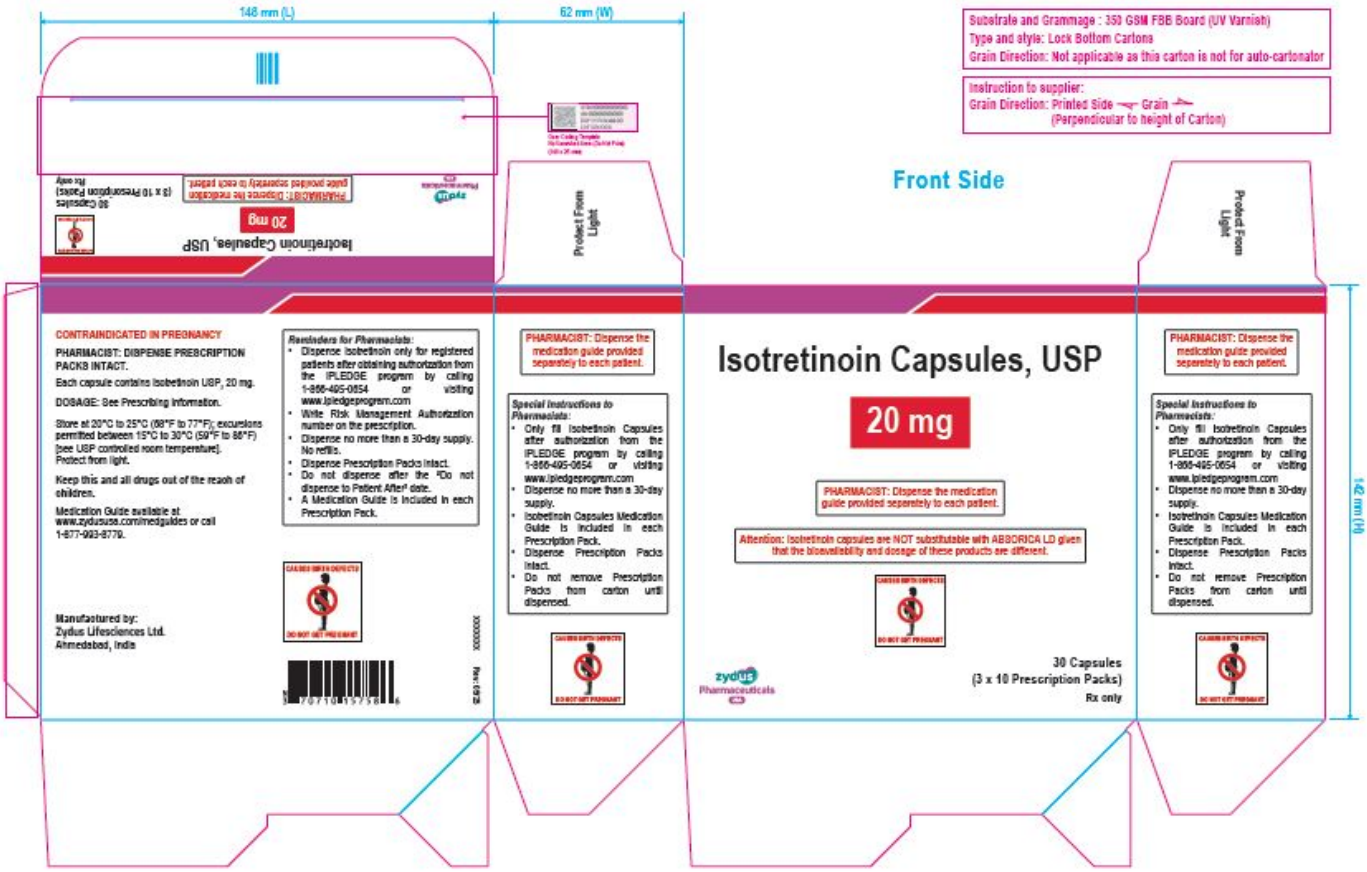


NDC 70771-1663-8

Isotretinoin Capsules USP, 20 mg

30 Capsules

Rx only

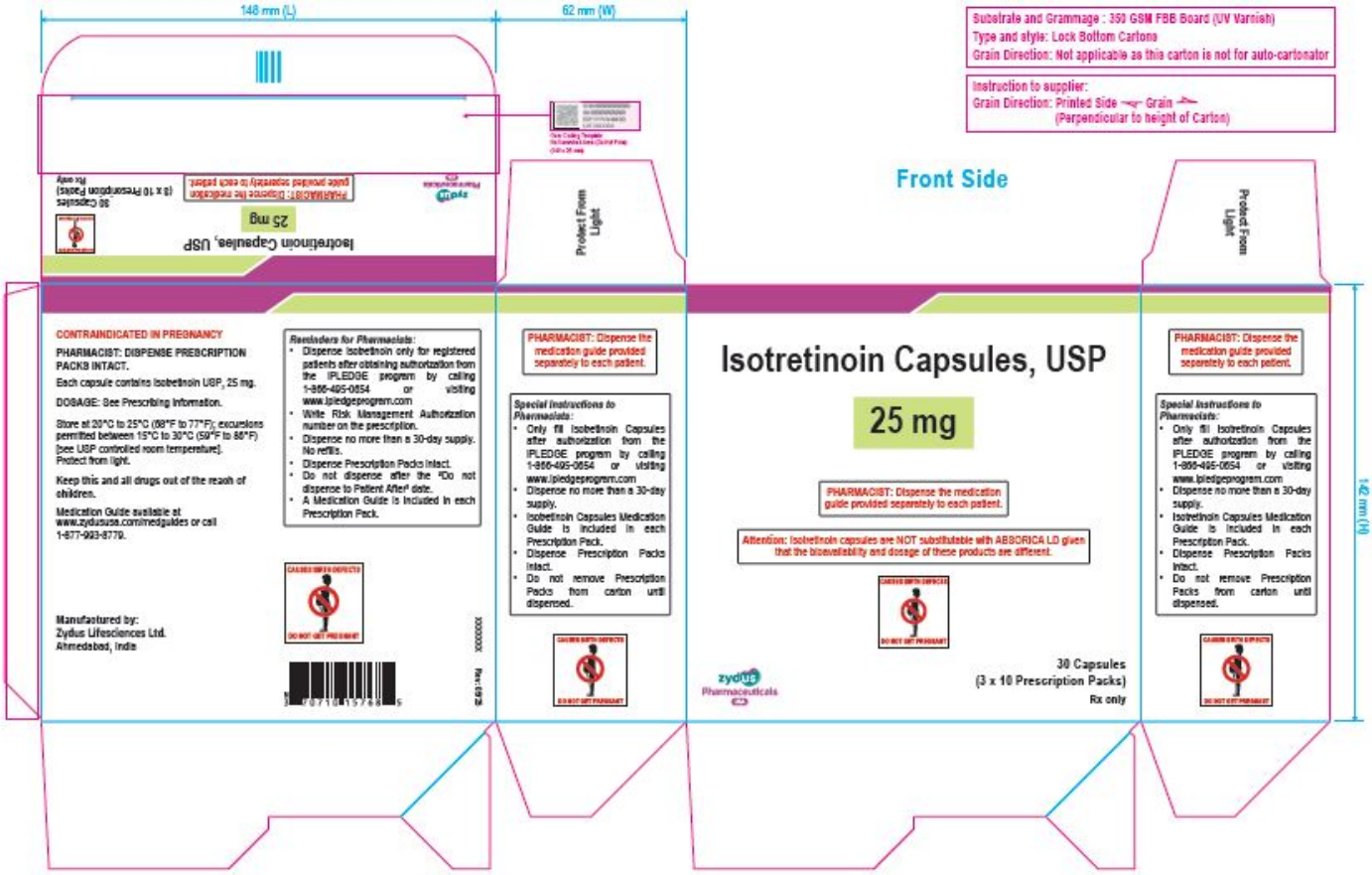


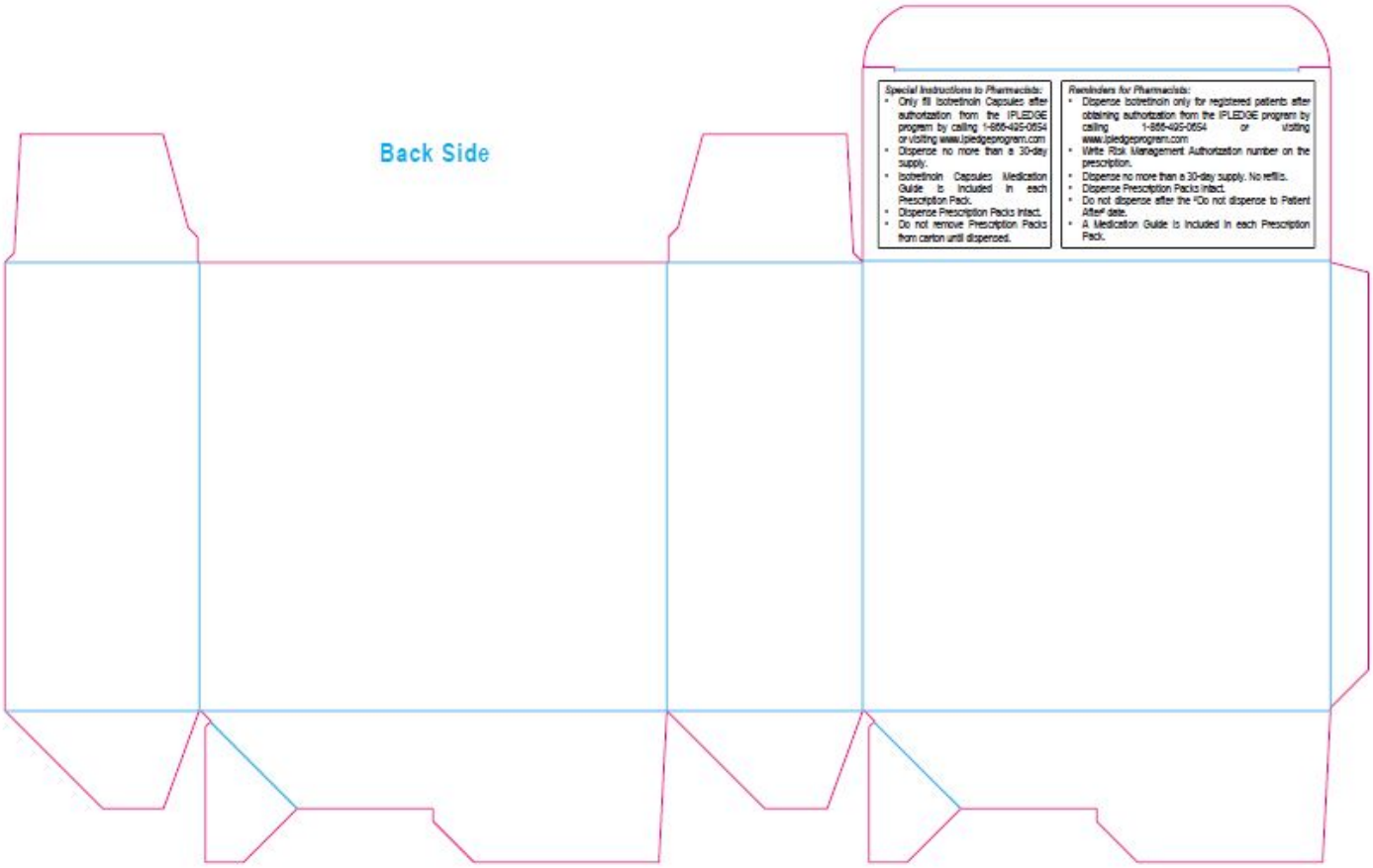
NDC 70771-1664-8

Isotretinoin Capsules USP, 25 mg

30 Capsules

Rx only



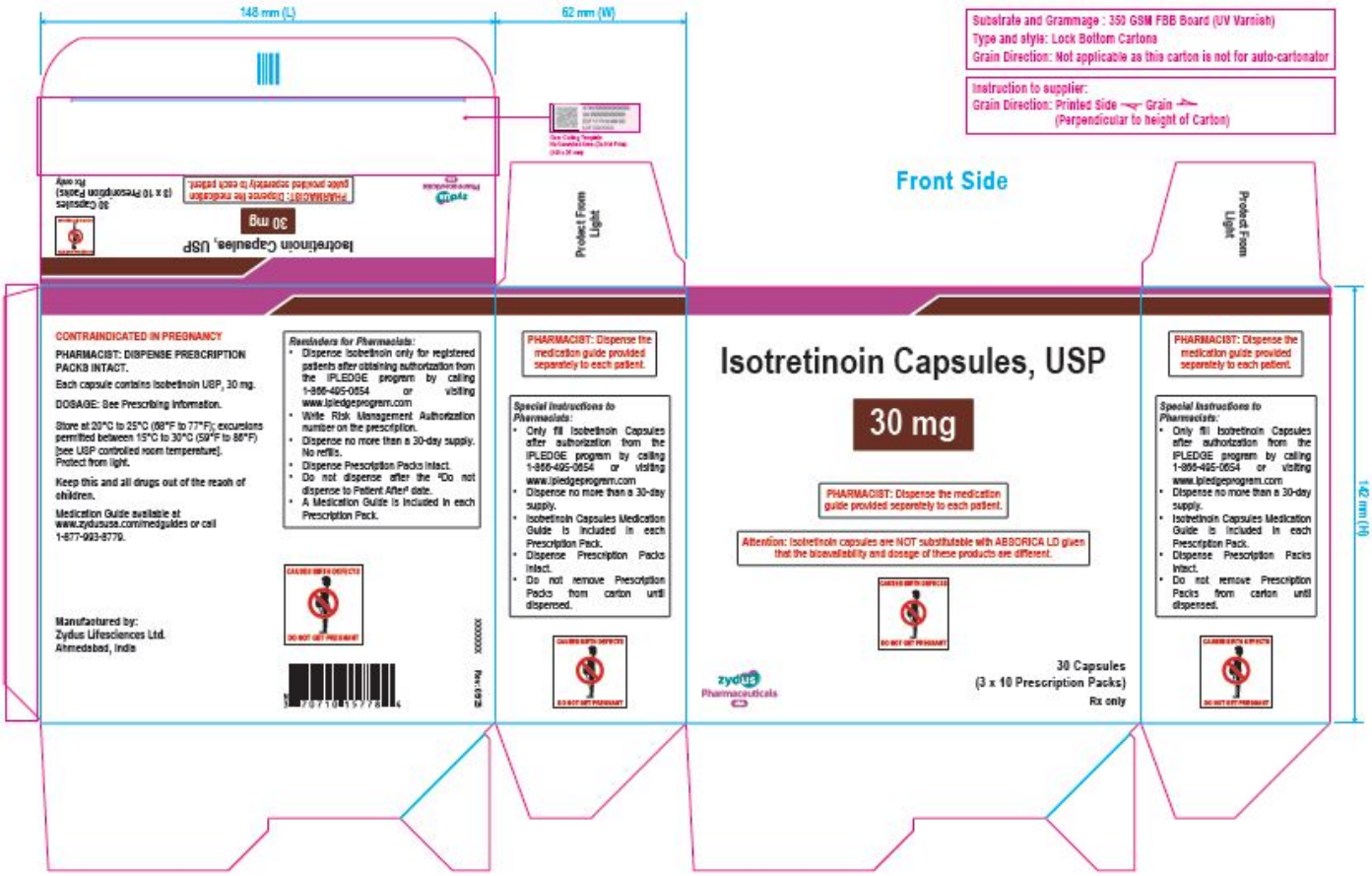


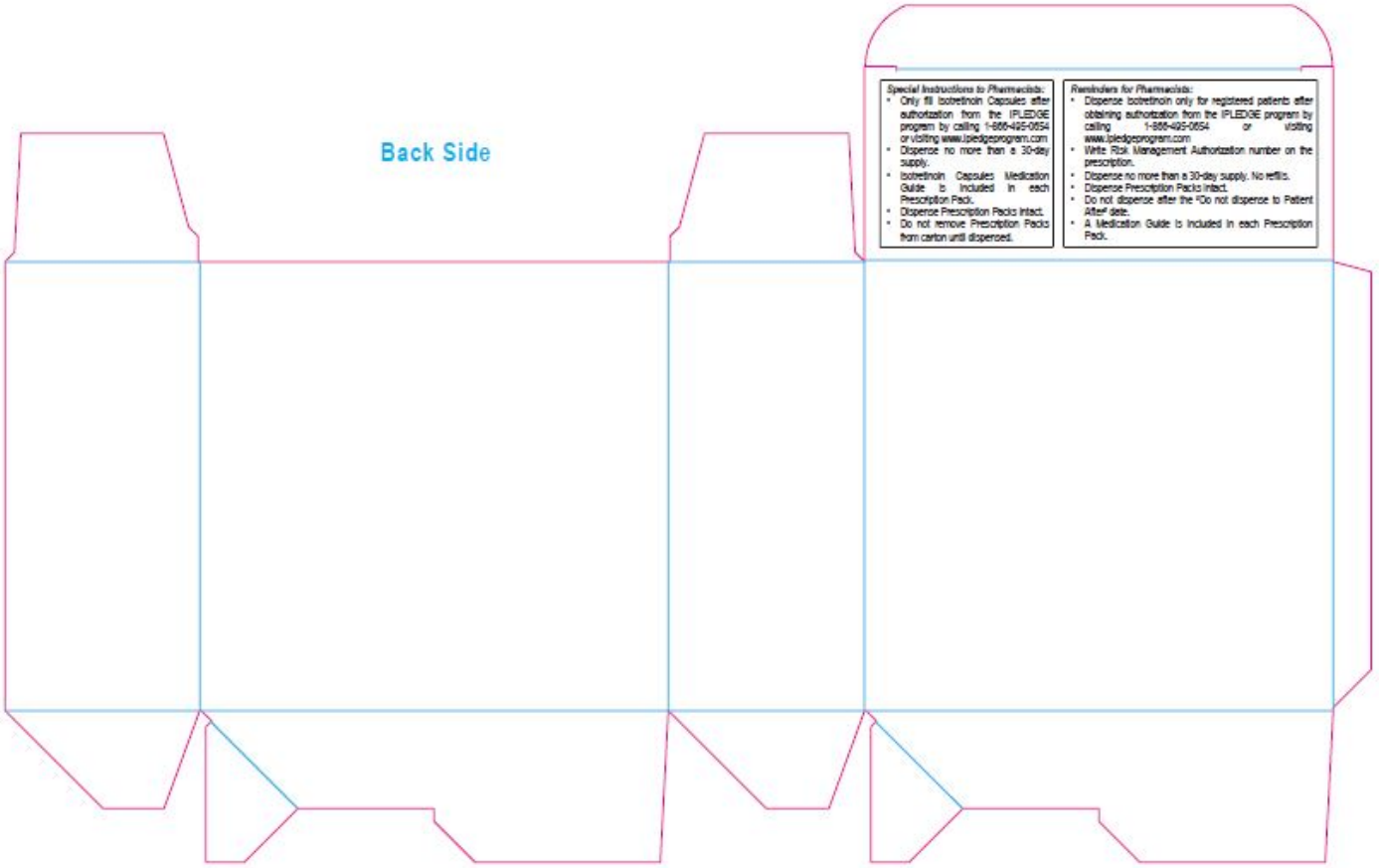
NDC 70771-1665-8

Isotretinoin Capsules USP, 30 mg

30 Capsules

Rx only


148 mm (L)
62 mm (W)
Substrate and Grammage : 350 GSM FBB Board (UV Varnish)
Type and style: Lock Bottom Cartons
Grain Direction: Not applicable as this carton is not for auto-cartonator
Instruction to supplier:
Grain Direction: Printed Side Grain
(Perpendicular to height of Carton)
Front Side
Isotretinoin Capsules, USP
30 mg
Protect From Light
CONTRAINDICATED IN PREGNANCY
PHARMACIST: DISPENSE PRESCRIPTION PACKS INTACT.
Each capsule contains Isotretinoin USP, 30 mg.
DOSAGE: See Prescribing Information.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP controlled room temperature].
Protect from light.
Keep this and all drugs out of the reach of children.
Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.
Manufactured by:
Zydus Lifesciences Ltd.
Ahmedabad, India
Reminders for Pharmacists:
• Dispense Isotretinoin only for registered patients after obtaining authorization from the IPLEDGE program by calling 1-866-495-0654 or visiting www.ipledgeprogram.com
• Write Risk Management Authorization number on the prescription.
• Dispense no more than a 30-day supply. No refills.
• Dispense Prescription Packs intact.
• Do not dispense after the [a]Do not dispense to Patient After[a] date.
• A Medication Guide is included in each Prescription Pack.
PHARMACIST: Dispense the medication guide provided separately to each patient.
Special Instructions to Pharmacists:
• Only fill Isotretinoin Capsules after authorization from the IPLEDGE program by calling 1-866-495-0654 or visiting www.ipledgeprogram.com
• Dispense no more than a 30-day supply.
• Isotretinoin Capsules Medication Guide is included in each Prescription Pack.
• Dispense Prescription Packs intact.
• Do not remove Prescription Packs from carton until dispensed.
PHARMACIST: Dispense the medication guide provided separately to each patient.
Attention: Isotretinoin capsules are NOT substitutable with ABBORICA LD given that the bioavailability and dosage of these products are different.
30 Capsules
(3 x 10 Prescription Packs)
Rx only
Special Instructions to Pharmacists:
• Only fill Isotretinoin Capsules after authorization from the IPLEDGE program by calling 1-866-495-0654 or visiting www.ipledgeprogram.com
• Dispense no more than a 30-day supply.
• Isotretinoin Capsules Medication Guide is included in each Prescription Pack.
• Dispense Prescription Packs intact.
• Do not remove Prescription Packs from carton until dispensed.
142 mm (H)


Back Side
Special Instructions to Pharmacists:
• Only fill Isotretinoin Capsules after authorization from the IPLEDGE program by calling 1-866-495-0654 or visiting www.ipledgeprogram.com
• Dispense no more than a 30-day supply.
• Isotretinoin Capsules Medication Guide is included in each Prescription Pack.
• Dispense Prescription Packs intact.
• Do not remove Prescription Packs from carton until dispensed.
Reminders for Pharmacists:
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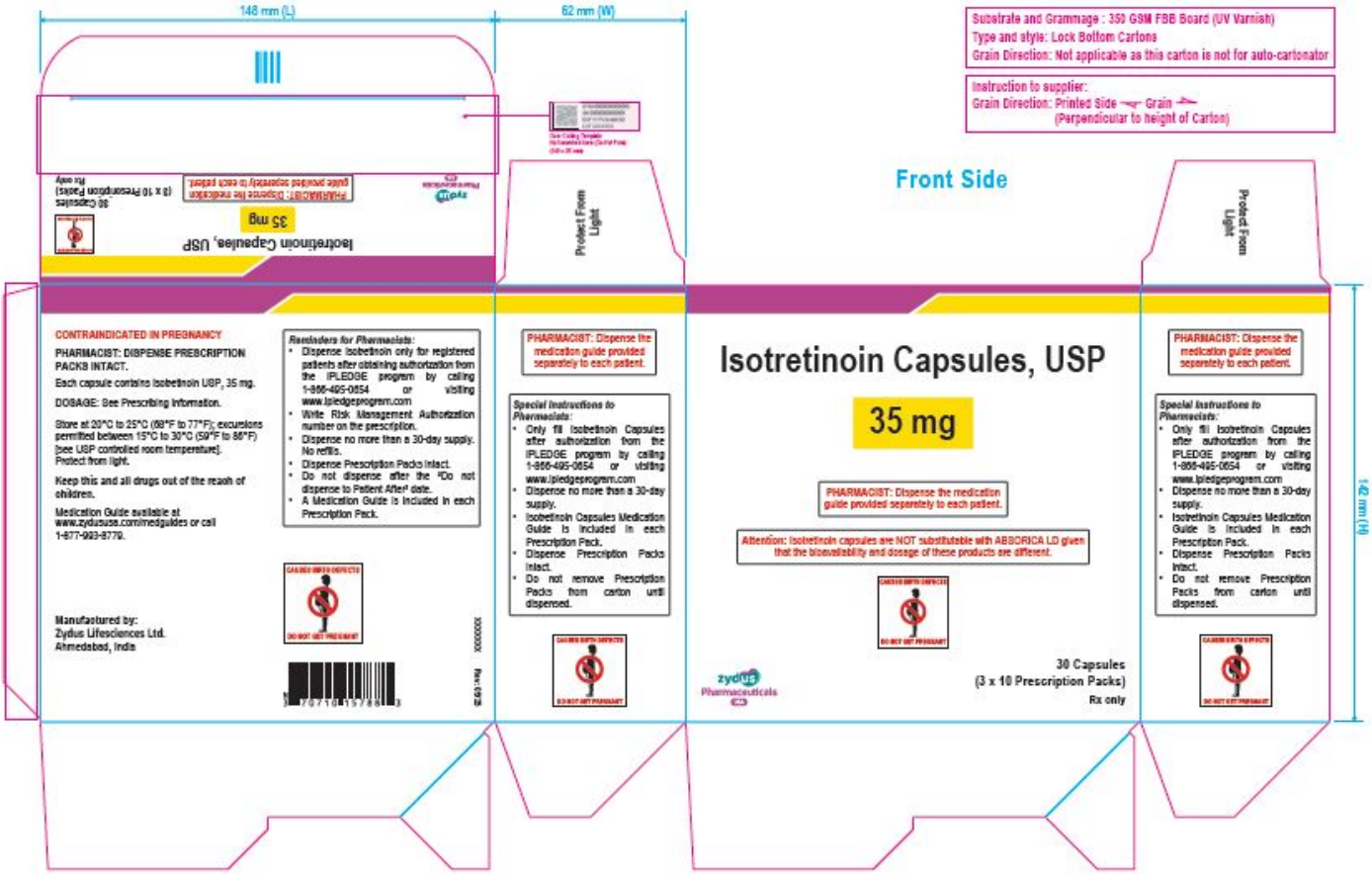
• Write Risk Management Authorization number on the prescription.
• Dispense no more than a 30-day supply. No refills.
• Dispense Prescription Packs intact.
• Do not dispense after the [a]Do not dispense to Patient After[a] date.
• A Medication Guide is included in each Prescription Pack.

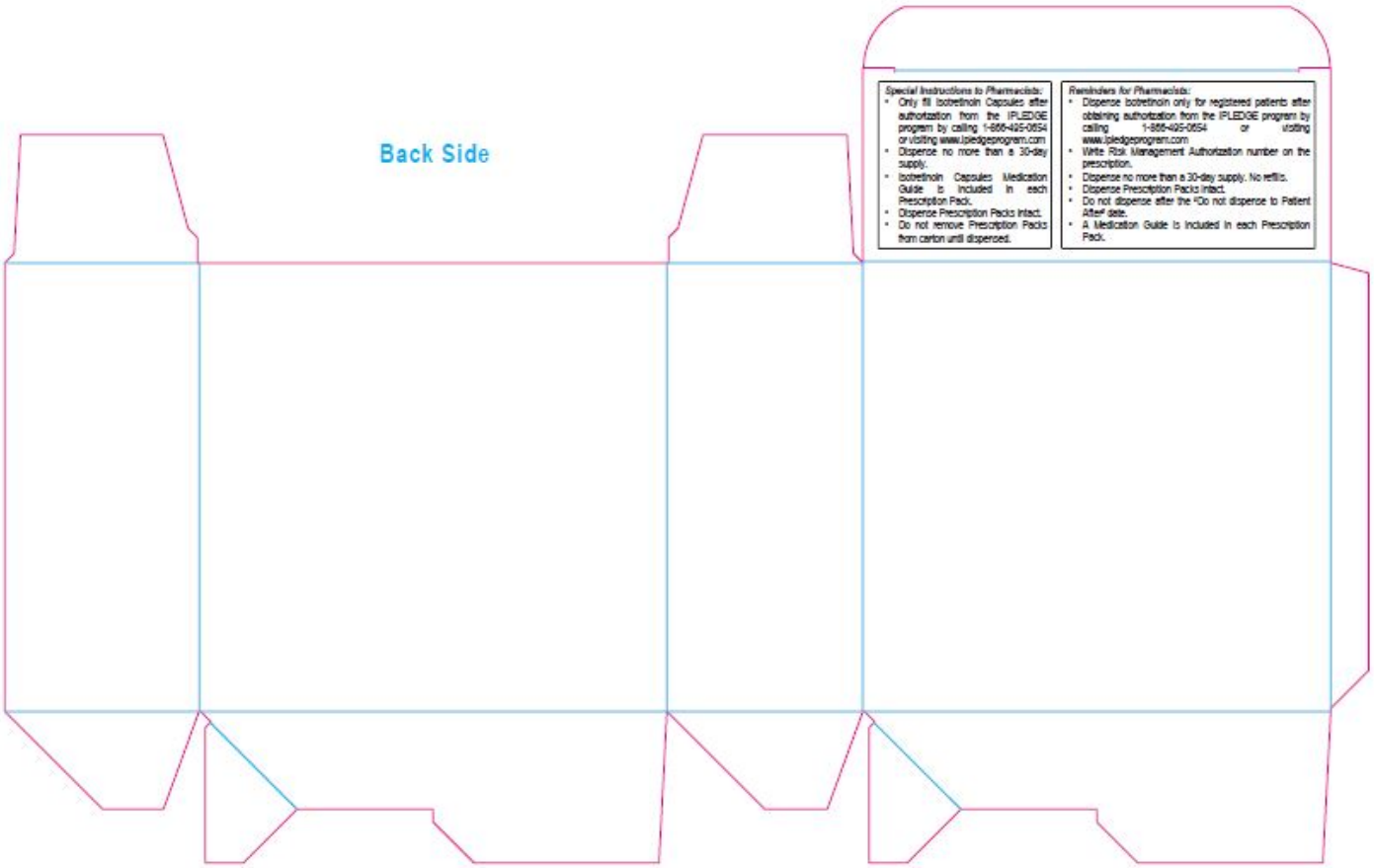
NDC 70771-1666-8

Isotretinoin Capsules USP, 35 mg

30 Capsules

Rx only



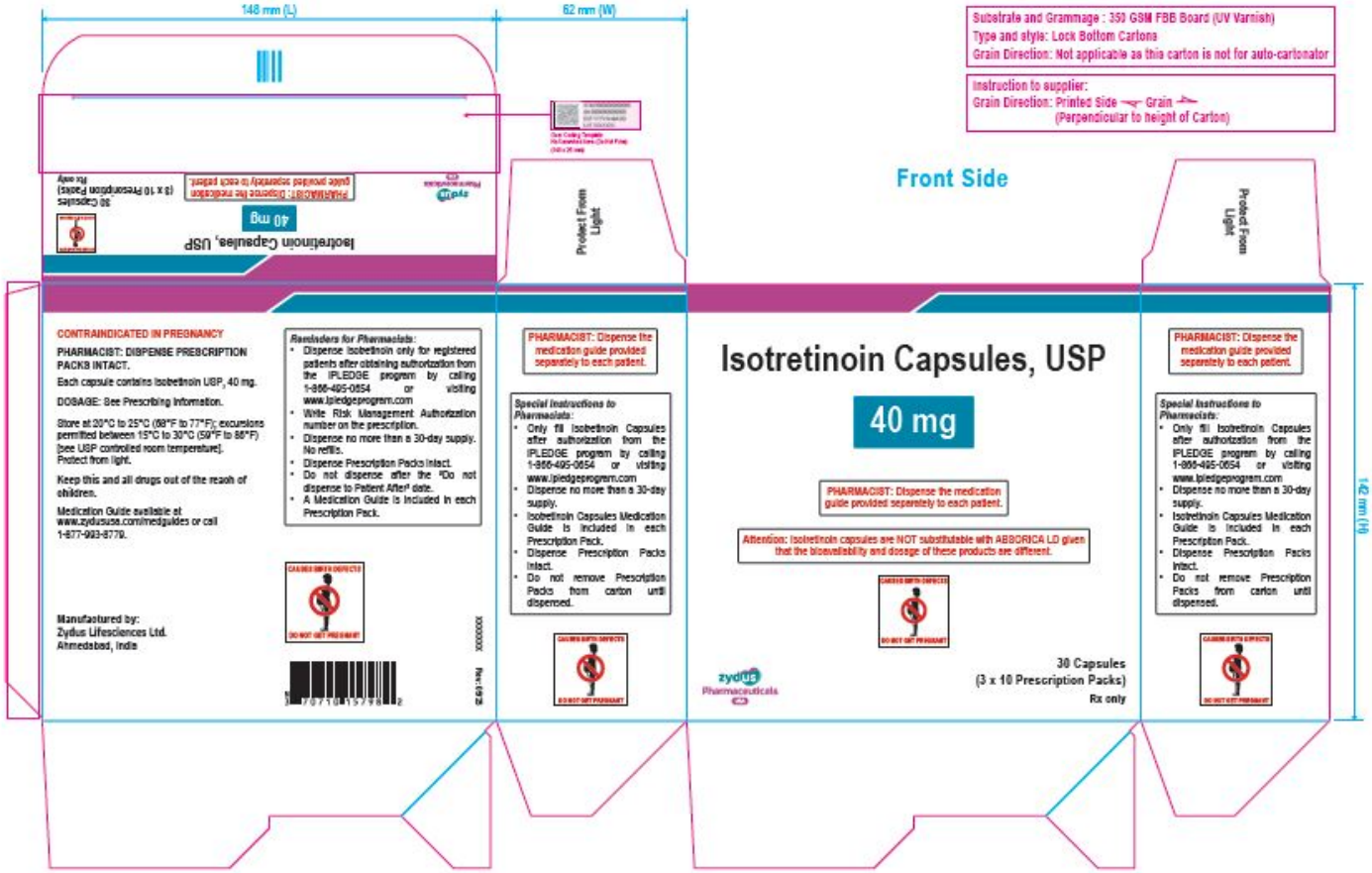


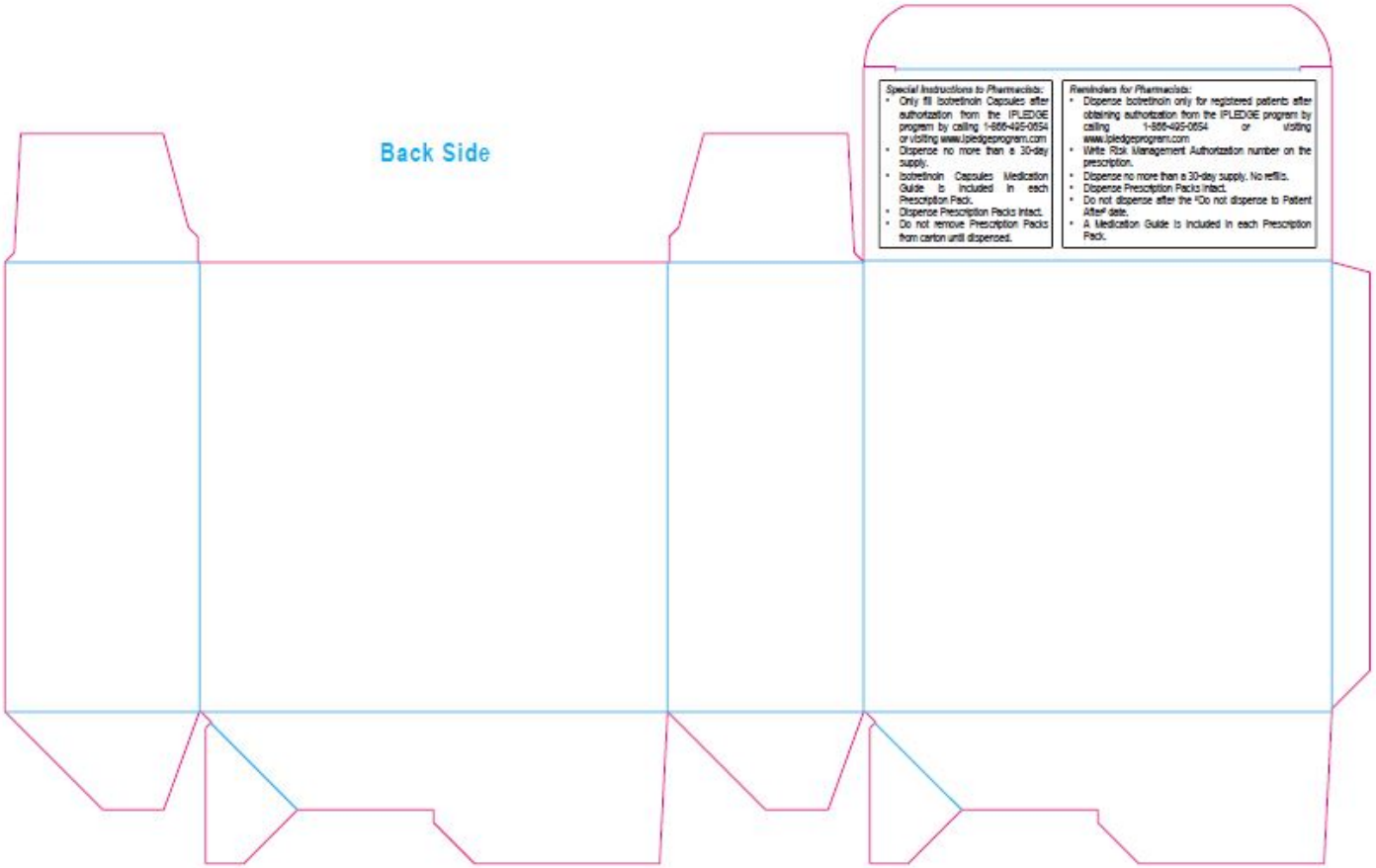
NDC 70771-1667-8

Isotretinoin Capsules USP, 40 mg

30 Capsules

Rx only


148 mm (L)
62 mm (W)
Substrate and Grammage : 350 GSM FBB Board (UV Varnish)
Type and style: Lock Bottom Cartons
Grain Direction: Not applicable as this carton is not for auto-cartonator
Instruction to supplier:
Grain Direction: Printed Side Grain
(Perpendicular to height of Carton)
Front Side
Protect From Light
Isotretinoin Capsules, USP
40 mg
CONTRAINDICATED IN PREGNANCY
PHARMACIST: DISPENSE PRESCRIPTION PACKS INTACT.
Each capsule contains Isotretinoin USP, 40 mg.
DOSAGE: See Prescribing Information.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP controlled room temperature].
Protect from light.
Keep this and all drugs out of the reach of children.
Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.
Manufactured by:
Zydus Lifesciences Ltd.
Ahmedabad, India
Reminders for Pharmacists:
• Dispense Isotretinoin only for registered patients after obtaining authorization from the IPLEDGE program by calling 1-866-495-0654 or visiting www.ipledgeprogram.com
• Write Risk Management Authorization number on the prescription.
• Dispense no more than a 30-day supply. No refills.
• Dispense Prescription Packs intact.
• Do not dispense after the [4]Do not dispense to Patient After[4] date.
• A Medication Guide is included in each Prescription Pack.
PHARMACIST: Dispense the medication guide provided separately to each patient.
Special Instructions to Pharmacists:
• Only fill Isotretinoin Capsules after authorization from the IPLEDGE program by calling 1-866-495-0654 or visiting www.ipledgeprogram.com
• Dispense no more than a 30-day supply.
• Isotretinoin Capsules Medication Guide is included in each Prescription Pack.
• Dispense Prescription Packs intact.
• Do not remove Prescription Packs from carton until dispensed.
PHARMACIST: Dispense the medication guide provided separately to each patient.
Attention: Isotretinoin capsules are NOT substitutable with ABBORICA LD given that the bioavailability and dosage of these products are different.
30 Capsules
(3 x 10 Prescription Packs)
Rx only
142 mm (H)


Back Side
Special Instructions to Pharmacists:
• Only fill Isotretinoin Capsules after authorization from the IPLEDGE program by calling 1-866-495-0654 or visiting www.ipledgeprogram.com
• Dispense no more than a 30-day supply.
• Isotretinoin Capsules Medication Guide is included in each Prescription Pack.
• Dispense Prescription Packs intact.
• Do not remove Prescription Packs from carton until dispensed.
Reminders for Pharmacists:
• Dispense Isotretinoin only for registered patients after obtaining authorization from the IPLEDGE program by calling 1-866-495-0654 or visiting www.ipledgeprogram.com
• Write Risk Management Authorization number on the prescription.
• Dispense no more than a 30-day supply. No refills.
• Dispense Prescription Packs intact.
• Do not dispense after the [4]Do not dispense to Patient After[4] date.
• A Medication Guide is included in each Prescription Pack.

ISOTRETINOIN

isotretinoin capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1662
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOTRETINOIN (UNII: EH28UP18IF) (ISOTRETINOIN - UNII:EH28UP18IF)	ISOTRETINOIN	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
PEG-32 HYDROGENATED PALM GLYCERIDES (UNII: G6EP177239)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
SOYBEAN OIL (UNII: 241ATL177A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	YELLOW (yellow opaque cap) , YELLOW (yellow opaque body)	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	1574
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1662-8	3 in 1 CARTON	06/09/2025	
1	NDC:70771-1662-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA216633	06/09/2025	

ISOTRETINOIN

isotretinoin capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1663
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOTRETINOIN (UNII: EH28UP18IF) (ISOTRETINOIN - UNII:EH28UP18IF)	ISOTRETINOIN	20 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
PEG-32 HYDROGENATED PALM GLYCERIDES (UNII: G6EP177239)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
SOYBEAN OIL (UNII: 241ATL177A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	ORANGE (orange opaque cap) , ORANGE (orange opaque body)	**Score**	no score
Shape	CAPSULE	**Size**	22mm
Flavor		**Imprint Code**	1575
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1663-8	3 in 1 CARTON	06/09/2025	
1	NDC:70771-1663-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216633	06/09/2025	

ISOTRETINOIN

isotretinoin capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1664
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOTRETINOIN (UNII: EH28UP18IF) (ISOTRETINOIN - UNII:EH28UP18IF)	ISOTRETINOIN	25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
PEG-32 HYDROGENATED PALM GLYCERIDES (UNII: G6EP177239)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
SOYBEAN OIL (UNII: 241ATL177A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	GREEN (light green opaque cap) , GREEN (light green opaque body)	**Score**	no score
Shape	CAPSULE	**Size**	22mm
Flavor		**Imprint Code**	1576
Contains			

Packaging

			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1664-8	3 in 1 CARTON	06/09/2025	
1	NDC:70771-1664-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216633	06/09/2025	

ISOTRETINOIN

isotretinoin capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1665
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOTRETINOIN (UNII: EH28UP18IF) (ISOTRETINOIN - UNII:EH28UP18IF)	ISOTRETINOIN	30 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
PEG-32 HYDROGENATED PALM GLYCERIDES (UNII: G6EP177239)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
SOYBEAN OIL (UNII: 241ATL177A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	BROWN (light brown opaque cap) , BROWN (light brown opaque body)	**Score**	no score
Shape	CAPSULE	**Size**	24mm
Flavor		**Imprint Code**	1577

Contains

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1665-8	3 in 1 CARTON	06/09/2025	
1	NDC:70771-1665-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216633	06/09/2025	

ISOTRETINOIN

isotretinoin capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1666
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOTRETINOIN (UNII: EH28UP18IF) (ISOTRETINOIN - UNII:EH28UP18IF)	ISOTRETINOIN	35 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
PEG-32 HYDROGENATED PALM GLYCERIDES (UNII: G6EP177239)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
SOYBEAN OIL (UNII: 241ATL177A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	BLUE (light blue opaque cap) , BLUE (light blue opaque body)	**Score**	no score
Shape	CAPSULE	**Size**	24mm
Flavor		**Imprint Code**	1578
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1666-8	3 in 1 CARTON	06/09/2025	
1	NDC:70771-1666-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216633	06/09/2025	

ISOTRETINOIN

isotretinoin capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1667
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOTRETINOIN (UNII: EH28UP18IF) (ISOTRETINOIN - UNII:EH28UP18IF)	ISOTRETINOIN	40 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
PEG-32 HYDROGENATED PALM GLYCERIDES (UNII: G6EP177239)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
SOYBEAN OIL (UNII: 241ATL177A)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	PINK (light pink opaque cap) , PINK (light pink opaque body)	**Score**	no score
Shape	CAPSULE	**Size**	24mm
Flavor		**Imprint Code**	1579
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1667-8	3 in 1 CARTON	06/09/2025	
1	NDC:70771-1667-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216633	06/09/2025	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1662, 70771-1663, 70771-1664, 70771-1665, 70771-1666, 70771-1667) , MANUFACTURE(70771-1662, 70771-1663, 70771-1664, 70771-1665, 70771-1666, 70771-1667)

Revised: 6/2025 Zydus Lifesciences Limited