

# ISOTRETINOIN- isotretinoin capsule

## Zydus Lifesciences Limited

### Isotretinoin Capsules, USP Rx Only

### CAUSES BIRTH DEFECTS

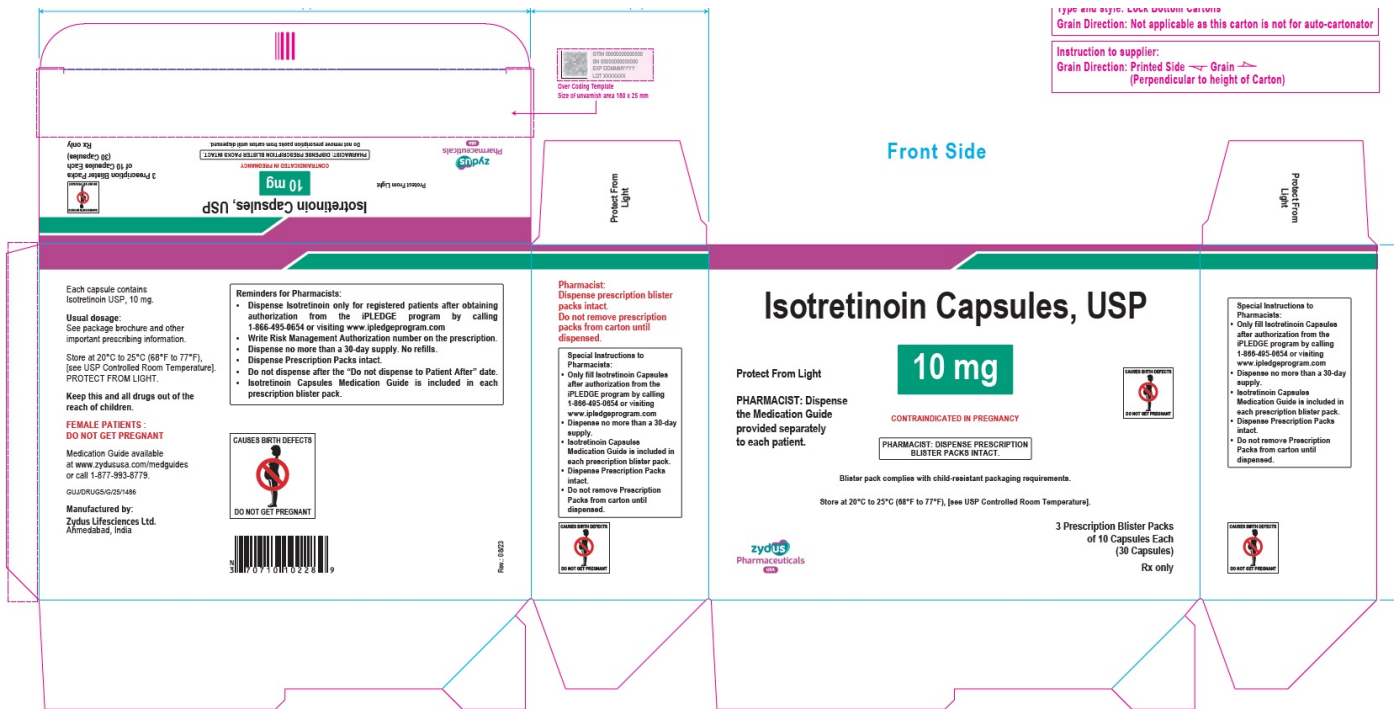
### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1557-8

Isotretinoin Capsules, USP 10 mg

30 Capsules

Rx only



Back Side

**Reminders for Pharmacists:**

- Dispense Isotretinoin only for registered patients after obtaining authorization from the IPLEDGE program by calling 1-866-495-8654 or visiting [www.ipledgeprogram.com](http://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 "Do not dispense to Patient After" date.
- Isotretinoin Capsules Medication Guide is included in each prescription blister pack.

**Special Instructions to Pharmacists:**

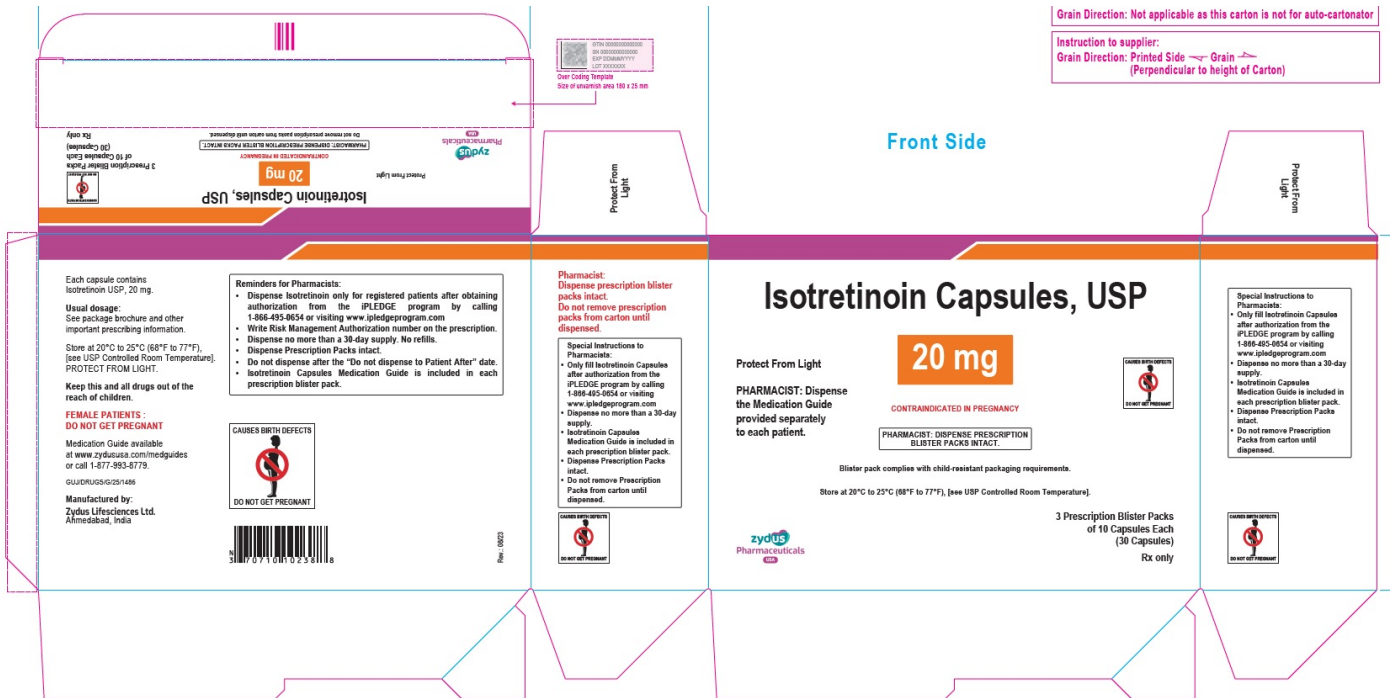
- Only fill Isotretinoin Capsules after authorization from the IPLEDGE program by calling 1-866-495-8654 or visiting [www.ipledgeprogram.com](http://www.ipledgeprogram.com)
- Dispense no more than a 30-day supply.
- Isotretinoin Capsules Medication Guide is included in each prescription blister pack.
- Dispense Prescription Packs intact.
- Do not remove Prescription Packs from carton until dispensed.

NDC 70771-1558-8

Isotretinoin Capsules, USP 20 mg

30 Capsules

Rx only



Back Side

**Reminders for Pharmacists:**

- Dispense Isotretinoin only for registered patients after obtaining authorization from the iPLEDGE program by calling 1-866-495-8654 or visiting [www.ipledgeprogram.com](http://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 "Do not dispense to Patient After" date.
- Isotretinoin Capsules Medication Guide is included in each prescription blister pack.

**Special Instructions to Pharmacists:**

- Only fill Isotretinoin Capsules after authorization from the iPLEDGE program by calling 1-866-495-8654 or visiting [www.ipledgeprogram.com](http://www.ipledgeprogram.com)
- Dispense no more than a 30-day supply.
- Isotretinoin Capsules Medication Guide is included in each prescription blister pack.
- Dispense Prescription Packs intact.
- Do not remove Prescription Packs from carton until dispensed.

NDC 70771-1559-8

Isotretinoin Capsules, USP 30 mg

30 Capsules

Rx only

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

Each capsule contains isotretinoin USP, 30 mg.

**Usual dosage:**  
See package brochure and other important prescribing information.

Store at 20°C to 25°C (68°F to 77°F). [see USP Controlled Room Temperature].  
PROTECT FROM LIGHT.


Keep this and all drugs out of the reach of children.

**FEMALE PATIENTS :  
DO NOT GET PREGNANT**

Medication Guide available at [www.zydususa.com/medguides](http://www.zydususa.com/medguides) or call 1-877-993-8779.

GLADURUGS/G251486

Manufactured by:  
Zydus Lifesciences Ltd.  
Ahmedabad, India



CAUSES BIRTH DEFECTS  
DO NOT GET PREGNANT

**Reminders for Pharmacists:**

- Dispense Isotretinoin only for registered patients after obtaining authorization from the iPLEDGE program by calling 1-866-495-8654 or visiting [www.ipledgeprogram.com](http://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 "Do not dispense to Patient After" date.
- Isotretinoin Capsules Medication Guide is included in each prescription blister pack.

**Special Instructions to Pharmacists:**

- Only fill Isotretinoin Capsules after authorization from the iPLEDGE program by calling 1-866-495-8654 or visiting [www.ipledgeprogram.com](http://www.ipledgeprogram.com)
- Dispense no more than a 30-day supply.
- Isotretinoin Capsules Medication Guide is included in each prescription blister pack.
- Dispense Prescription Packs intact.
- Do not remove Prescription Packs from carton until dispensed.

**Isotretinoin Capsules, USP**

**30 mg**

Protect From Light

PHARMACIST: DISPENSE PRESCRIPTION BLISTER PACKS INTACT.

CONTRAINDICATED IN PREGNANCY

Blister pack complies with child-resistant packaging requirements.

Store at 20°C to 25°C (68°F to 77°F). [see USP Controlled Room Temperature].

3 Prescription Blister Packs of 10 Capsules Each (30 Capsules)  
Rx only

Back Side

**Reminders for Pharmacists:**

- Dispense Isotretinoin only for registered patients after obtaining authorization from the IPLEDGE program by calling 1-866-495-8634 or visiting [www.ipledgeprogram.com](http://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 "Do not dispense to Patient After" date.
- Isotretinoin Capsules Medication Guide is included in each prescription blister pack.

**Special Instructions to Pharmacists:**

- Only fill Isotretinoin Capsules after authorization from the IPLEDGE program by calling 1-866-495-8634 or visiting [www.ipledgeprogram.com](http://www.ipledgeprogram.com)
- Dispense no more than a 30-day supply.
- Isotretinoin Capsules Medication Guide is included in each prescription blister pack.
- Dispense Prescription Packs intact.
- Do not remove Prescription Packs from carton until dispensed.

NDC 70771-1560-8

Isotretinoin Capsules, USP 40 mg

30 Capsules

Rx only

Front Side

Instruction to supplier:  
Grain Direction: Printed Side ← Grain →  
(Perpendicular to height of Carton)

Each capsule contains Isotretinoin USP, 40 mg.

**Usual dosage:**  
See package brochure and other important prescribing information.

Store at 20°C to 25°C (68°F to 77°F), (see USP Controlled Room Temperature).  
**PROTECT FROM LIGHT.**

Keep this and all drugs out of the reach of children.

**FEMALE PATIENTS : DO NOT GET PREGNANT**

Medication Guide available at [www.zydus.com/medguides](http://www.zydus.com/medguides) or call 1-877-963-6779.

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 1-866-495-8634 or visiting [www.ipledgeprogram.com](http://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 "Do not dispense to Patient After" date.
- Isotretinoin Capsules Medication Guide is included in each prescription blister pack.

**Pharmacist: Dispense prescription blister packs intact. Do not remove prescription packs from carton until dispensed.**

**Special Instructions to Pharmacists:**

- Only fill Isotretinoin Capsules after authorization from the IPLEDGE program by calling 1-866-495-8634 or visiting [www.ipledgeprogram.com](http://www.ipledgeprogram.com)
- Dispense no more than a 30-day supply.
- Isotretinoin Capsules Medication Guide is included in each prescription blister pack.
- Dispense Prescription Packs intact.
- Do not remove Prescription Packs from carton until dispensed.

## Isotretinoin Capsules, USP

# 40 mg

**CONTRAINDICATED IN PREGNANCY**

**PHARMACIST: DISPENSE PRESCRIPTION BLISTER PACKS INTACT.**

Blister pack complies with child-resistant packaging requirements.

Store at 20°C to 25°C (68°F to 77°F), (see USP Controlled Room Temperature).

**3 Prescription Blister Packs of 10 Capsules Each (30 Capsules)**  
Rx only

**Protect From Light**

**PHARMACIST: Dispense the Medication Guide provided separately to each patient.**

**zydus Pharmaceuticals**

**Protect From Light**

**PHARMACIST: Dispense prescription blister packs intact. Do not remove prescription packs from carton until dispensed.**

**Special Instructions to Pharmacists:**

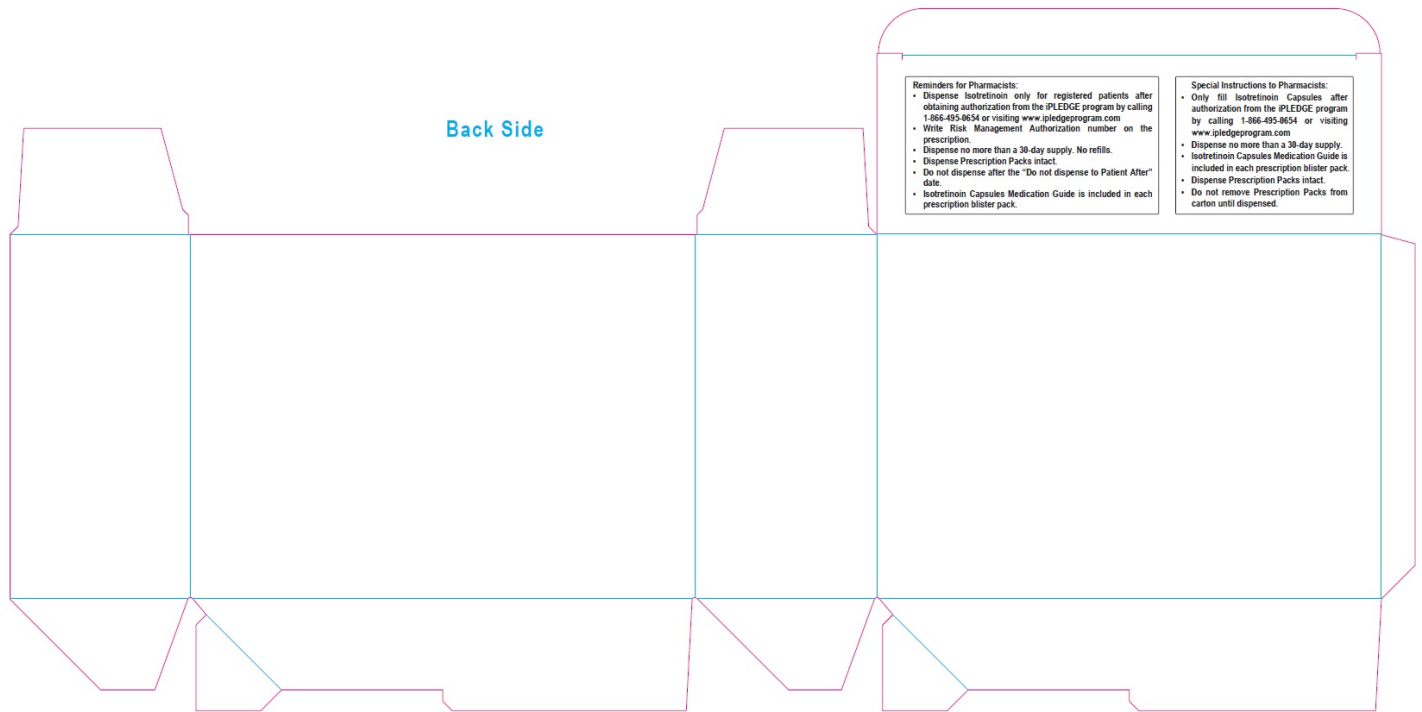
- Only fill Isotretinoin Capsules after authorization from the IPLEDGE program by calling 1-866-495-8634 or visiting [www.ipledgeprogram.com](http://www.ipledgeprogram.com)
- Dispense no more than a 30-day supply.
- Isotretinoin Capsules Medication Guide is included in each prescription blister pack.
- Dispense Prescription Packs intact.
- Do not remove Prescription Packs from carton until dispensed.

**Special Instructions to Pharmacists:**

- Only fill Isotretinoin Capsules after authorization from the IPLEDGE program by calling 1-866-495-8634 or visiting [www.ipledgeprogram.com](http://www.ipledgeprogram.com)
- Dispense no more than a 30-day supply.
- Isotretinoin Capsules Medication Guide is included in each prescription blister pack.
- Dispense Prescription Packs intact.
- Do not remove Prescription Packs from carton until dispensed.



Rev: 06/21



## ISOTRETINOIN

isotretinoin capsule

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1557
<b>Route of Administration</b>	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
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)	

<b>POLYVINYL ACETATE PHTHALATE</b> (UNII: 58QVG85GW3)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	

### Product Characteristics

<b>Color</b>	BROWN (reddish brown)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	1022
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1557-8	3 in 1 CARTON	09/12/2023	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70771-1557-4	10 in 1 CARTON	09/12/2023	
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	ANDA211568	09/12/2023	

## ISOTRETINOIN

isotretinoin capsule

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1558
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ISOTRETINOIN</b> (UNII: EH28UP18IF) (ISOTRETINOIN - UNII:EH28UP18IF)	ISOTRETINOIN	20 mg

### Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SOYBEAN OIL (UNII: 241ATL177A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
WHITE WAX (UNII: 7G1J5DA97F)	

### Product Characteristics

Color	YELLOW (CREAM)	Score	no score
Shape	OVAL	Size	11mm
Flavor		Imprint Code	1023
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1558-8	3 in 1 CARTON	09/12/2023	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70771-1558-4	10 in 1 CARTON	09/12/2023	
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	ANDA211568	09/12/2023	

## ISOTRETINOIN

isotretinoin capsule

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1559
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ISOTRETINOIN</b> (UNII: EH28UP18IF) (ISOTRETINOIN - UNII:EH28UP18IF)	ISOTRETINOIN	30 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDROGENATED SOYBEAN OIL</b> (UNII: A2M91M918C)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>POLYVINYL ACETATE PHTHALATE</b> (UNII: 58QVG85GW3)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	

## Product Characteristics

<b>Color</b>	YELLOW (BEIGE)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	1024
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70771-1559-8	3 in 1 CARTON	09/12/2023	
1		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	ANDA211568	09/12/2023	

## ISOTRETINOIN

isotretinoin capsule

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1560
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
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SOYBEAN OIL (UNII: 241ATL177A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
WHITE WAX (UNII: 7G1J5DA97F)	

### Product Characteristics

Color	BROWN (LIGHT BROWN)	Score	no score
Shape	OVAL	Size	14mm
Flavor		Imprint Code	1025
Contains			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1560-8	3 in 1 CARTON	09/12/2023	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70771-1560-4	10 in 1 CARTON	09/12/2023	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211568	09/12/2023	

**Labeler** - Zydus Lifesciences Limited (918596198)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1557, 70771-1558, 70771-1559, 70771-1560) , MANUFACTURE(70771-1557, 70771-1558, 70771-1559, 70771-1560)

Revised: 11/2024

Zydus Lifesciences Limited