

VALSARTAN- valsartan tablet, film coated
Zydus Lifesciences Limited

VALSARTAN tablets, for oral use

SPL UNCLASSIFIED

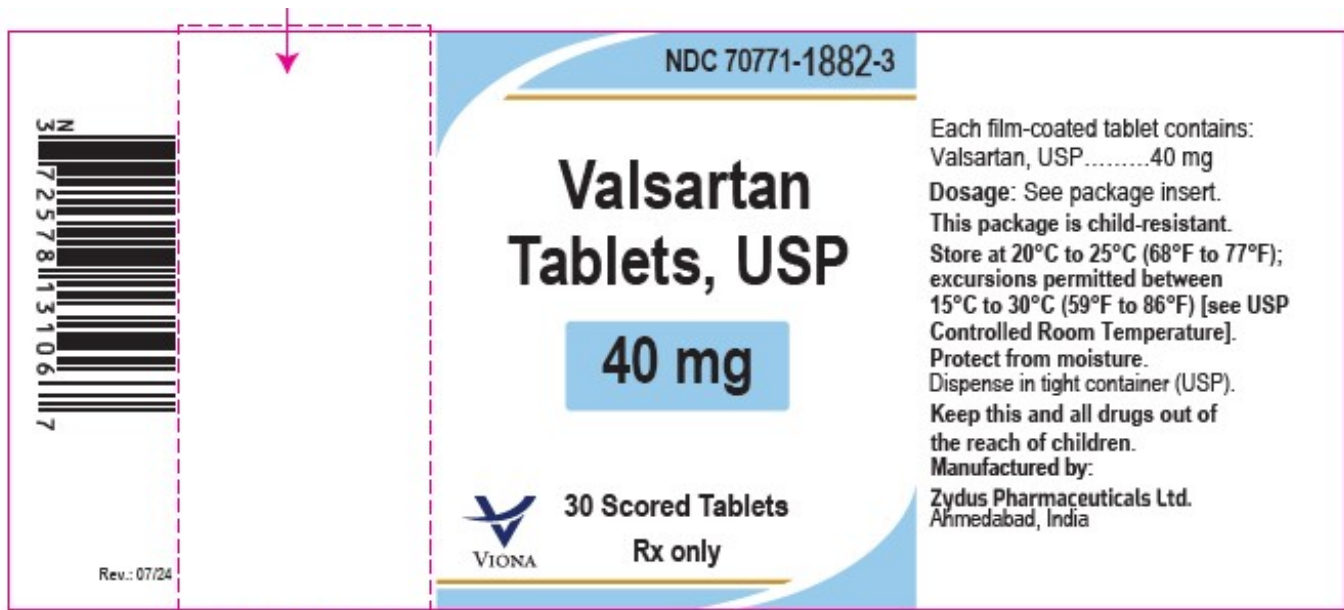
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Valsartan tablets USP, 40 mg

NDC 70771-1882-3

Bottle of 30 Scored Tablets

Rx only



Valsartan tablets USP, 80 mg

NDC 70771-1883-9

Bottle of 90 tablets

Rx only

NDC 70771-1883-9

3172578113216
3

**Valsartan
Tablets, USP**

80 mg

VIONA

90 Tablets
Rx only

Rev.: 07/24

Each film-coated tablet contains:
Valsartan, USP.....80 mg
Dosage: See package insert.
This package is child-resistant.
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 moisture.
Dispense in tight container (USP).
**Keep this and all drugs out of
the reach of children.**
Manufactured by:
Zydus Pharmaceuticals Ltd.
Ahmedabad, India

Valsartan tablets USP, 160 mg
NDC 70771-1884-9
Bottle of 90 tablets
Rx only

NDC 70771-1884-9

3172578113316
0

**Valsartan
Tablets, USP**

160 mg


VIONA

90 Tablets
Rx only

Rev.: 07/24

Each film-coated tablet contains:
Valsartan, USP.....160 mg
Dosage: See package insert.
This package is child-resistant.
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 moisture.
Dispense in tight container (USP).
**Keep this and all drugs out of
the reach of children.**
Manufactured by:
Zydus Pharmaceuticals Ltd.
Ahmedabad, India

Valsartan tablets USP, 320 mg
NDC 70771-1885-9
Bottle of 90 tablets
Rx only




Rev.: 07/24

NDC 70771-1885-9

Valsartan Tablets, USP

320 mg

 **90 Tablets**
Rx only

Each film-coated tablet contains:
Valsartan, USP.....320 mg

Dosage: See package insert.

This package is child-resistant.

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 moisture.
Dispense in tight container (USP).

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

Manufactured by:
Zydus Pharmaceuticals Ltd.
Ahmedabad, India

VALSARTAN

valsartan tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1882
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VALSARTAN (UNII: 80M03YXJ7I) (VALSARTAN - UNII:80M03YXJ7I)	VALSARTAN	40 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (light yellow to yellow)	Score	2 pieces
Shape	OVAL	Size	8mm
Flavor		Imprint Code	T;4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1882-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/30/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA218991	08/30/2024	

VALSARTAN

valsartan tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1883
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VALSARTAN (UNII: 80M03YXJ7I) (VALSARTAN - UNII:80M03YXJ7I)	VALSARTAN	80 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPROVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK (light pink to pink)	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	T7
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1883-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/30/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA218991	08/30/2024	

VALSARTAN

valsartan tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1884
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VALSARTAN (UNII: 80M03YXJ7I) (VALSARTAN - UNII:80M03YXJ7I)	VALSARTAN	160 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (light yellow to yellow)	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	277
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1884-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/30/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA218991	08/30/2024	

VALSARTAN

valsartan tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1885
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VALSARTAN (UNII: 80M03YXJ7I) (VALSARTAN - UNII:80M03YXJ7I)	VALSARTAN	320 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPROVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BROWN (light brown to brown)	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	278
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1885-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/30/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA218991	08/30/2024	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Pharmaceuticals Limited		650173735	MANUFACTURE(70771-1882, 70771-1883, 70771-1884, 70771-1885) , ANALYSIS(70771-1882, 70771-1883, 70771-1884, 70771-1885)

Revised: 7/2024

Zydus Lifesciences Limited