

DEXAMETHASONE- dexamethasone tablet
Zydus Lifesciences Limited

Dexamethasone Tablets

SPL UNCLASSIFIED

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

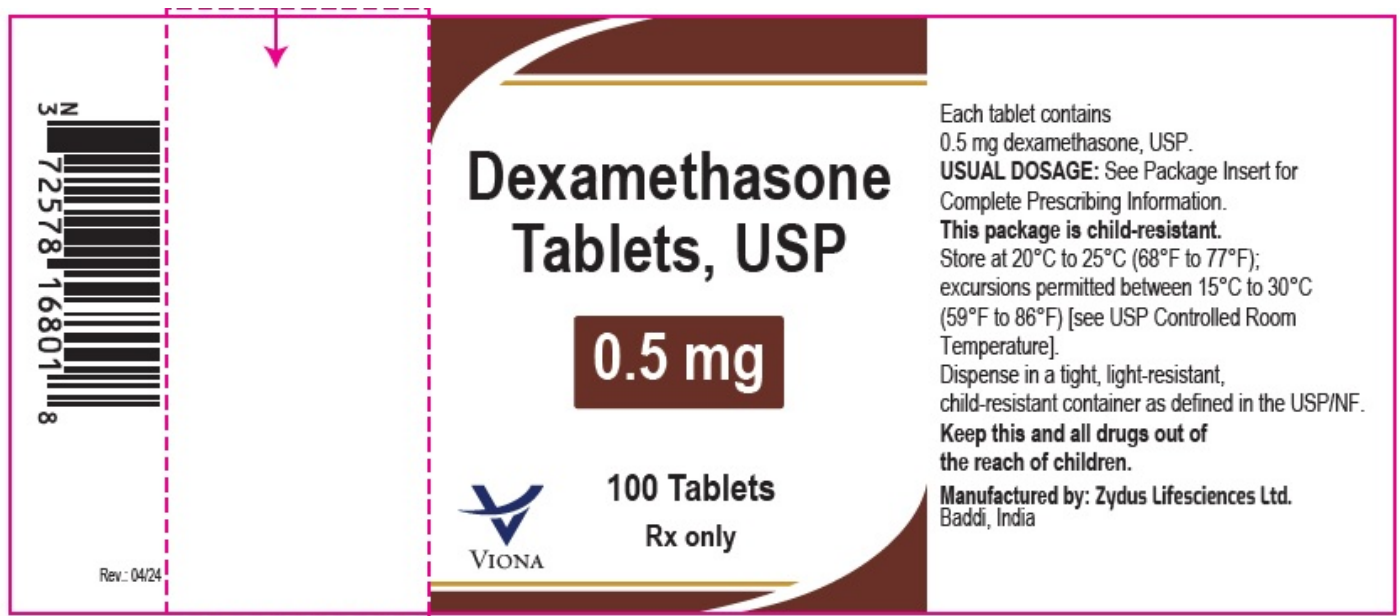
NDC 70771-1704-1

Dexamethasone Tablets, USP 0.5 mg

100 Tablets

Rx only

Zydus



NDC 70771-1705-1

Dexamethasone Tablets, USP 0.75 mg

100 Tablets

Rx only

Zydus

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725781 16901 5

Rev.: 04/24

Dexamethasone Tablets, USP

0.75 mg

100 Tablets
Rx only

VIONA

Each tablet contains 0.75 mg dexamethasone, USP.
USUAL DOSAGE: See Package Insert for Complete Prescribing Information.
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].
 Dispense in a tight, light-resistant, child-resistant container as defined in the USP/NF.
Keep this and all drugs out of the reach of children.
Manufactured by: Zydus Lifesciences Ltd. Baddi, India

NDC 70771-1707-1

Dexamethasone Tablets, USP 1.5 mg

100 Tablets

Rx only

Zydus

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725781 17001 1

Rev.: 04/24

Dexamethasone Tablets, USP

1.5 mg

100 Tablets
Rx only

VIONA

Each tablet contains 1.5 mg dexamethasone, USP.
USUAL DOSAGE: See Package Insert for Complete Prescribing Information.
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].
 Dispense in a tight, light-resistant, child-resistant container as defined in the USP/NF.
Keep this and all drugs out of the reach of children.
Manufactured by: Zydus Lifesciences Ltd. Baddi, India

NDC 70771-1699-1

Dexamethasone Tablets, USP 4 mg

100 Tablets

Rx only

Zydus

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Rev.: 04/24

Dexamethasone Tablets, USP

4 mg

100 Tablets
Rx only

VIONA

Each tablet contains 4 mg dexamethasone, USP.
USUAL DOSAGE: See Package Insert for Complete Prescribing Information.
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].
Dispense in a tight, light-resistant, child-resistant container as defined in the USP/NF.
Keep this and all drugs out of the reach of children.
Manufactured by: Zydus Lifesciences Ltd. Baddi, India

NDC 70771-1700-1

Dexamethasone Tablets, USP 6 mg

100 Tablets

Rx only

Zydus

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72578 17201 5

Rev.: 04/24

Dexamethasone Tablets, USP

6 mg

100 Tablets
Rx only

VIONA

Each tablet contains 6 mg dexamethasone, USP.
USUAL DOSAGE: See Package Insert for Complete Prescribing Information.
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].
Dispense in a tight, light-resistant, child-resistant container as defined in the USP/NF.
Keep this and all drugs out of the reach of children.
Manufactured by: Zydus Lifesciences Ltd. Baddi, India

DEXAMETHASONE

dexamethasone tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1699
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXAMETHASONE (UNII: 7S5I7G3JQL) (DEXAMETHASONE - UNII:7S5I7G3JQL)	DEXAMETHASONE	4 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	GREEN (off-white to light green)	Score	2 pieces
Shape	ROUND	Size	6mm
Flavor		Imprint Code	1736
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1699-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216282	04/15/2024	

DEXAMETHASONE

dexamethasone tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1700	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	DEXAMETHASONE (UNII: 7S5I7G3JQL) (DEXAMETHASONE - UNII:7S5I7G3JQL)	DEXAMETHASONE	6 mg	
Inactive Ingredients				
	Ingredient Name		Strength	
	FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)			
	LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
	MAGNESIUM STEARATE (UNII: 70097M6I30)			
	STARCH, CORN (UNII: O8232NY3SJ)			
	SUCROSE (UNII: C151H8M554)			
Product Characteristics				
Color	BLUE (off-white to light blue)	Score	2 pieces	
Shape	ROUND	Size	6mm	
Flavor		Imprint Code	1737	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1700-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2024	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA216282	04/15/2024		

DEXAMETHASONE			
dexamethasone tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1704
Route of Administration	ORAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
DEXAMETHASONE (UNII: 7S5I7G3JQL) (DEXAMETHASONE - UNII:7S5I7G3JQL)	DEXAMETHASONE	0.5 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	YELLOW (light yellow to yellow)	Score	2 pieces
Shape	OVAL	Size	6mm
Flavor		Imprint Code	1791
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1704-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216282	04/15/2024	

DEXAMETHASONE

dexamethasone tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1705
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXAMETHASONE (UNII: 7S5I7G3JQL) (DEXAMETHASONE - UNII:7S5I7G3JQL)	DEXAMETHASONE	0.75 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	GRAY (off-white to grey)	Score	2 pieces
Shape	OVAL	Size	7mm
Flavor		Imprint Code	1792
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1705-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216282	04/15/2024	

DEXAMETHASONE

dexamethasone tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1707
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXAMETHASONE (UNII: 7S5I7G3JQL) (DEXAMETHASONE - UNII:7S5I7G3JQL)	DEXAMETHASONE	1.5 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	PINK (light-pink to pink)	Score	2 pieces
Shape	ROUND	Size	6mm
Flavor		Imprint Code	1795
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1707-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216282	04/15/2024	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		677605858	ANALYSIS(70771-1704, 70771-1705, 70771-1707, 70771-1699, 70771-1700) , MANUFACTURE(70771-1704, 70771-1705, 70771-1707, 70771-1699, 70771-1700)

Revised: 3/2024

Zydus Lifesciences Limited