METHYLPREDNISOLONE- methylprednisolone tablet
Zydus Lifesciences Limited

Methylprednisolone Tablets, USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1348-1 in bottle of 100 tablets

Methylprednisolone tablets, USP

R_x only

100 tablets

NDC 70771-1349-8 in bottle of 25 tablets

Methylprednisolone tablets, USP

R_x only

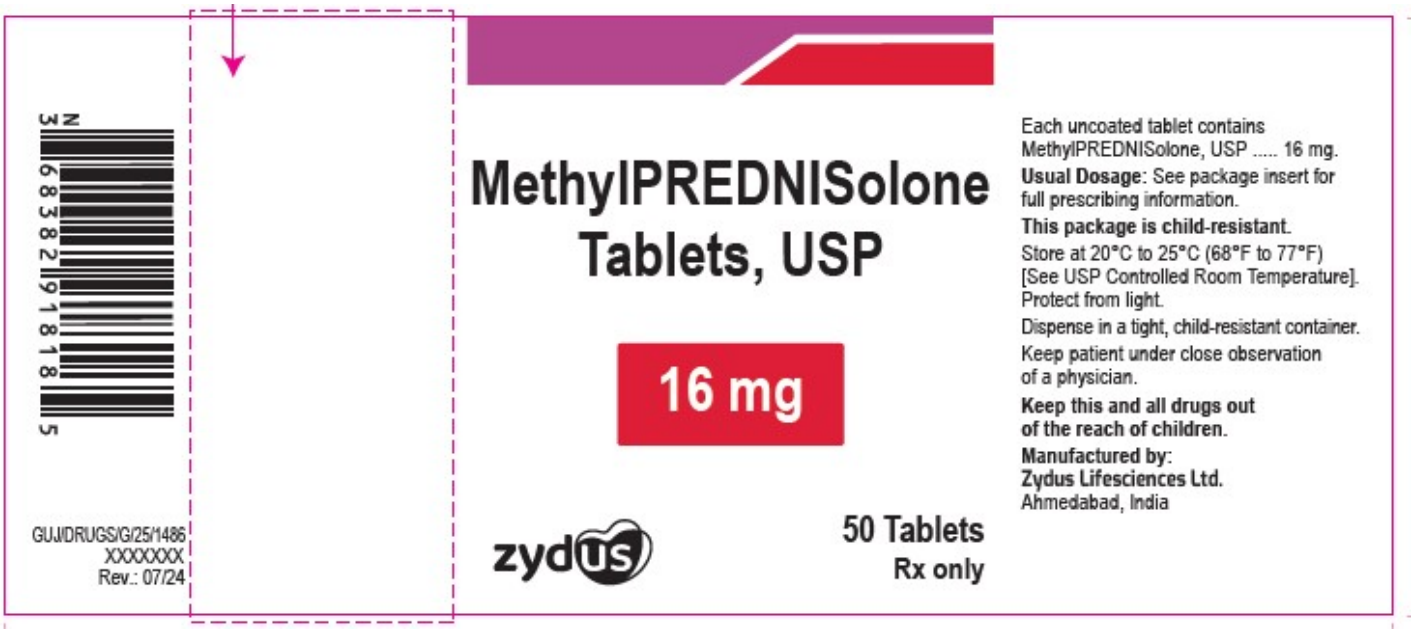
25 tablets

NDC 70771-1350-7 in bottle of 50 tablets

Methylprednisolone tablets, USP

R_x only

50 tablets

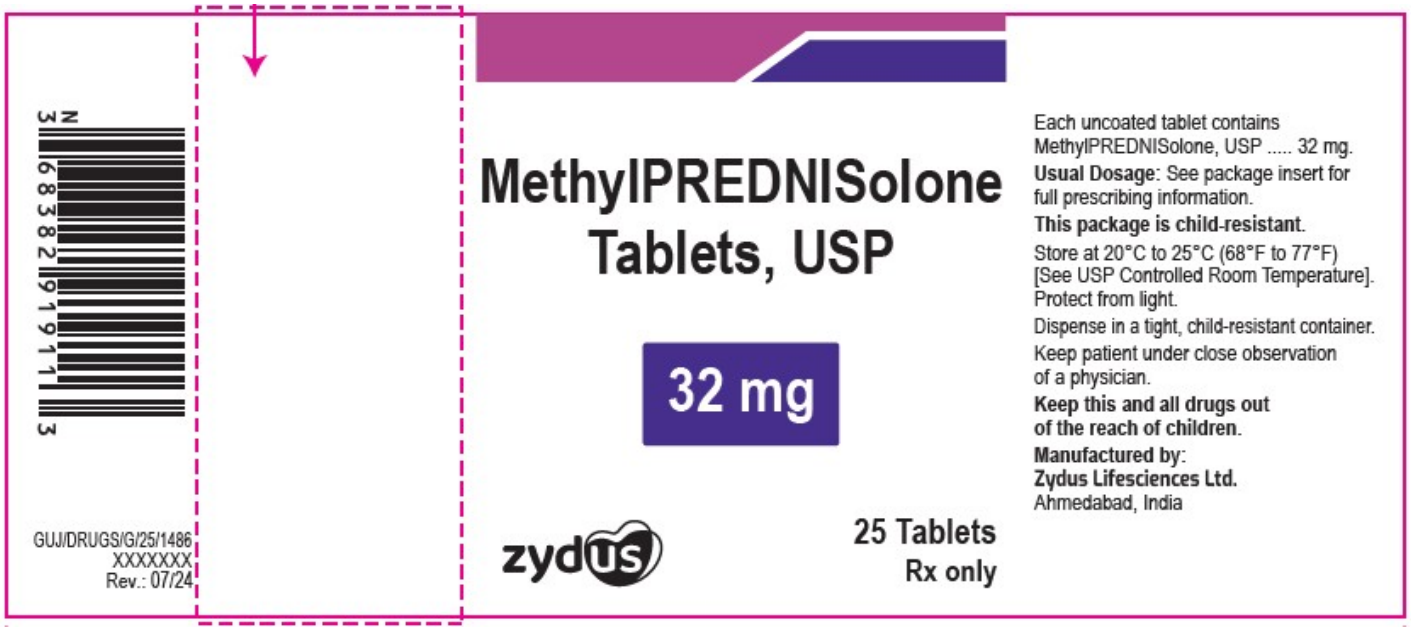


NDC 70771-1351-8 in bottle of 25 tablets

Methylprednisolone tablets, USP

R_x only

25 tablets



METHYLPREDNISOLONE

methylprednisolone tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1348
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METHYLPREDNISOLONE (UNII: X4W7ZR7023) (METHYLPREDNISOLONE - UNII:X4W7ZR7023)	METHYLPREDNISOLONE	4 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	4 pieces
Shape	OVAL (OVAL)	**Size**	8mm
Flavor		**Imprint Code**	916
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1348-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2018	
2	NDC:70771-1348-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2018	
3	NDC:70771-1348-3	1 in 1 CARTON	05/01/2018	
3		21 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	ANDA206751	05/01/2018	

METHYLPREDNISOLONE

methylprednisolone tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1349
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYLPREDNISOLONE (UNII: X4W7ZR7023) (METHYLPREDNISOLONE - UNII:X4W7ZR7023)	METHYLPREDNISOLONE	8 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	10mm
Flavor		**Imprint Code**	917
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1349-8	25 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2018	
2	NDC:70771-1349-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2018	
3	NDC:70771-1349-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2018	
4	NDC:70771-1349-4	10 in 1 CARTON	05/01/2018	
4	NDC:70771-1349-2	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	ANDA206751	05/01/2018	

METHYLPREDNISOLONE

methylprednisolone tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1350
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYLPREDNISOLONE (UNII: X4W7ZR7023) (METHYLPREDNISOLONE - UNII:X4W7ZR7023)	METHYLPREDNISOLONE	16 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	4 pieces
Shape	OVAL (OVAL)	**Size**	10mm
Flavor		**Imprint Code**	918
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1350-7	50 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2018	
2	NDC:70771-1350-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2018	
3	NDC:70771-1350-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2018	
4	NDC:70771-1350-4	10 in 1 CARTON	05/01/2018	
4	NDC:70771-1350-2	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	ANDA206751	05/01/2018	

METHYLPREDNISOLONE

methylprednisolone tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1351
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYLPREDNISOLONE (UNII: X4W7ZR7023) (METHYLPREDNISOLONE - UNII:X4W7ZR7023)	METHYLPREDNISOLONE	32 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	14mm
Flavor		**Imprint Code**	919
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1351-8	25 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2018	
2	NDC:70771-1351-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2018	
3	NDC:70771-1351-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2018	
4	NDC:70771-1351-4	10 in 1 CARTON	05/01/2018	
4	NDC:70771-1351-2	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	ANDA206751	05/01/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1348, 70771-1349, 70771-1350, 70771-1351) , MANUFACTURE(70771-1348, 70771-1349, 70771-1350, 70771-1351)