

**METHYLPREDNISOLONE- methylprednisolone tablet**  
**Zydus Lifesciences Limited**

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**Methylprednisolone Tablets, USP**

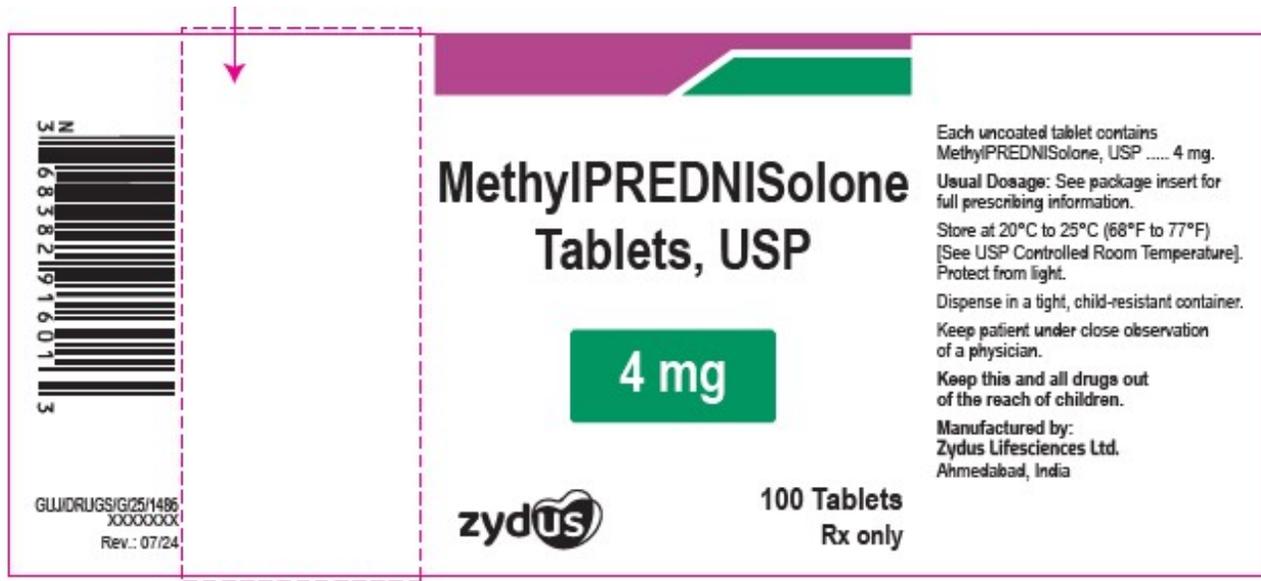
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1348-1 in bottle of 100 tablets

Methylprednisolone tablets, USP

R<sub>x</sub> only

100 tablets



NDC 70771-1349-8 in bottle of 25 tablets

Methylprednisolone tablets, USP

R<sub>x</sub> only

25 tablets

3 N  
6 8 3 8 2 9 1 7 1 1  
9

GUJDRUGS/G/25/1486  
XXXXXXXX  
Rev.: 07/24

# Methyprednisolone Tablets, USP

**8 mg**

zydus

**25 Tablets  
Rx only**

Each uncoated tablet contains Methyprednisolone, USP ..... 8 mg.  
**Usual Dosage:** See package insert for full prescribing information.  
**This package is child-resistant.**  
 Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].  
 Protect from light.  
 Dispense in a tight, child-resistant container.  
 Keep patient under close observation of a physician.  
**Keep this and all drugs out of the reach of children.**  
**Manufactured by:**  
 Zydus Lifesciences Ltd.  
 Ahmedabad, India

NDC 70771-1350-7 in bottle of 50 tablets

Methylprednisolone tablets, USP

R<sub>x</sub> only

50 tablets

3 N  
6 8 3 8 2 9 1 8 1 8  
5

GUJDRUGS/G/25/1486  
XXXXXXXX  
Rev.: 07/24

# Methyprednisolone Tablets, USP

**16 mg**

zydus

**50 Tablets  
Rx only**

Each uncoated tablet contains Methyprednisolone, USP ..... 16 mg.  
**Usual Dosage:** See package insert for full prescribing information.  
**This package is child-resistant.**  
 Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].  
 Protect from light.  
 Dispense in a tight, child-resistant container.  
 Keep patient under close observation of a physician.  
**Keep this and all drugs out of the reach of children.**  
**Manufactured by:**  
 Zydus Lifesciences Ltd.  
 Ahmedabad, India

NDC 70771-1351-8 in bottle of 25 tablets

Methylprednisolone tablets, USP

R<sub>x</sub> only

25 tablets

3 N  
68382919113

**MethylPREDNISolone  
Tablets, USP**

**32 mg**

zydus

25 Tablets  
Rx only

Each uncoated tablet contains MethylPREDNISolone, USP ..... 32 mg.  
**Usual Dosage:** See package insert for full prescribing information.  
**This package is child-resistant.**  
Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].  
Protect from light.  
Dispense in a tight, child-resistant container.  
Keep patient under close observation of a physician.  
**Keep this and all drugs out of the reach of children.**  
**Manufactured by:**  
Zydus Lifesciences Ltd.  
Ahmedabad, India

GUJ/DRUGS/G/25/1486  
XXXXXXX  
Rev.: 07/24

## METHYLPREDNISOLONE

methylprednisolone tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1348
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>METHYLPREDNISOLONE</b> (UNII: X4W7ZR7023) (METHYLPREDNISOLONE - UNII:X4W7ZR7023)	METHYLPREDNISOLONE	4 mg

### Inactive Ingredients

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

STARCH, CORN (UNII: O8232NY3SJ)

### Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	4 pieces
<b>Shape</b>	OVAL (OVAL)	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	916
<b>Contains</b>			

### 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1349
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>METHYLPREDNISOLONE</b> (UNII: X4W7ZR7023) (METHYLPREDNISOLONE - UNII:X4W7ZR7023)	METHYLPREDNISOLONE	8 mg

### Inactive Ingredients

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

**STARCH, CORN** (UNII: O8232NY3SJ)

### Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL (OVAL)	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	917
<b>Contains</b>			

### 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1350
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>METHYLPREDNISOLONE</b> (UNII: X4W7ZR7023) (METHYLPREDNISOLONE - UNII:X4W7ZR7023)	METHYLPREDNISOLONE	16 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	

**LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X)

**MAGNESIUM STEARATE** (UNII: 70097M6I30)

**SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2)

**STARCH, CORN** (UNII: O8232NY3SJ)

### Product Characteristics

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

### 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1351
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>METHYLPREDNISOLONE</b> (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)