

SIROLIMUS- sirolimus tablet, film coated
Zydus Lifesciences Limited

SIROLIMUS TABLETS

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Sirolimus Tablets, 0.5 mg

NDC 65841-771-01

100 Tablets

Rx only

NDC 65841-771-01

Sirolimus Tablets

0.5 mg

For oral use only

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

zydus

100 Tablets
Rx only

Each tablet contains 0.5 mg of sirolimus
Usual Dosage: See package insert for complete prescribing information.
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
Dispense in a tight, light-resistant container as defined in the USP.
Keep this and all drugs out of the reach of children.
Manufactured by:
Zydus Lifesciences Ltd.
Ahmedabad, India

PHN-0023

Sirolimus Tablets, 1 mg

NDC 65841-772-01

100 Tablets

Rx only

NDC 65841-772-01

3
N
6584177201
2

GUJ/DRUG/1486
Rev.: 02/23

Sirolimus Tablets

1 mg

FOR ORAL USE ONLY.

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

zydus

100 Tablets
Rx only

Each tablet contains 1 mg of sirolimus.

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)
[See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container as defined in the USP.

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

Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.

Mfg. by: Zydus Lifesciences Ltd.
Ahmedabad, India

Sirolimus Tablets, 2 mg
NDC 65841-773-01
100 Tablets
Rx only

NDC 65841-773-01

3
N
6584177301
9

GUJ/DRUG/1486
Rev.: 02/23

Sirolimus Tablets

2 mg

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

zydus

100 Tablets
Rx only

Each tablet contains 2 mg of sirolimus.

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)
[See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container as defined in the USP.

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

Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.

Mfg. by: Zydus Lifesciences Ltd.
Ahmedabad, India

SIROLIMUS

sirolimus tablet, film coated

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:65841-771

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SIROLIMUS (UNII: W36ZG6FT64) (SIROLIMUS - UNII:W36ZG6FT64)	SIROLIMUS	0.5 mg

Inactive Ingredients

Ingredient Name	Strength
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CROSPVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
POLOXAMER 188 (UNII: LQA7B6G8JG)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (YELLOW)	Score	no score
Shape	ROUND (ROUND)	Size	5mm
Flavor		Imprint Code	1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-771-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2014	
2	NDC:65841-771-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2014	
3	NDC:65841-771-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2014	
4	NDC:65841-771-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2014	
5	NDC:65841-771-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2014	
6	NDC:65841-771-77	10 in 1 CARTON	01/15/2014	
6	NDC:65841-771-30	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	ANDA201676	01/15/2014	

SIROLIMUS

sirolimus tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-772
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SIROLIMUS (UNII: W36ZG6FT64) (SIROLIMUS - UNII:W36ZG6FT64)	SIROLIMUS	1 mg

Inactive Ingredients

Ingredient Name	Strength
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CROSPROVIDONE (120 .MU.M) (UNII: 68401960MK)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
POLOXAMER 188 (UNII: LQA7B6G8JG)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POVIDONE K30 (UNII: U725QWY32X)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	7mm
Flavor		Imprint Code	11
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-772-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/16/2023	
2	NDC:65841-772-77	10 in 1 CARTON	02/16/2023	
2	NDC:65841-772-30	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	ANDA201676	02/16/2023	

SIROLIMUS

sirolimus tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-773
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SIROLIMUS (UNII: W36ZG6FT64) (SIROLIMUS - UNII:W36ZG6FT64)	SIROLIMUS	2 mg

Inactive Ingredients

Ingredient Name	Strength
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CROSPVIDONE (120 .MU.M) (UNII: 68401960MK)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
POLOXAMER 188 (UNII: LQA7B6G8JG)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
POVIDONE K30 (UNII: U725QWY32X)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (YELLOW)	Score	no score
Shape	ROUND (ROUND)	Size	9mm
Flavor		Imprint Code	21
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-773-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/16/2023	
2	NDC:65841-773-77	10 in 1 CARTON	02/16/2023	
2	NDC:65841-773-30	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	ANDA201676	02/16/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-771, 65841-772, 65841-773) , MANUFACTURE(65841-771, 65841-772, 65841-773)

Revised: 9/2023

Zydus Lifesciences Limited