SIROLIMUS- sirolimus tablet, film coated
Zydus Lifesciences Limited

SIROLIMUS TABLETS

SPL MEDGUIDE

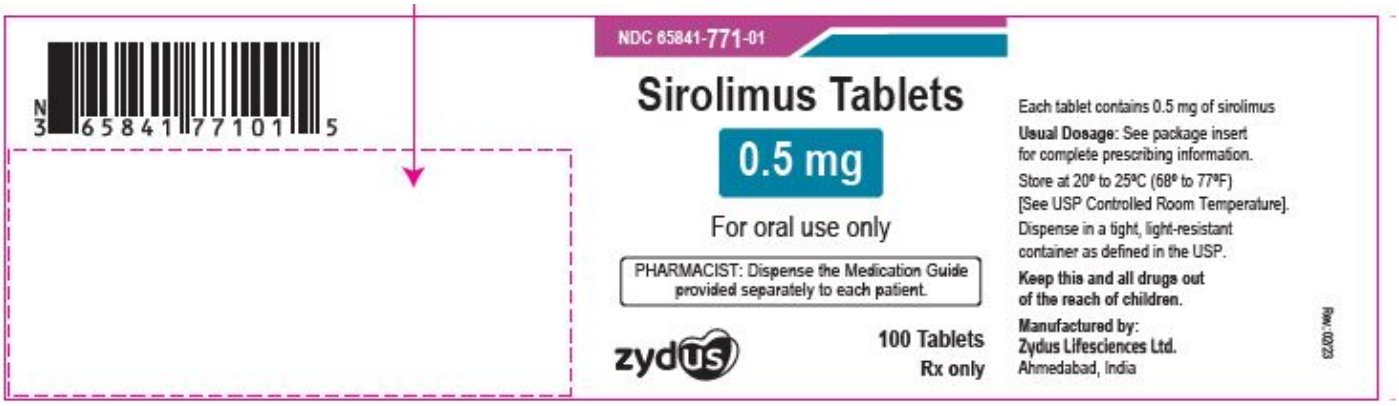
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Sirolimus Tablets, 0.5 mg

NDC 65841-771-01

100 Tablets

Rx only



Sirolimus Tablets, 1 mg

NDC 65841-772-01

100 Tablets

Rx only

Sirolimus Tablets, 2 mg

NDC 65841-773-01

100 Tablets

Rx only

SIROLIMUS

sirolimus tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-771

Route of Administration	ORAL

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)	
CROSPOVIDONE (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: 3WQ0SDW1A)	
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)	
CROSPOVIDONE (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)	
CROSPOVIDONE (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