VALACYCLOVIR - valacyclovir tablet, film coated
Zydus Lifesciences Limited

VALACYCLOVIR TABLETS

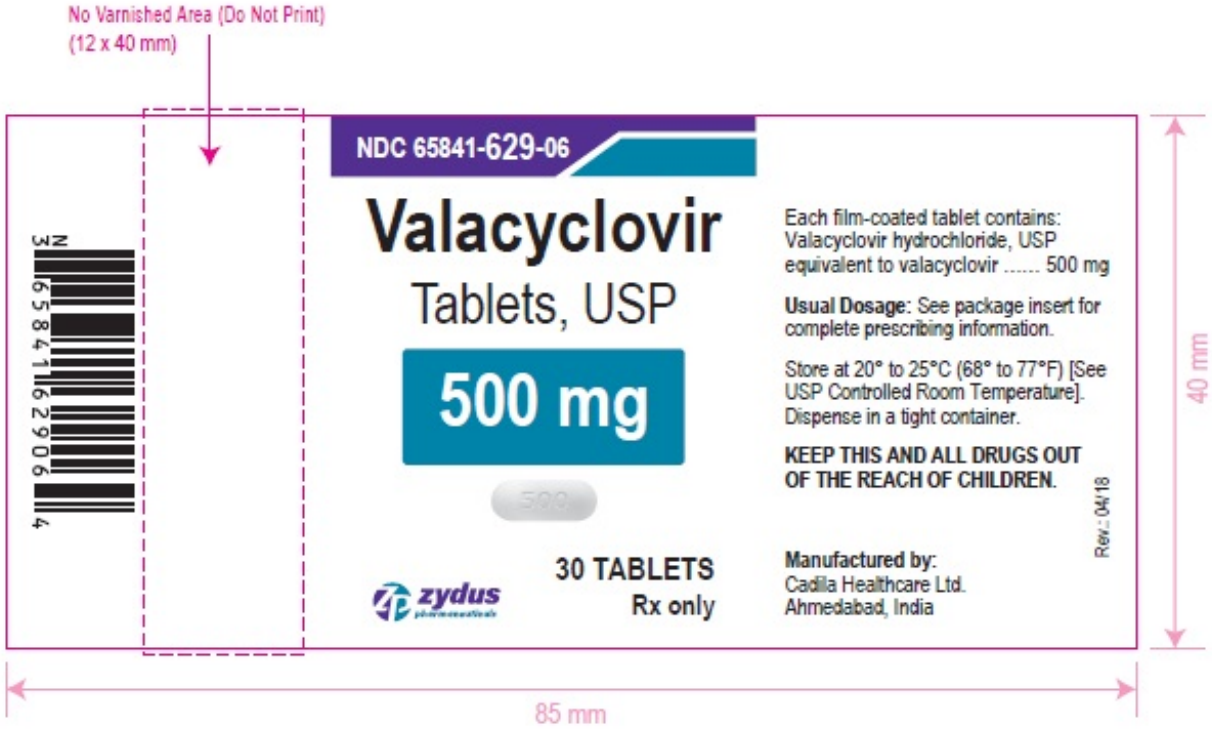
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-629-06 in bottle of 30 tablets

Valacyclovir Tablets USP, 500 mg

R_x only

30 tablets



NDC 65841-630-06 in bottle of 30 tablets

Valacyclovir Tablets USP, 1 gram

R_x only

30 tablets

VALACYCLOVIR

valacyclovir tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-629
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
VALACYCLOVIR HYDROCHLORIDE (UNII: G447S0T1VC) (ACYCLOVIR - UNII:X4HES1O11F)	VALACYCLOVIR	500 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSPOVIDONE (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics			
Color	WHITE (WHITE)	**Score**	no score
Shape	OVAL (CAPSULE)	**Size**	18mm
Flavor		**Imprint Code**	500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-629-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
2	NDC:65841-629-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
3	NDC:65841-629-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
4	NDC:65841-629-77	10 in 1 CARTON	04/05/2018	
4	NDC:65841-629-30	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	ANDA079137	04/05/2018	

VALACYCLOVIR

valacyclovir tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-630
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VALACYCLOVIR HYDROCHLORIDE (UNII: G447S0T1VC) (ACYCLOVIR - UNII:X4HES1O11F)	VALACYCLOVIR	1000 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE (WHITE)	**Score**	2 pieces
Shape	OVAL (CAPSULE)	**Size**	23mm
Flavor		**Imprint Code**	1000
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-630-34	21 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
2	NDC:65841-630-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
3	NDC:65841-630-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079137	04/05/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-629, 65841-630) , MANUFACTURE(65841-629, 65841-630)

Revised: 11/2022 Zydus Lifesciences Limited