WARFARIN SODIUM- warfarin sodium tablet
Zydus Lifesciences Limited

WARFARIN SODIUM TABLETS, USP

SPL MEDGUIDE

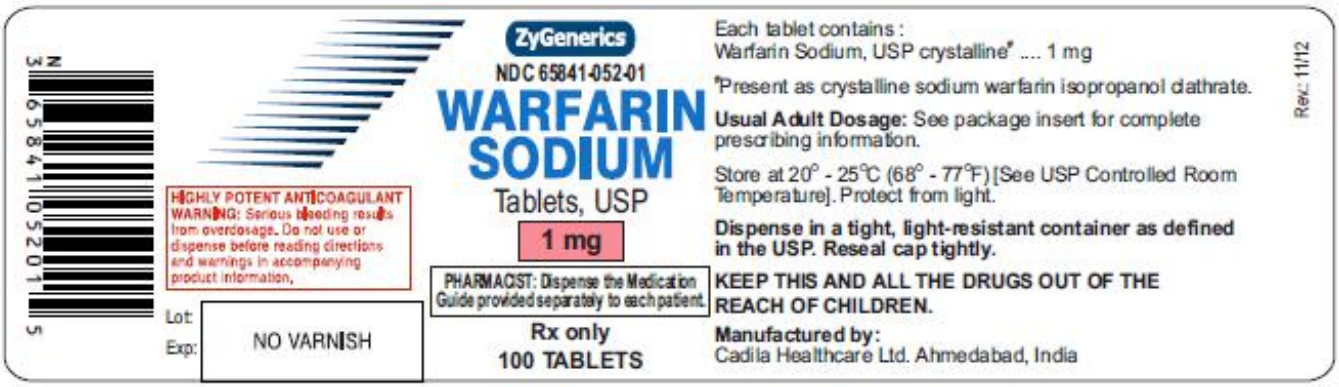
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-052-01 in bottle of 100 tablets

Warfarin Sodium Tablets USP, 1 mg

R_x only

100 tablets

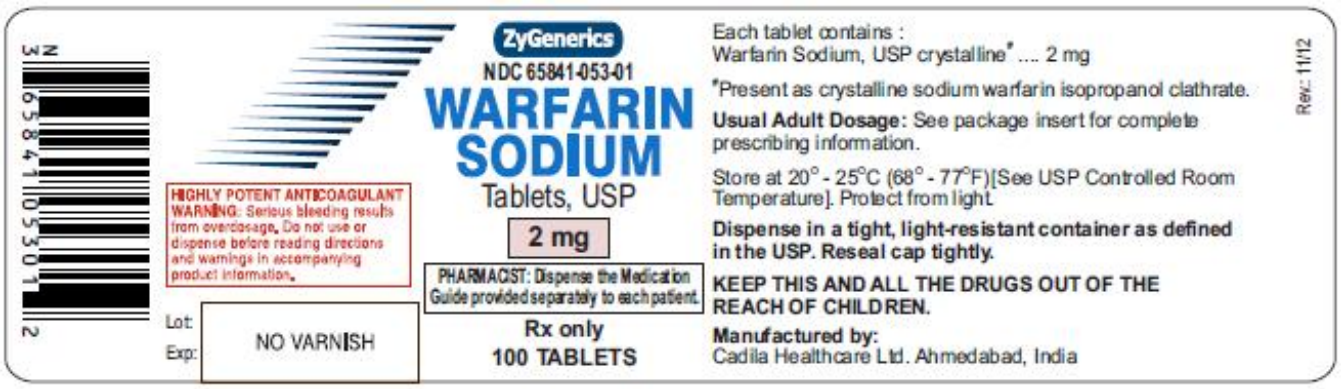


NDC 65841-053-01 in bottle of 100 tablets

Warfarin Sodium Tablets USP, 2 mg

R_x only

100 tablets



NDC 65841-064-01 in bottle of 100 tablets

Warfarin Sodium Tablets USP, 2.5 mg

R_x only

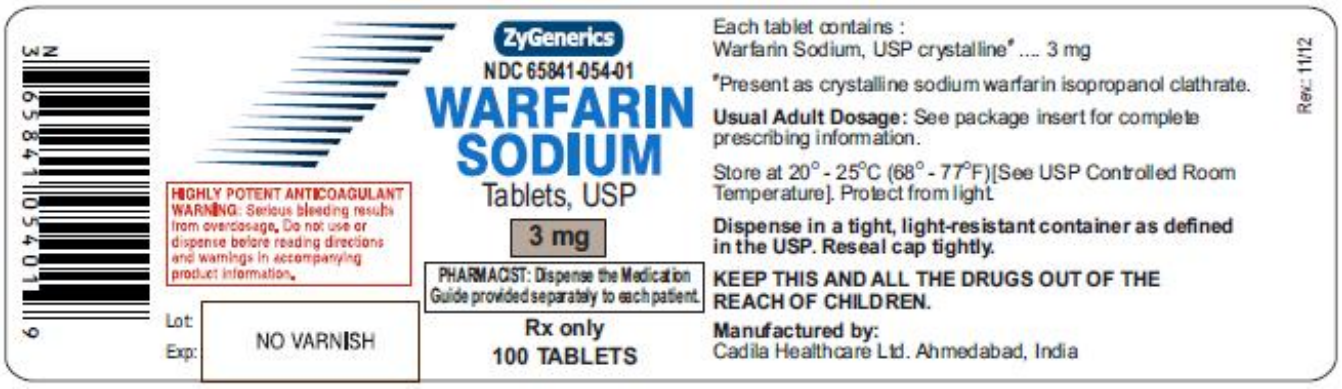
100 tablets

NDC 65841-054-01 in bottle of 100 tablets

Warfarin Sodium Tablets USP, 3 mg

R_x only

100 tablets

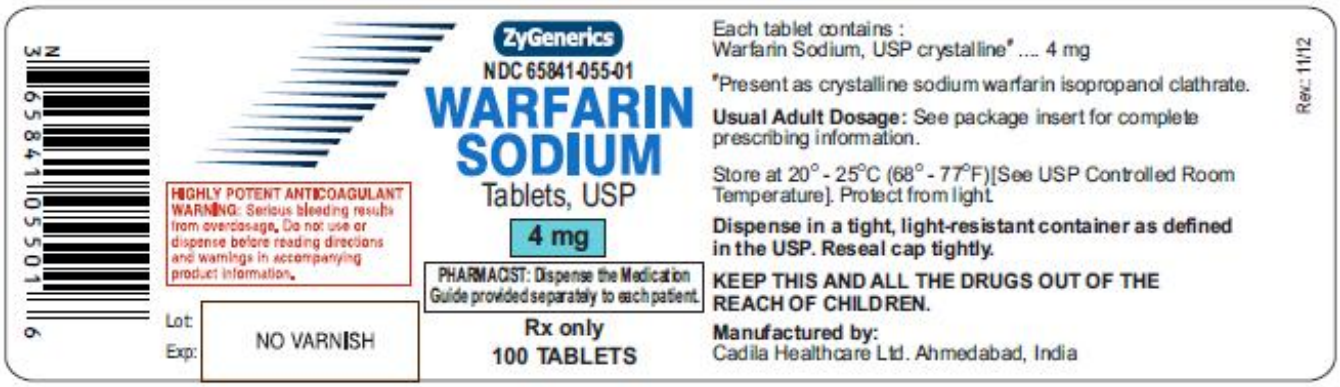


NDC 65841-055-01 in bottle of 100 tablets

Warfarin Sodium Tablets USP, 4 mg

R_x only

100 tablets

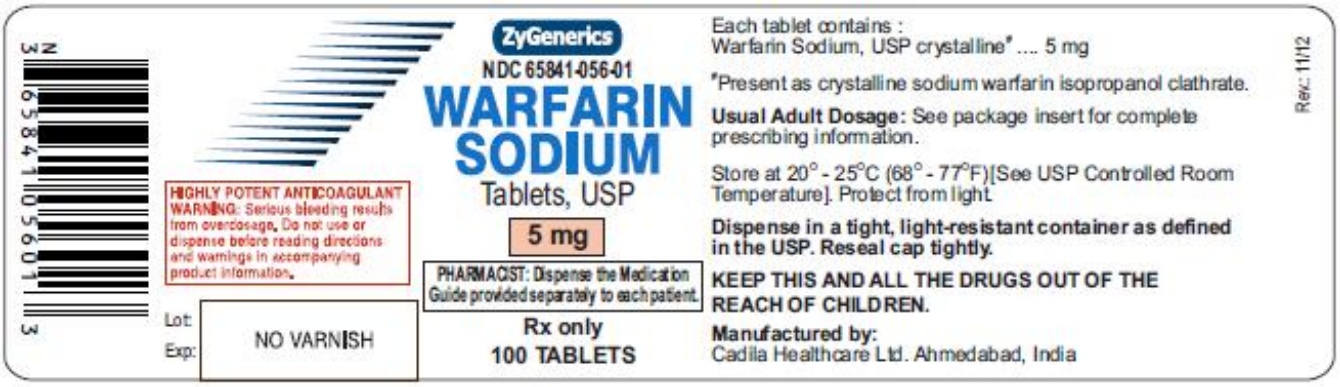


NDC 65841-056-01 in bottle of 100 tablets

Warfarin Sodium Tablets USP, 5 mg

R_x only

100 tablets

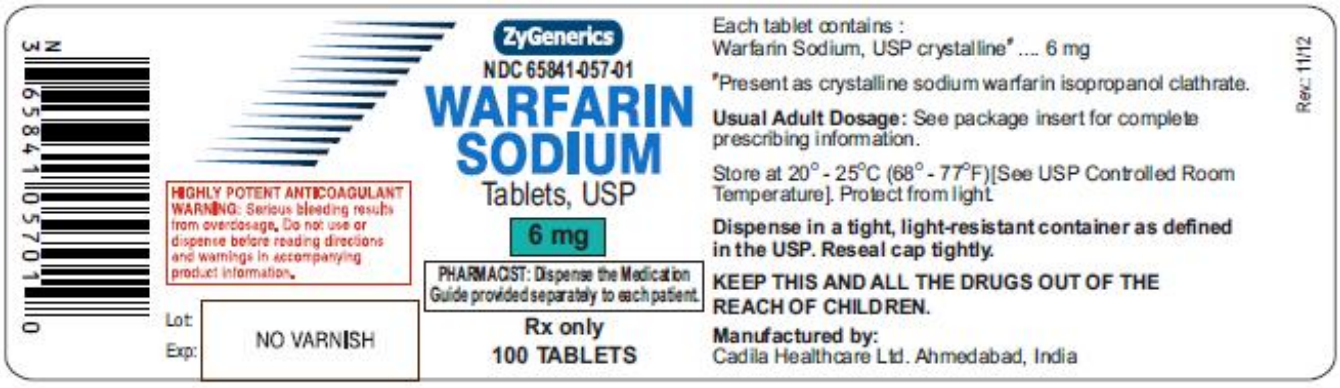


NDC 65841-057-01 in bottle of 100 tablets

Warfarin Sodium Tablets USP, 6 mg

R_x only

100 tablets

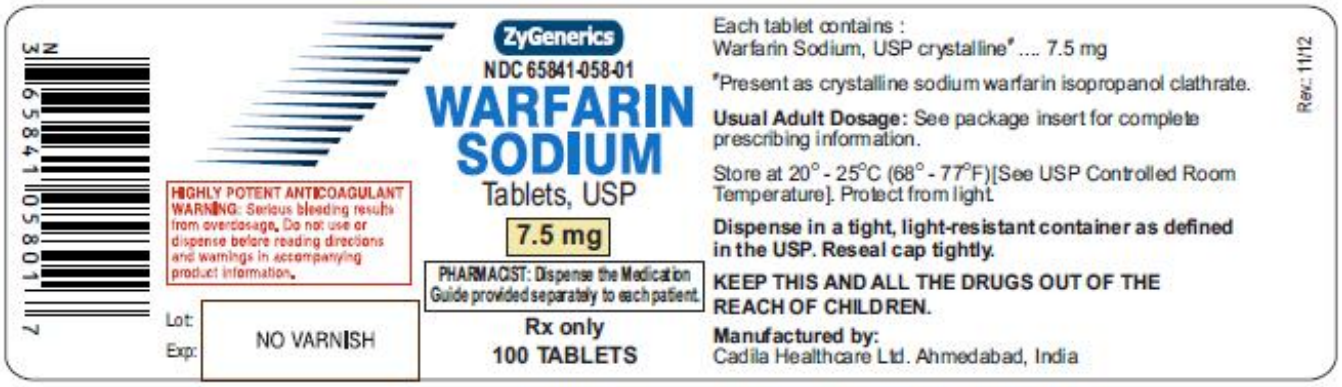


NDC 65841-058-01 in bottle of 100 tablets

Warfarin Sodium Tablets USP, 7.5 mg

R_x only

100 tablets

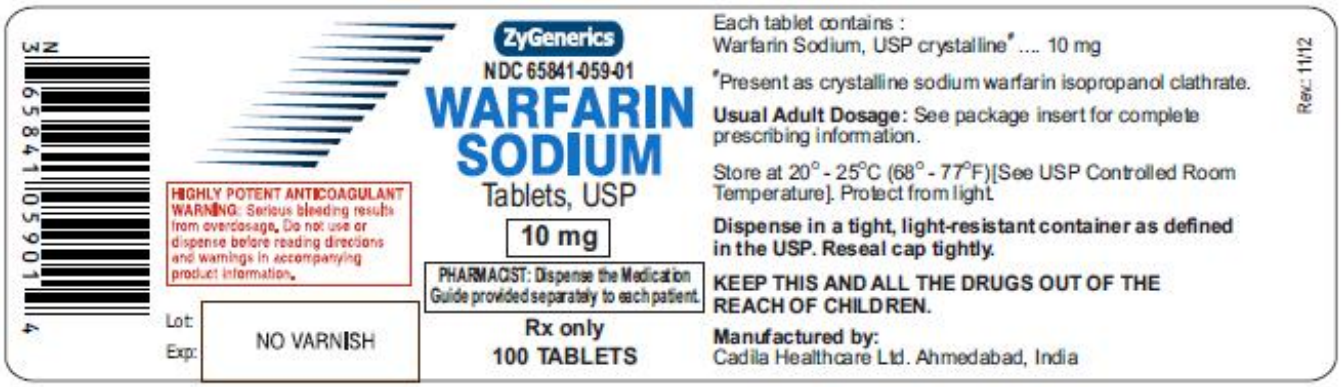


NDC 65841-059-01 in bottle of 100 tablets

Warfarin Sodium Tablets USP, 10 mg

R_x only

100 tablets



WARFARIN SODIUM

warfarin sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-052
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WARFARIN SODIUM (UNII: 6153CWM0CL) (WARFARIN - UNII:5Q7ZVV76EI)	WARFARIN SODIUM	1 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 6 BARIUM LAKE (UNII: K4XZD9W99K)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	PINK (PINK)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	11mm
Flavor		**Imprint Code**	WAR;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-052-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	
2	NDC:65841-052-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040663	06/19/2006	

WARFARIN SODIUM

warfarin sodium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-053
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WARFARIN SODIUM (UNII: 6153CWM0CL) (WARFARIN - UNII:5Q7ZVV76EI)	WARFARIN SODIUM	2 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
STARCH, CORN (UNII: O8232NY3SJ)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics			
Color	PURPLE (LAVENDER)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	11mm
Flavor		**Imprint Code**	WAR;2
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-053-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	
2	NDC:65841-053-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040663	06/19/2006	

WARFARIN SODIUM

warfarin sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-064
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
WARFARIN SODIUM (UNII: 6153CWM0CL) (WARFARIN - UNII:5Q7ZVV76EI)	WARFARIN SODIUM	2.5 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQA3S2JM)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	GREEN (GREEN)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	11mm
Flavor		**Imprint Code**	WAR;2;1;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-064-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	
2	NDC:65841-064-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040663	06/19/2006	

WARFARIN SODIUM

warfarin sodium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-054
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WARFARIN SODIUM (UNII: 6153CWM0CL) (WARFARIN - UNII:5Q7ZVV76EI)	WARFARIN SODIUM	3 mg

Inactive Ingredients

Ingredient Name	Strength

ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	BROWN (TAN)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	11mm
Flavor		**Imprint Code**	WAR;3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-054-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	
2	NDC:65841-054-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040663	06/19/2006	

WARFARIN SODIUM

warfarin sodium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-055
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WARFARIN SODIUM (UNII: 6153CWM0CL) (WARFARIN - UNII:5Q7ZVV76EI)	WARFARIN SODIUM	4 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQA3S2JM)	

HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	BLUE (BLUE)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	11mm
Flavor		**Imprint Code**	WAR;4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-055-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	
2	NDC:65841-055-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040663	06/19/2006	

WARFARIN SODIUM

warfarin sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-056
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WARFARIN SODIUM (UNII: 6153CWM0CL) (WARFARIN - UNII:5Q7ZVV76EI)	WARFARIN SODIUM	5 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	ORANGE (PEACH)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	11mm
Flavor		**Imprint Code**	WAR;5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-056-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	
2	NDC:65841-056-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	
3	NDC:65841-056-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040663	06/19/2006	

WARFARIN SODIUM

warfarin sodium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-057
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WARFARIN SODIUM (UNII: 6153CWM0CL) (WARFARIN - UNII:5Q7ZVV76EI)	WARFARIN SODIUM	6 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

STARCH, CORN (UNII: O8232NY3SJ)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics			
Color	GREEN (TEAL)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	11mm
Flavor		**Imprint Code**	WAR;6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-057-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	
2	NDC:65841-057-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040663	06/19/2006	

WARFARIN SODIUM

warfarin sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-058
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WARFARIN SODIUM (UNII: 6153CWM0CL) (WARFARIN - UNII:5Q7ZVV76EI)	WARFARIN SODIUM	7.5 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	YELLOW (YELLOW)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	11mm
Flavor		**Imprint Code**	WAR;7;1;2
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-058-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040663	06/19/2006	

WARFARIN SODIUM

warfarin sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-059
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
WARFARIN SODIUM (UNII: 6153CWM0CL) (WARFARIN - UNII:5Q7ZVV76EI)	WARFARIN SODIUM	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	11mm
Flavor		**Imprint Code**	WAR;10

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-059-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040663	06/19/2006	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-052, 65841-053, 65841-064, 65841-054, 65841-055, 65841-056, 65841-057, 65841-058, 65841-059) , MANUFACTURE(65841-052, 65841-053, 65841-064, 65841-054, 65841-055, 65841-056, 65841-057, 65841-058, 65841-059)

Revised: 10/2023 Zydus Lifesciences Limited