METHOTREXATE - methotrexate tablet
Zydus Lifesciences Limited

Methotrexate tablet, USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1058-1

Methotrexate tablets, USP 2.5 mg

Rx only

36 tablets

METHOTREXATE

methotrexate tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1058
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METHOTREXATE (UNII: YL5FZ2Y5U1) (METHOTREXATE - UNII:YL5FZ2Y5U1)	METHOTREXATE	2.5 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	YELLOW (YELLOW)	**Score**	2 pieces
Shape	ROUND (ROUND)	**Size**	6mm
Flavor		**Imprint Code**	L2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1058-3	36 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2017	
2	NDC:70771-1058-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2017	
3	NDC:70771-1058-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2017	
4	NDC:70771-1058-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2017	
5	NDC:70771-1058-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2017	
6	NDC:70771-1058-7	100 in 1 CARTON	02/09/2017	
6	NDC:70771-1058-2	1 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	ANDA207812	02/09/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Pharmaceuticals USA Inc. (156861945)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1058) , MANUFACTURE(70771-1058)