

COLCHICINE- colchicine tablet
Zydus Lifesciences Limited

COLCHICINE TABLETS

SPL MEDGUIDE

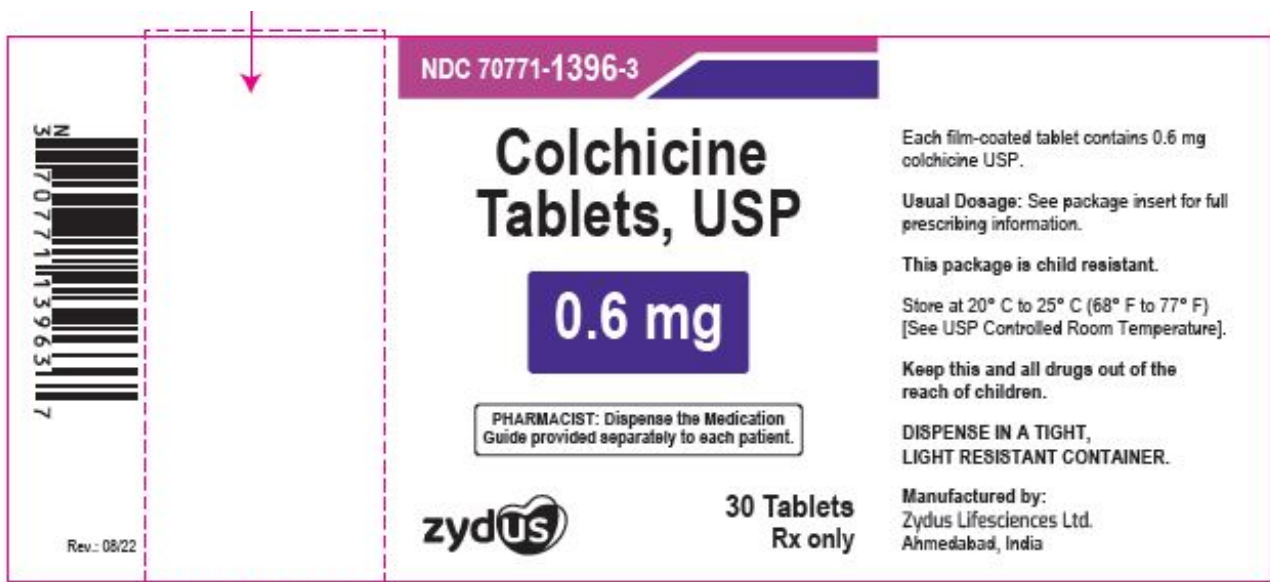
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1396-3

Colchicine tablets, USP 0.6 mg

30 Tablets

Rx only




NDC 70771-1590-3

Colchicine tablets, USP 0.3 mg

30 Tablets

Rx only

NDC 70771-1590-3




Rev.:08/22

Colchicine Tablets, USP

0.3 mg

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



Each film-coated tablet contains 0.3 mg colchicine USP.

Usual Dosage: See package insert for full prescribing information.

This package is child resistant.

Store at 20° C to 25° C (68° F to 77° F) [See USP Controlled Room Temperature].

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

DISPENSE IN A TIGHT, LIGHT RESISTANT CONTAINER.

Manufactured by:
Zydus Lifesciences Ltd.
Ahmedabad, India

30 Tablets
Rx only

COLCHICINE

colchicine tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1396
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COLCHICEINE (UNII: HJ30158L57) (COLCHICEINE - UNII:HJ30158L57)	COLCHICEINE	0.6 mg

Inactive Ingredients

Ingredient Name	Strength
CARMINIC ACID (UNII: CID8Z8N95N)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PURPLE	Score	2 pieces
Shape	CAPSULE	Size	8mm
Flavor		Imprint Code	1351
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1396-3	1 in 1 CARTON	06/12/2019	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70771-1396-9	1 in 1 CARTON	06/12/2019	
2		90 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:70771-1396-1	1 in 1 CARTON	06/12/2019	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:70771-1396-5	1 in 1 CARTON	06/12/2019	
4		500 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211519	06/12/2019	

COLCHICINE

colchicine tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1590
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COLCHICEINE (UNII: HJ30158L57) (COLCHICEINE - UNII:HJ30158L57)	COLCHICEINE	0.3 mg

Inactive Ingredients

Ingredient Name	Strength
CARMINIC ACID (UNII: CID8Z8N95N)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

FERROSFERRIC OXIDE (UNII: XM0M87F357)
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)
MAGNESIUM STEARATE (UNII: 70097M6I30)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)
STARCH, CORN (UNII: O8232NY3SJ)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	PURPLE	Score	2 pieces
Shape	ROUND (Round)	Size	7mm
Flavor		Imprint Code	1571
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1590-3	1 in 1 CARTON	05/10/2021	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70771-1590-9	1 in 1 CARTON	05/10/2021	
2		90 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:70771-1590-1	1 in 1 CARTON	05/10/2021	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:70771-1590-5	1 in 1 CARTON	05/10/2021	
4		500 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211519	05/10/2021	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zyduş Lifesciences Limited		863362789	ANALYSIS(70771-1396, 70771-1590) , MANUFACTURE(70771-1396, 70771-1590)

Revised: 9/2023

Zyduş Lifesciences Limited