

INDOMETHACIN- indomethacin capsule
Zydus Lifesciences Limited

INDOMETHACIN CAPSULES

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1004-01

Indomethacin capsules USP, 25 mg

100 Capsules

Rx only

ZyGenerics
NDC 70771-1004-1
INDOMETHACIN
Capsules, USP
25 mg

PHARMACIST: PLEASE DISPENSE
WITH MEDICATION GUIDE PROVIDED
SEPARATELY.

Rx only
100 Capsules

Each capsule contains:
Indomethacin, USP 25 mg

Contains color additives including
FD & C Yellow No. 5 (Tartrazine).

Usual Dosage: One or two capsules 2
or 3 times a day. See package insert
for complete prescribing information.

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

Keep container tightly closed.

Dispense in a tight, light-resistant
container with child-resistant closure.

**KEEP THIS AND ALL DRUGS OUT
OF THE REACH OF CHILDREN.**

Manufactured by:
Cadilla Healthcare Ltd.
Ahmedabad, India

Lot: **UNVARNISHED
AREA**
Exp:
Rev: 07/16

NDC 70771-1005-01

Indomethacin capsules USP, 50 mg

100 Capsules

Rx only



ZyGenerics

NDC 70771-1005-1

INDOMETHACIN

Capsules, USP

50 mg

PHARMACIST: PLEASE DISPENSE WITH MEDICATION GUIDE PROVIDED SEPARATELY.

Rx only

100 Capsules

Each capsule contains:
Indomethacin, USP 50 mg

Contains color additives including FD & C Yellow No. 5 (Tartrazine).

Usual Dosage: One capsule 2 or 3 times a day. See package insert for complete prescribing information.

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

Keep container tightly closed.

Dispense in a tight, light-resistant container with child-resistant closure.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Lot: UNVARNISHED AREA
Exp:
Rev.: 07/16

INDOMETHACIN

indomethacin capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
INDOMETHACIN (UNII: XXE1CET956) (INDOMETHACIN - UNII:XXE1CET956)	INDOMETHACIN	50 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GELATIN (UNII: 2G86QN327L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN (GREEN)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	19mm
Flavor		Imprint Code	294;50mg
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1004-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/21/2016	
2	NDC:70771-1004-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/21/2016	
3	NDC:70771-1004-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/21/2016	
4	NDC:70771-1004-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/21/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090403	07/21/2016	

INDOMETHACIN

indomethacin capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1005
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
INDOMETHACIN (UNII: XXE1CET956) (INDOMETHACIN - UNII:XXE1CET956)	INDOMETHACIN	25 mg

Inactive Ingredients	
Ingredient Name	Strength
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GELATIN (UNII: 2G86QN327L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	GREEN (GREEN)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	16mm
Flavor		Imprint Code	293;25mg
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1005-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/21/2016	
2	NDC:70771-1005-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/21/2016	
3	NDC:70771-1005-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/21/2016	
4	NDC:70771-1005-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/21/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090403	07/21/2016	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment			
Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1004, 70771-1005) , MANUFACTURE(70771-1004, 70771-1005)