

**INDOMETHACIN- indomethacin capsule, extended release**  
**Zydus Lifesciences Limited**

**INDOMETHACIN EXTENDED-RELEASE CAPSULES**

**SPL MEDGUIDE**

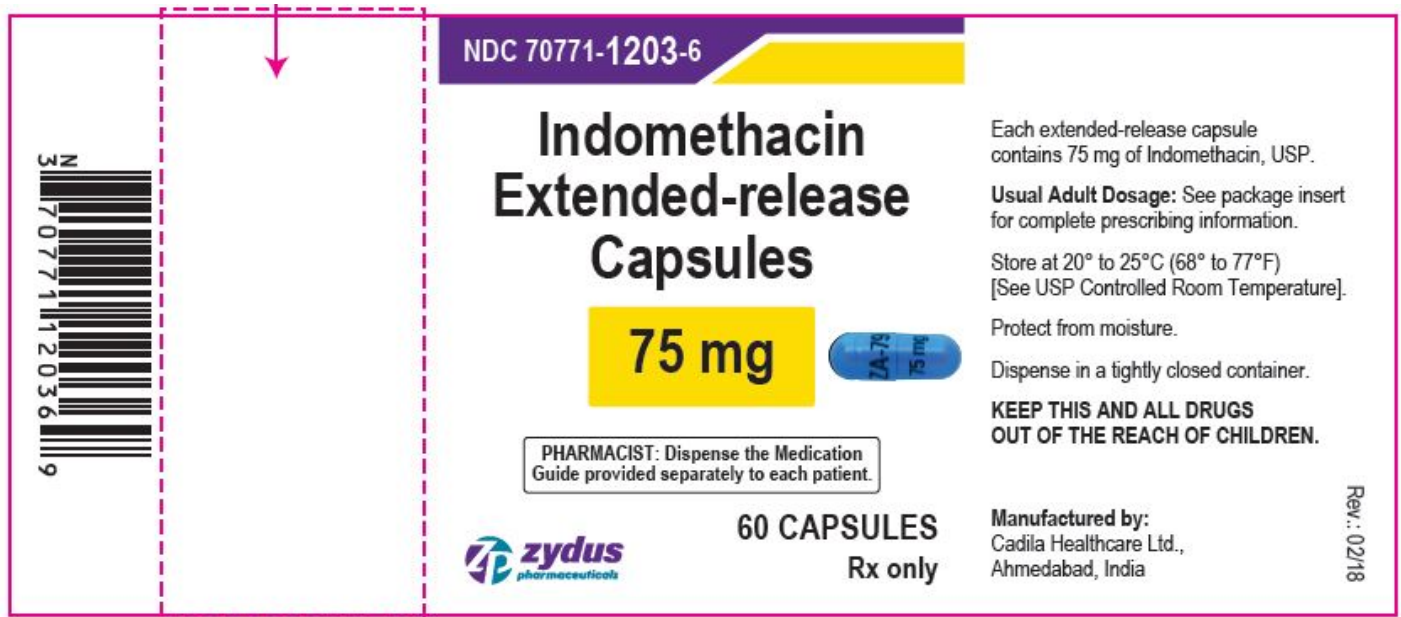
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1203-6

Indomethacin Extended-release Capsules, 75 mg

60 Capsules

Rx only



**INDOMETHACIN**

indomethacin capsule, extended release

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1203
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>INDOMETHACIN</b> (UNII: XXE1CET956) (INDOMETHACIN - UNII:XXE1CET956)	INDOMETHACIN	75 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	BLUE (DARK BLUE) , BLUE (DARK BLUE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	ZA;79;75mg
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1203-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
2	NDC:70771-1203-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
3	NDC:70771-1203-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
4	NDC:70771-1203-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
5	NDC:70771-1203-4	10 in 1 CARTON	02/08/2018	
5	NDC:70771-1203-2	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	ANDA202711	02/08/2018	

**Labeler** - Zydus Lifesciences Limited (918596198)

**Registrant** - Zydus Lifesciences Limited (918596198)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1203) , MANUFACTURE(70771-1203)

Revised: 9/2023

Zydus Lifesciences Limited