

**ACETAMINOPHEN 500 MG ROUND- acetaminophen tablet**  
**Granules India Limited**

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**Acetaminophen tablets USP 500 mg (Round)**

# Acetaminophen Tablets, USP 500mg

Each film coated tablet contains Acetaminophen USP 500 mg.

<b>Batch No.</b> : XXXXXXX	<b>No. of Units</b> : 5x3000
<b>Mfg. Dt.</b> : MM/YYYY	<b>Gross Wt.</b> : 00.000 Kg
<b>Exp. Dt.</b> : MM/YYYY	<b>Tare Wt.</b> : 00.000 Kg
<b>Mfg.Lic.No.</b> : 37/RR/AP/2003/F/R	<b>Net Wt.</b> : 00.000 Kg
<b>NDC No.</b> : 62207-538-87	<b>Box No.</b> : 000

**Storage** : Store at room temperature between 15°C to 25°C (59°F to 77°F).

**Caution** : For repacking only.



(01)50362207538874(17)000000(10)XXXXXX

Country of Origin: INDIA



(00)189038320000000004

FG Code: 700000003263

## ACETAMINOPHEN 500 MG ROUND

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62207-538
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

### Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z 65AP)	

<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	L;1
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-538-87	15000 in 1 BOX; Type 0: Not a Combination Product	02/13/2023	
2	NDC:62207-538-85	90000 in 1 BOX; Type 0: Not a Combination Product	02/13/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		02/13/2023	

**Labeler** - Granules India Limited (915000087)

**Registrant** - Granules India Limited (918609236)

### Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918609236	manufacture(62207-538) , analysis(62207-538) , pack(62207-538) , label(62207-538)

Revised: 1/2023

Granules India Limited