

**ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE- acetaminophen and diphenhydramine hydrochloride capsule
Granules India Limited**

Acetaminophen and Diphenhydramine Hydrochloride Rapid Release Gelcaps

**ACETAMINOPHEN 500 mg & DIPHENHYDRAMINE HCl 25 mg
RAPID RELEASE GELCAPS**

**Each Rapid Release Gelcap Contains:
Acetaminophen USP 500 mg and Diphenhydramine Hydrochloride USP 25 mg**

BOX LABEL

Batch No.:	XXX	No. of Units	5 x 5000
Mfg. Dt.:	MMM/YYYY	Gross Wt.:	0.00 kg
Exp. Dt.:	MMM/YYYY	Tare Wt.:	0.00 kg
Mfg. Lic. No.:	37/RR/AP/2003/F/R	Net Wt.:	0.00 kg
NDC No.	XXXXX-XXX-XX	Box Number:	000
Storage:	Store at 20 - 25C (68 - 77F); excursions permitted to 15 - 30 C (59 - 86F); Preserve in tightly closed containers.		
Caution	For Repacking only.		

POUCH LABEL

Batch No.:	XXX	No. of Units	5000
Mfg. Dt.:	MMM/YYYY		
Exp. Dt.:	MMM/YYYY		
Mfg. Lic. No.:	37/RR/AP/2003/F/R		
NDC No.	XXXXX-XXX-XX		
Storage:	Store at 20 - 25C (68 - 77F); excursions permitted to 15 - 30 C (59 - 86F); Preserve in tightly closed containers.		
Caution	For Repacking only.		

Gil/PL/041

Product Code: XXXXXXXX

**Manufactured in India by:
Granules India Limited**

Plot No. 160/A, 161/E, Gagillapur Village
Qutbullapur Mandal, Ranga Reddy Dt - 500 043, AP.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

**ACETAMINOPHEN 500 mg AND DIPHENHYDRAMINE HYDROCHLORIDE 25 mg
RAPID RELEASE GELCAPS**

Each Rapid Release Gelcap Contains:

Acetaminophen, USP500 mg,

Diphenhydramine Hydrochloride, USP25 mg

Batch No. : XXXXXXX

Mfg.Dt. : MM/YYYY

Exp.Dt. : MM/YYYY

Mfg.Lic.No. : 37/RR/AP/2003/F/R

NDC No. : 62207-664-35

No. of Units : 25,000 (5 x 5,000)

Gross Wt. : 00.000 Kg

Tare Wt. : 00.000 Kg

Net Wt. : 00.000 Kg

Box number : 000

Storage: Store at controlled room temperature [store at 20° - 25°C (68° - 77°F);
excursions permitted to 15° -30°C (59°- 86°F); Preserve in tightly closed containers.]

Caution : For repacking only.



(01)50362207664351(17)000000(10)XXXXXX

Country of Origin: INDIA



(00)189038320000000004

Product code : 70000001072

ACETAMINOPHEN 500 mg AND DIPHENHYDRAMINE HYDROCHLORIDE 25 mg RAPID RELEASE GELCAPS

Each Rapid Release Gelcap Contains:
Acetaminophen, USP500 mg,
Diphenhydramine Hydrochloride, USP25 mg

No. of Units : 5000

Batch No. : XXXXXXX
Mfg.Dt. : MM/YYYY
Exp.Dt. : MM/YYYY
Mfg.Lic.No. : 37/RR/AP/2003/F/R
NDC No. : 62207-664-31

Storage : Store at controlled room temperature [Store at 20° - 25°C (68° - 77°F);
excursions permitted to 15° -30°C (59° - 86°F)];Preserve in tightly closed containers.]

Caution :For repacking only.

Country of Origin: INDIA

Product code : 700000001072

ACETAMINOPHEN 500 mg & DIPHENHYDRAMINE HCl 25 mg RAPID RELEASE GELCAPS

Each Rapid Release Gelcap Contains:
Acetaminophen USP 500 mg and Diphenhydramine Hydrochloride USP 25 mg

Batch No. : XXXXXXX	No. of Units : 5 x 5000
Mfg.Dt. : MMM/YYYY	Gross Wt. : 0.00 kg
Exp.Dt. : MMM/YYYY	Tare Wt. : 0.00 kg
Mfg.Lic.No. : 37/RR/AP/2003/F/R	Net Wt. : 0.00 kg
NDC No. : 62207-664-21	Box number : 000

Storage : Store at 20°-25°C (68°-77°F); excursions permitted to
15°-30°C (59°-86°F); Preserve in tightly closed containers.

Caution : For repacking only.



(01)000000000000(17)YYMMDD(16)XXXXXX



(06)1890532000000011

GIL/PL/041



Manufactured in india by:
Granules India Limited
Plot No. 160/A, 161/E, Gagillapur Village,
Qutbullapur Mandal, Ranga Reddy Dt - 500 043, AP.

Product code : XXXXXXX

ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE

acetaminophen and diphenhydramine hydrochloride capsule

Product Information

Product Type	BULK INGREDIENT	Item Code (Source)	NDC:62207-664
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
HYDROXYPROPYL CELLULOSE (1200000 WAMW) (UNII: U3JF91U133)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
TRIACETIN (UNII: XHX3C3X673)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SHELLAC (UNII: 46N107B71O)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	blue (dark blue/light blue)	Score	no score
Shape	CAPSULE (banded two-part capsule)	Size	20mm
Flavor		Imprint Code	G;3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-664-21	5000 in 1 BOX	01/14/2014	
2	NDC:62207-664-22	25000 in 1 BOX	01/14/2014	
3	NDC:62207-664-23	30000 in 1 BOX	01/14/2014	
4	NDC:62207-664-31	5000 in 1 POUCH	01/14/2014	
5	NDC:62207-664-32	10000 in 1 POUCH	01/14/2014	
6	NDC:62207-664-33	25000 in 1 POUCH	01/14/2014	11/13/2019
7	NDC:62207-664-35	25000 in 1 BOX	11/14/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		01/14/2014	

Labeler - Granules India Limited (915000087)

Registrant - Granules India Limited (915000087)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918609236	manufacture(62207-664) , analysis(62207-664)

Revised: 8/2023

Granules India Limited