

NAPROXEN SODIUM- naproxen sodium tablet, film coated
Granules India Limited

NAPROXEN SODIUM TABLETS USP 220 MG (TABLET/CAPLET)

Each film coated tablet/caplet contains
Naproxen Sodium USP 220 mg (naproxen 200 mg)

BOX

Batch No.:	XXX	No. of Units	50,000 (5 x 10,000)
Mfg. Dt.:	XXX	Gross Wt.:	XXX kg
Exp. Dt.:	XXX	Tare Wt.:	XXX kg
NDC No.	XXX	Net Wt.:	XXX kg
Mfg. Lic. No.:	37/RR/AP/2003/F/R	Box No.:	XXX
Storage:	Store at controlled room temperature [store at 20° - 25°C (68° - 77°F); Avoid humidity and excessive heat above 40°C (104°F).		
Caution:	For repacking only.		

POUCH

Batch No.:	XXX	No. of Units	10,000
Mfg. Dt.:	XXX		
Exp. Dt.:	XXX		
NDC No.	XXX		
Mfg. Lic. No.:	37/RR/AP/2003/F/R		
Storage:	Store at controlled room temperature [store at 20° - 25°C (68° - 77°F); Avoid humidity and excessive heat above 40°C (104°F).		
Caution:	For repacking only.		

Country of Origin: INDIA

Product code: XXXXXX

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

NAPROXEN SODIUM TABLETS USP 220 mg (ROUND)

Each Film coated tablet contains:

Naproxen sodium USP 220 mg

Batch No. : XXXXXXXX

No. of Units : 10,000

Mfg.Dt. : MM/00/YYYY

Exp.Dt. : MM/00/YYYY

NDC No. : 62207-761-32

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

Storage : Store at controlled room temperature [store at 20°-25°C (68°-77°F);
Avoid humidity and excessive heat above 40°C (104°F)]

Caution : For repacking only.

Country of Origin: INDIA

GIL/PL/041C



Manufactured by:

Granules India Limited

Sy.No.160/A, 161/E, 162, & 174/A, Gagillapur Village,
Dundigal-Gandimaisamma Mandal, Medchal-Malkhajiri District - 500043,
Telangana, INDIA

Product Code : F1181D20

NAPROXEN SODIUM TABLETS USP 220 mg (ROUND)

Each Film coated tablet contains:

Naproxen sodium USP 220 mg

Batch No.	: XXXXXXXX	No. of Units	: 50,000
Mfg.Dt.	: MM/00/YYYY	Gross Wt.	: 00.000 Kg
Exp.Dt.	: MM/00/YYYY	Tare Wt.	: 00.000 Kg
NDC No.	: 62207-761-36	Net Wt.	: 00.000 Kg
Mfg.Lic.No.	: 37/RR/AP/2003/F/R	Box number	: 000

Storage : Store at controlled room temperature [store at 20°-25°C (68°-77°F);

Avoid humidity and excessive heat above 40°C (104°F)]

Caution : For repacking only.



(01)58903832303035(17)000000(10)XXXXXXX

Country of Origin: INDIA



(00)189038320000000004

Product code : F1181D20

GIL/PL/041C



Manufactured by:

Granules India Limited

Sy.No.160/A, 161/E, 162, & 174/A, Gagillapur Village,
Dundigal-Gandimaisamma Mandal, Medchal-Malkhajiri District - 500043,
Telangana, INDIA

NAPROXEN SODIUM TABLETS USP 220 mg (CAPLET)

Each Film coated tablet contains:

Naproxen sodium USP 220 mg

Batch No.	: XXXXXXXX	No. of Units	: 10,000
Mfg.Dt.	: MM/DD/YYYY		
Exp.Dt.	: MM/DD/YYYY		
NDC No.	: 62207-762-32		
Mfg. Lic. No.:	37/RR/AP/2003/F/R		

Storage : Store at controlled room temperature [store at 20°-25°C (68°-77°F);

Avoid humidity and excessive heat above 40°C (104°F)]

Caution :For repacking only.

Country of Origin: INDIA

Product Code : F1182D20

GIL/PL/041C



Manufactured by:

Granules India Limited

Sy.No.160/A, 161/E, 162, & 174/A, Gagillapur Village,
Dundigal-Gandimaisamma Mandal, Medchal-Malkhajiri District - 500043,
Telangana, INDIA

NAPROXEN SODIUM TABLETS USP 220 mg (CAPLET)

Each Film coated tablet contains:

Naproxen sodium USP 220 mg

Batch No. : XXXXXXXX

No. of Units : 50,000

Mfg.Dt. : MM/00/YYYY

Gross Wt. : 00.000 Kg

Exp.Dt. : MM/00/YYYY

Tare Wt. : 00.000 Kg

NDC No. : 62207-762-36

Net Wt. : 00.000 Kg

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

Box number : 000

Storage : Store at controlled room temperature [store at 20°-25°C (68°-77°F);

Avoid humidity and excessive heat above 40°C (104°F)]

Caution : For repacking only.



(01)58903832303042(17)000000(10)XXXXXXX

Country of Origin: INDIA



(00)189038320000000004

Product code : F1182D20

GIL/PL/041C



Manufactured by:

Granules India Limited

Sy.No.160/A, 161/E, 162, & 174/A, Gagillapur Village,
Dundigal-Gandimaisamma Mandal, Medchal-Malkajgiri District - 500043,
Telangana, INDIA

NAPROXEN SODIUM

naproxen sodium tablet, film coated

Product Information

Product Type	BULK INGREDIENT	Item Code (Source)	NDC:62207-761
Route of Administration	NOT APPLICABLE		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z 65AP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)

Product Characteristics

Color	blue (light blue)	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	220
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-761-21	5000 in 1 BOX	03/12/2014	
2	NDC:62207-761-22	25000 in 1 BOX	03/12/2014	
3	NDC:62207-761-24	48000 in 1 BOX	03/12/2014	
4	NDC:62207-761-28	50000 in 1 BOX	03/12/2014	
5	NDC:62207-761-31	5000 in 1 POUCH	03/12/2014	
6	NDC:62207-761-32	10000 in 1 POUCH	03/12/2014	
7	NDC:62207-761-33	25000 in 1 POUCH	03/12/2014	
8	NDC:62207-761-34	15000 in 1 POUCH	03/12/2014	
9	NDC:62207-761-36	50000 in 1 POUCH	03/12/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		03/12/2014	

NAPROXEN SODIUM

naproxen sodium tablet, film coated

Product Information

Product Type	BULK INGREDIENT	Item Code (Source)	NDC:62207-762
Route of Administration	NOT APPLICABLE		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z 65AP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

Product Characteristics

Color	blue (light blue)	Score	no score
Shape	OVAL (caplet-shaped)	Size	12mm
Flavor		Imprint Code	220
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-762-21	5000 in 1 BOX	03/12/2014	
2	NDC:62207-762-22	25000 in 1 BOX	03/12/2014	
3	NDC:62207-762-24	48000 in 1 BOX	03/12/2014	
4	NDC:62207-762-28	50000 in 1 BOX	03/12/2014	
5	NDC:62207-762-31	5000 in 1 POUCH	03/12/2014	
6	NDC:62207-762-32	10000 in 1 POUCH	03/12/2014	
7	NDC:62207-762-33	25000 in 1 POUCH	03/12/2014	
8	NDC:62207-762-34	15000 in 1 POUCH	03/12/2014	
9	NDC:62207-762-36	50000 in 1 POUCH	03/12/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		03/12/2014	

Labeler - Granules India Limited (915000087)

Registrant - Granules India Limited (915000087)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918609236	manufacture(62207-761, 62207-762) , analysis(62207-761, 62207-762) , pack(62207-761, 62207-762)