DAYTIME NIGHTTIME COLD/FLU RELIEF A P J- daytime nighttime cold/flu relief A P J Laboratories Limited

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ACTIVE INGREDIENT PART 1 OF 2 DAYTIME COLD AND FLU RELIEF

Acetaminophen 325 mg Dextromethorphan Hydrobromide 10 mg Phenylephrine HCl 5 mg

PART 2 OF 2 NIGHTTIME COLD AND FLU RELIEF

Acetaminophen 325 mg Dextromethorphan Hydrobromide 10 mg Chlorpheniramine Maleate 6.25 mg

PURPOSE

Purpose for Daytime

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Purpose for Nighttime

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Keep out of reach of children

Overdose warning: Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults and for children even if you do not notice any signs or symptoms.

USES

Temporarily relieves common cold/flu symptoms:

•cough due to minor throat and bronchial irritation •sore throat •headache

minor aches and pains fever runny nose and sneezing (Nighttime only) nasal congestion (Daytime only)

WARNINGS

Liver warning: These products contain acetaminophen. Severe liver damage may occur if you take

•more than 4 doses in 24 hours, which is the maximum daily amount for these products

•with other drugs containing acetaminophen

•3 or more alcoholic drinks every day while using these products

Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see a doctor promptly.

Do not use

•with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

•if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

•to make a child sleep (Nighttime only)

DIRECTIONS

•take only as directed – see Overdose warning
•take Nighttime OR Daytime.
Nighttime tablets
•do not exceed 4 doses per 24 hours
adults and children 12 years and over swallow 2 softgels with water every 6 hrs
children 4 to under 12 years ask a doctor
children under 4 years do not use
DayTime tablets
•do not exceed 4 doses per 24 hours
adults and children 12 years and over swallow 2 softgels with water every 4 hrs
children 12 years ask a doctor
children under 12 years ask a doctor
children under 12 years ask a doctor
children 4 to under 12 years ask a doctor
children 4 to under 12 years and over swallow 2 softgels with water every 4 hrs
children 4 to under 12 years ask a doctor
children under 4 years do not use
•when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

INACTIVE INGREDIENT

CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS

STARCH, CORN BUTYLATED HYDROXYTOLUENE METHYLPARABEN PROPYLPARABEN SODIUM STARCH GLYCOLATE TYPE A POTATO TALC MAGNESIUM STEARATE SILICON DIOXIDE CROSCARMELLOSE SODIUM SODIUM LAURYL SULFATE ISOPROPYL ALCOHOL METHYLENE CHLORIDE FD and C YELLOW NO. 6 HYPROMELLOSES





DAYTIME NIGHTTIME COLD/FLU RELIEF A P J

daytime nighttime cold/flu relief kit

Product Information						
Product Type	HUMAN OTC DRUG		Item Code (Source)		NDC:46084-121	
	initial of block			`		
Packaging						
# Item Code	Pacl	kage Description	Marketing Start Date		Marketing End Date	
1 NDC:46084-121-01	1 in 1 PAC	KAGE				
Quantity of Parts						
Part # Pac	kage Qua	antity	То	tal Product Q	uantity	
Part 1 1 BLISTER PACK			20			
Part 2 1 BLISTER PACK			20			
D . 4 6 0						
Part 1 of 2						
DAYTIME COLD	/FLU F	RELIEF APJ				
acetaminophen, dextrom	nethorpha	n hydrobromide, ph	enylephrine hydrochlo	oride tablet		
Product Information						
Item Code (Source)		NDC:46084-122				
Route of Administration ORAL		ORAL				
Active Ingredient/Act	tive Moi	o tx				
Active Ingredient/Act		edient Name		Basis of	Strength	Strength
ACETAMINOPHEN (UNII: 30	-		UNII:362O9ITL9D)	ACETAMINOPH	0	325 mg
DEXTROMETHORPHAN H (DEXTROMETHORPHAN - U	YDRO BRO	MIDE (UNII: 9D2RTI9F		DEXTROMETH HYDROBROMI		10 mg
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) UNII:1WS297W6MV)		E (UNII: 04JA59TNSJ) (I	PHENYLEPHRINE -	PHENYLEPHRIN HYDROCHLOR		5 mg
Inactive Ingredients						

CALCHINA DUO CDI	IATE DI	DACTO AND	LIVIDIO LIE / LINIL, 1 11/2						
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: L11K75P92J) STARCH, CORN (UNII: 08232NY3SJ)								mg mg	
						mg			
BUTYLATED HYDRO XYTOLUENE (UNII: 1P9 D0 Z171K) METHVI DADABEN (UNII: A218 C7H9 T)						mg			
METHYLPARABEN (UNII: A2I8C7HI9T) PROPYLPARABEN (UNII: Z8IX2SC10H)						-			
			" E A POTATO (UNII: 585	5613C2A2)					mg mg
TALC (UNII: 7SEV7				J0J3G2A2)					mg
MAGNESIUM STEA		NII: 70007	M6130)						mg
SILICON DIO XIDE									mg
CROSCARMELLO									mg
SODIUM LAURYL		,	,						mg
SOPROPYL ALCO									mg
METHYLENE CHL									mg
FD&C YELLOW N									mg
HYPROMELLOSES									mg
Product Chara	cteristi	cs							
Color	pink (Ll	GHT YELL	OWISH PINK)		Sc	ore		2	pieces
Shape		CAPSULE			Siz)mm
Flavor			-			print Code			25mg
Contains						print cour			8
Packaging									
Packaging # Item Cod	de	Pack	age Description	Marketii	ng Star	t Date	Ma	arketing	End Date
# Item Coo			age Description ISTER PACK	Marketin	ng Star	t Date	Ma	arketing	End Date
# Item Coo			•	Marketin	ng Star	t Date	Ma	arketing	End Date
# Item Coo			•	Marketin	ng Star	t Date	Ma	arketing	End Date
# Item Coc 1 NDC:46084-122-2	20	20 in 1 BL	•	Marketin	ng Star	t Date	Ma	arketing	End Date
 Item Cool NDC:46084-122-2 Marketing In 	20 nform	20 in 1 BL ation	ISTER PACK						
# Item Coo 1 NDC:46084-122-2 Marketing In Marketing Categ	20 nform ory A	20 in 1 BL ation .pplicatio	•		Mark	seting Start			End Date
# Item Coo 1 NDC:46084-122-2 Marketing In Marketing Categ	20 nform ory A	20 in 1 BL ation .pplicatio	ISTER PACK			seting Start			
# Item Coo 1 NDC:46084-122-2 Marketing In Marketing Categ	20 nform ory A	20 in 1 BL ation .pplicatio	ISTER PACK		Mark	seting Start			
# Item Cool NDC:46084-122-2 Marketing In Marketing Categ	20 nform ory A	20 in 1 BL ation .pplicatio	ISTER PACK		Mark	seting Start			
 Item Cool NDC:46084-122-2 Marketing In Marketing Categ OTC monograph fin 	20 nform ory A	20 in 1 BL ation .pplicatio	ISTER PACK		Mark	seting Start			
 Item Cool NDC:46084-122-2 Marketing In Marketing Categ OTC monograph fin Part 2 of 2 	20 nform ory A al part	20 in 1 BL ation pplicatio 341	ISTER PACK	aph Citation	Mark	seting Start			
# Item Cool 1 NDC:46084-122-2 Marketing In Marketing Categ OTC monograph fin Part 2 of 2 NIGHTTIM	nform ory A al part	20 in 1 BL ation pplicatio (341 LD/FLU	ISTER PACK n Number or Monogr U RELIEF A P	aph Citation	Marl 06/01/	xe ting Start 2013			
# Item Cool 1 NDC:46084-122-2 Marketing In Marketing Categ OTC monograph fin Part 2 of 2 NIGHTTIM	nform ory A al part	20 in 1 BL ation pplicatio (341 LD/FLU	ISTER PACK	aph Citation	Marl 06/01/	xe ting Start 2013			
# Item Cool 1 NDC:46084-122-2 Marketing In Marketing Categ OTC monograph fin Part 2 of 2 NIGHTTIM	nform ory A al part	20 in 1 BL ation pplicatio (341 LD/FLU	ISTER PACK n Number or Monogr U RELIEF A P	aph Citation	Marl 06/01/	xe ting Start 2013			
 I tem Cool NDC:46084-122-2 Marketing In Marketing Categ OTC monograph fin Part 2 of 2 NIGHTTIM 	nform ory A al part	20 in 1 BL ation pplicatio (341 LD/FLU	ISTER PACK n Number or Monogr U RELIEF A P	aph Citation	Marl 06/01/	xe ting Start 2013			
I Item Cool I NDC:46084-122-2 Marketing In Marketing Categ OTC monograph fin Part 2 of 2 NIGHTTIM acetaminophen, of	nform ory A al part ECOI dextrom	20 in 1 BL ation pplicatio (341 LD/FLU	ISTER PACK n Number or Monogr U RELIEF A P	aph Citation	Marl 06/01/	xe ting Start 2013			
# Item Cool 1 NDC:46084-122-2 Marketing In Marketing Categ OTC monograph fin Part 2 of 2 NIGHTTIM acetaminophen, of	20 nform ory A al part dextrom nation	20 in 1 BL ation pplicatio (341 LD/FLU	ISTER PACK n Number or Monogr U RELIEF A P	aph Citation	Marl 06/01/	xe ting Start 2013			
# Item Cool # Item Cool 1 NDC:46084-122-2 Marketing In Marketing Categ OTC monograph fin Part 2 of 2 NIGHTTIM acetaminophen, of Product Inform Item Code (Source)	20 nform ory A al part E COI dextrom mation ce)	20 in 1 BL ation pplicatio (341 LD/FLU	n Number or Monogr U RELIEF A P n hydrobromide, chlo NDC:46084-123	aph Citation	Marl 06/01/	xe ting Start 2013			
# Item Cool I Item Cool I NDC:46084-122-2 Marketing In Marketing Categ OTC monograph fin Part 2 of 2 NIGHTTIM acetaminophen, of	20 nform ory A al part E COI dextrom mation ce)	20 in 1 BL ation pplicatio (341 LD/FLU	ISTER PACK	aph Citation	Marl 06/01/	xe ting Start 2013			
# Item Cool 1 NDC:46084-122-2 Marketing In Marketing Categ OTC monograph fin OTC monograph fin Part 2 of 2 NIGHTTIM acetaminophen, of OTC monograph fin Item Code (Source Route of Adminis	20 al part begin{tabular}{ c c c c c c c c c c c c c c c c c c c	20 in 1 BL ation pplicatio 341 LD/FLU ethorphan	n Number or Monogr U RELIEF A P h hydrobromide, chlo NDC:46084-123 ORAL	aph Citation	Marl 06/01/	xe ting Start 2013			
# Item Cool 1 NDC:46084-122-2 Marketing In Marketing Categ OTC monograph fin Part 2 of 2 NIGHTTIM acetaminophen, of Product Inform Item Code (Source)	20 al part begin{tabular}{ c c c c c c c c c c c c c c c c c c c	20 in 1 BL ation pplicatio 341 LD/FLU ethorphan	n Number or Monogr U RELIEF A P h hydrobromide, chlo NDC:46084-123 ORAL	aph Citation	Marl 06/01/	e tablet		Marketi	

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	6.25 mg

Ingredient Name	Strength
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: L11K75P92J)	30 mg
STARCH, CORN (UNII: O8232NY3SJ)	12 mg
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	.5 mg
METHYLPARABEN (UNII: A218C7HI9T)	.8 mg
PROPYLPARABEN (UNII: Z8IX2SC1OH)	.4 mg
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	8 mg
TALC (UNII: 7SEV7J4R1U)	6 mg
MAGNESIUM STEARATE (UNII: 70097M6I30)	6 mg
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	2 mg
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	3 mg
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	2 mg
ISOPROPYL ALCOHOL (UNII: ND2M416302)	10 mg
METHYLENE CHLORIDE (UNII: 588X2YUY0A)	20 mg
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	2 mg
HYPROMELLOSES (UNII: 3NXW29V3WO)	3 mg

Product Characteristics					
Color	white	Score	2 pieces		
Shape	OVAL (CAPSULE)	Size	20mm		
Flavor		Imprint Code	425mg		
Contains					

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:46084-123-20	20 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/01/2013	

Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC monograph finalpart34106/01/201306/01/2013

Registrant - A P J Laboratories Limited (677378339)

Establishment					
Name	Address	ID/FEI	Business Operations		
A P J Laboratories Limited		677378339	manufacture(46084-121)		

Revised: 5/2013

A P J Laboratories Limited