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 4 to under 12 years ask a doctor

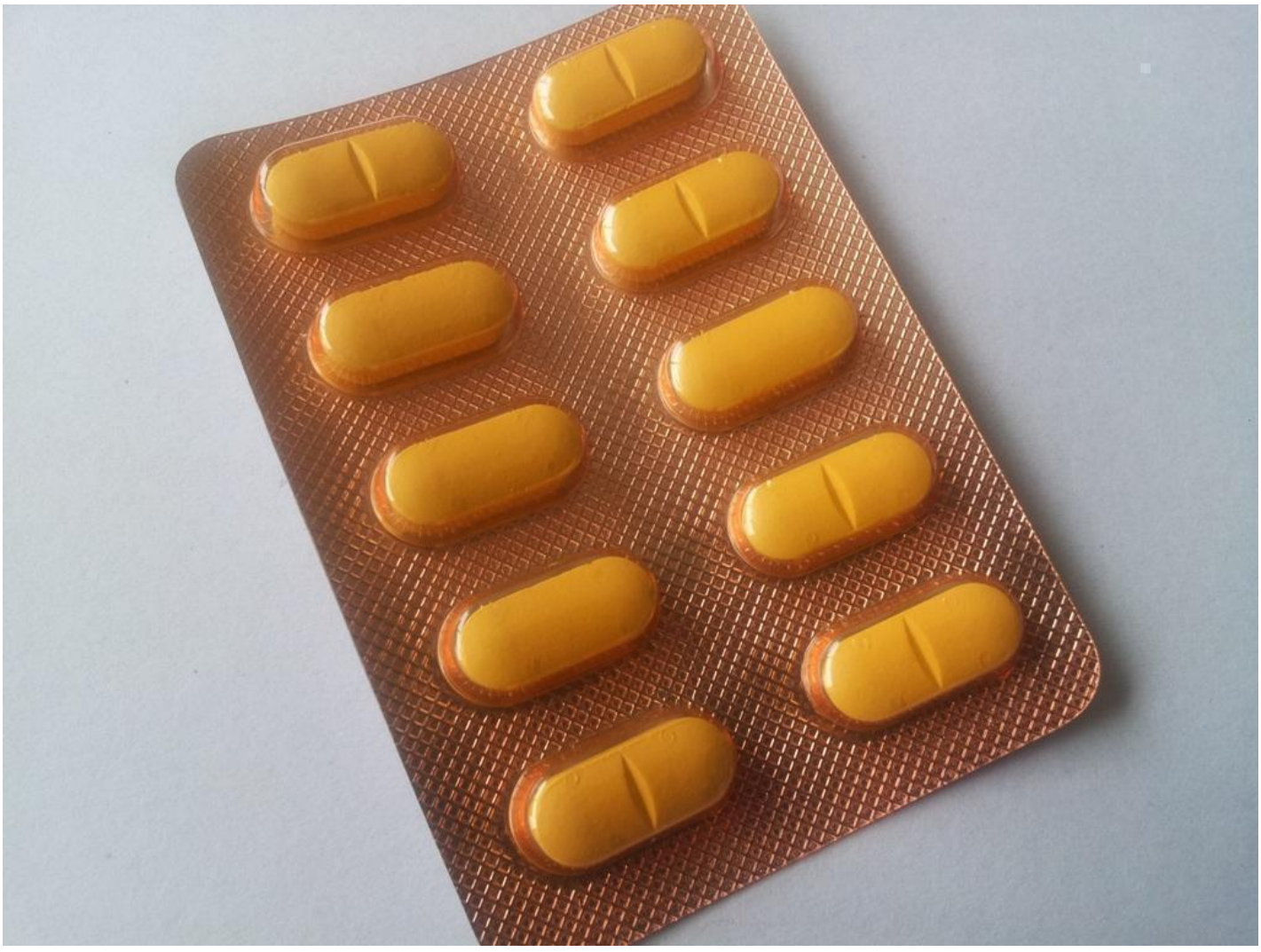
children under 4 years do not use

•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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:46084-121-01	1 in 1 PACKAGE		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BLISTER PACK	20
Part 2	1 BLISTER PACK	20

Part 1 of 2

DAYTIME COLD/FLU RELIEF A P J

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride tablet

Product Information	
Item Code (Source)	NDC:46084-122
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**

CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	30 mg
STARCH, CORN (UNII: O8232NY3SJ)	12 mg
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	.5 mg
METHYLPARABEN (UNII: A2I8C7HI9T)	.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 DIOXIDE (UNII: ETJ7Z6XBU4)	2 mg
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	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	pink (LIGHT YELLOWISH PINK)	**Score**	2 pieces
Shape	OVAL (CAPSULE)	**Size**	20mm
Flavor		**Imprint Code**	425mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46084-122-20	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	

Part 2 of 2

NIGHTTIME COLD/FLU RELIEF A P J

acetaminophen, dextromethorphan hydrobromide, chlorpheniramine maleate tablet

Product Information

Item Code (Source)	NDC:46084-123
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	30 mg
STARCH, CORN (UNII: O8232NY3SJ)	12 mg
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	.5 mg
METHYLPARABEN (UNII: A2I8C7HI9T)	.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 DIOXIDE (UNII: ETJ7Z6XBU4)	2 mg
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	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			

Packaging

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

Marketing Information

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OTC monograph final	part341	06/01/2013	

Labeler - A P J Laboratories Limited (677378339)

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