

**ACETAMINOPHEN SINUS CONGESTION AND PAIN A P J COATED- acetaminophen,
phenylephrine hydrochloride tablet
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.

ACETAMINOPHEN 325 mg

PHENYLEPHRINE HYDROCHLORIDE 5mg

- Alleviates Sinus Headache & Pain (Acetaminophen)
- Relieves Sinus Pressure Clears Nasal Congestion (Phenylephrine HCl)

Keep out of reach of children.

for the temporary relief of:

- headache
- sinus
- congestion and pressurenasal congestion
- minor aches and pains
- helps decongest sinus openings and passages
- promotes sinus drainage
- helps clear nasal passages

Liver warning:

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 gelcaps in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Overdose warning:

- Taking more than the recommended dose (overdose) may cause liver damage.
- In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- Do not take more than directed (see overdose warning)
- Adults and children 12 years and over: Take 2 gelcaps every 4 hoursdo not take more than 12 gelcaps in 24 hours
- Children under 12 years: Do not use this adult product in children under 12 years of age

- CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS
- CELLULOSE, MICROCRYSTALLINE
- STARCH, CORN
- BUTYLATED HYDROXYTOLUENE
- METHYLPARABEN
- PROPYLPARABEN
- SODIUM STARCH GLYCOLATE TYPE A POTATO
- TALC
- MAGNESIUM STEARATE
- SALICYLIC ACID
- CROSCARMELLOSE SODIUM
- SODIUM LAURYL SULFATE
- ISOPROPYL ALCOHOL
- METHYLENE CHLORIDE
- TITANIUM DIOXIDE
- HYPROMELLOSES



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acetaminophen, phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46084-101
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	160 mg
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	120 mg
STARCH, CORN (UNII: O8232NY3SJ)	30 mg
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	.5 mg
METHYL PARABEN (UNII: A2I8C7HI9T)	.8 mg
PROPYL PARABEN (UNII: Z8IX2SC1OH)	.4 mg
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	20 mg
TALC (UNII: 7SEV7J4R1U)	15 mg
MAGNESIUM STEARATE (UNII: 70097M6I30)	13 mg
SALICYLIC ACID (UNII: O414PZ4LPZ)	4 mg
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	7 mg
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	2 mg
ISOPROPYL ALCOHOL (UNII: ND2M416302)	130 mg
METHYLENE CHLORIDE (UNII: 588X2YUY0A)	280 mg
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	1.5 mg
HYPROMELLOSES (UNII: 3NXW29V3WO)	3 mg

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL	Size	18mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46084-101-30	30 in 1 BLISTER PACK		

Marketing Information

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

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(46084-101)

Revised: 6/2013

A P J Laboratories Limited