## ALLERGY RELIEF MULTISYMPTOM - acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet, coated Select Corporation

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.

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## **Drug Facts**

Active Ingredients
Acetaminophen 325 mg......Pain Reliever/Fever Reducer
Chlorpheniramine Maleate 2 mg.....Antihistamine
Phenylephrine HCl 5 mg......Nasal Decongestant

Pain Reliever, Fever Reducer, Antihistamine, Nasal Decongestant

Directions: Adults and children 12 years of age and older • take 2 tablets every 4 to 6 hours as needed, do not exceed 8 tablets in 24 hours, or as directed by a doctor • Children under 12 years, consult a doctor

Uses: Temporarily: • relieves nasal congestion associated with sinusitis
• relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies • relieves sinus congestion and pressure, helps decongest sinus openings and passages • restores free breathing
• helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passages of bothersome mucus, drain bronchial tubes, and make coughs more productive • Temporarily relieves minor aches, pains, and fever associated with: • headache • common cold • toothache
• backache • muscular aches • menstrual cramps

Warnings: Liver Warning: This

product contains acetaminophen. Severe liver damage may occur if you take: • more than 8 tablets in 24 hours • with other drugs containing acetaminophen (prescription or nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure. • 3 or more alcoholic drinks every day while using this product Do not: use with any other product containing acetaminophen this will provide more than the recommended dose (overdose) of acetaminophen and could cause serious health concerns. • use more than the recommended dose • for more than 10 days for pain unless directed by a doctor • for more than 3 days for fever unless directed by a doctor • 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 MAOI drug. If you do not know if your prescription drug contains an MAOI, consult a doctor or pharmacist before taking this product. Stop use and ask a doctor if: • symptoms do not improve • pain or fever persists or gets worse • new symptoms occur • redness or swelling is present • nervousness, dizziness or sleeplessness occur • symptoms do not improve within 7 days or are accompanied by fever Ask a doctor before use if you have: • heart disease • high blood pressure • thyroid disease • diabetes

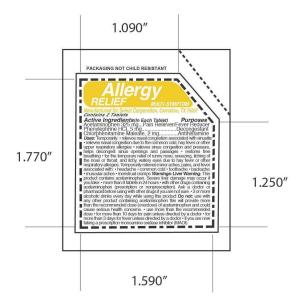
• difficulty in urination due to enlargement of the prostate gland • a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland • may cause excitability especially in children • may cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect • avoid alcoholic beverages while taking this product • do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor • use caution when operating machinery.

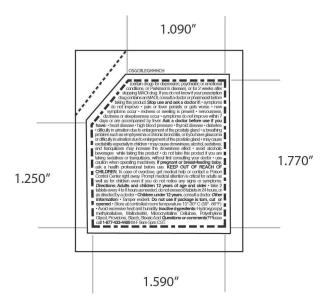
If pregnant or breast-feeding baby, ask a health professional before use.

## KEEP OUT OF REACH OF CHILDREN.

Inactive ingredients: FDC Red 40, Maltodextrin, Microcrystalline Cellulose, Povidone, Sodium Starch Glycolate, Starch, Stearic Acid

MM1





acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52904-457
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg	
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients			
Ingredient Name	Strength		
PO VIDO NE K29/32 (UNII: 390 RMW2PEQ)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
MALTO DEXTRIN (UNII: 7CVR7L4A2D)			
STARCH, CORN (UNII: O8232NY3SJ)			

Product Characteristics			
Color	white (snow white)	Score	no score
Shape	ROUND (FR11)	Size	11mm
Flavor		Imprint Code	FR11
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:52904-457-02	2 in 1 PACKET			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/15/2012	

## Labeler - Select Corporation (053805599)

Revised: 10/2012 Select Corporation