ARAMARK MULTI-SYMPTOM COLD RELIEF- acetaminophen, guaifenesin, phenylephrine hcl, dextromethorphan hbr tablet Western First Aid Safety DBA Aramark

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.

Aramark Multi-Symptom Cold Relief

Drug Facts

Cold Relief Tablets

Active Ingredients (in each tablet) Acetaminophen 325 mg Guaifenesein 200 mg Phenylephrine HCl 5 mg Dextromethorphan HBr 15 mg

Purpose

Acetaminophen......Pain Reliever/Fever Reducer GuaifeneseinExpectorant Phenylephrine HClDecongestant Dextromethorphan HBr.Antitussive

Uses: temporarily:

- relieves nasal congestion associated with sinusitis
- relieves nasal confestion due to the common cold, hay fever or other 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 suppresses cough due to minor throat and bronchial irritation associated with a cold or inhaled irritants

Temporarily relieves minor aches, pains and fever associated with: • headache • backache • common cold • muscular aches • toothache • menstrual cramps o make coughs more productive

Warnings:

Liver Warning: This product contains a cetamin ophen. 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
- when using this product do not exceed recommended dose 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 a fever
- cough persists for more than 1 week, tends to recur, or is
- accompanied by a fever, rash, or persistant headache.
- A persistant cough may be a sign of a serious condition

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
- persistent or chronic cough such as occurs with smoking,
- asthma, chronic bronchitis, or emphysema or where cough is
- accompanied by excessive phlegm (mucus)

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

KEEP OUT OF REACH OF CHILDREN. In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions:

 Adults and children 12 years of age and older: Take 2 tablets every 6 to 8 hours as needed. Do not exceed 8 tablets in 24 hours, or as directed by a doctor.

Children under 12 years: Consult a doctor.

Other Information:

Tamper evident. Do not use if packet is torn, cut or opened Store at controlled room temperature 15° to 30°C (59° to 86° F) Avoid excessive heat and humidity

Inactive Ingredients:

Maltodextrin, Microcrystalline Cellulose, Povidone, Sodium Starch Glycolate, Starch, Stearic Acid

Product Labeling

aramark

100 TABLETS
PER BOX Part # 82233B

Multi-Symptom COLD RELIEF

Non-Pseudo Tablet Decongestant

Temporary relief of minor aches, pains, headache, muscular aches, fever and nasal congestion associated with the common cold.

Compare active ingredient to: DRISTAN Cold and Sinus® Registered Trademark of Pfizer

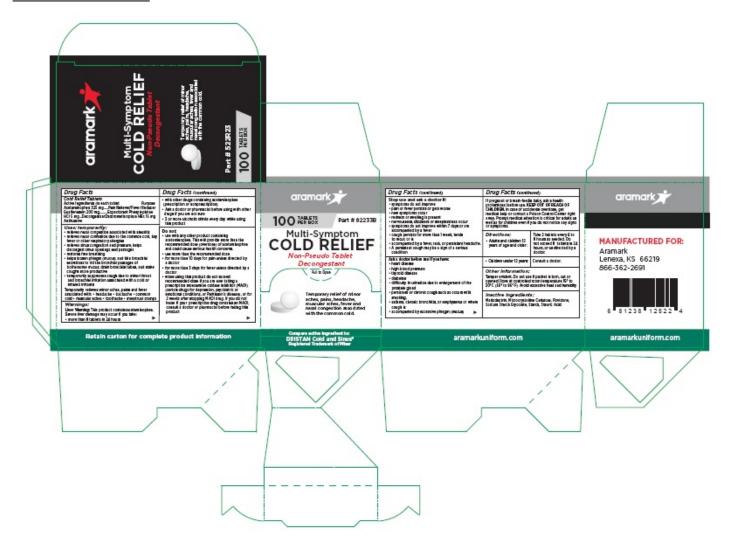
Retain carton for complete product information

MANUFACTURED FOR:

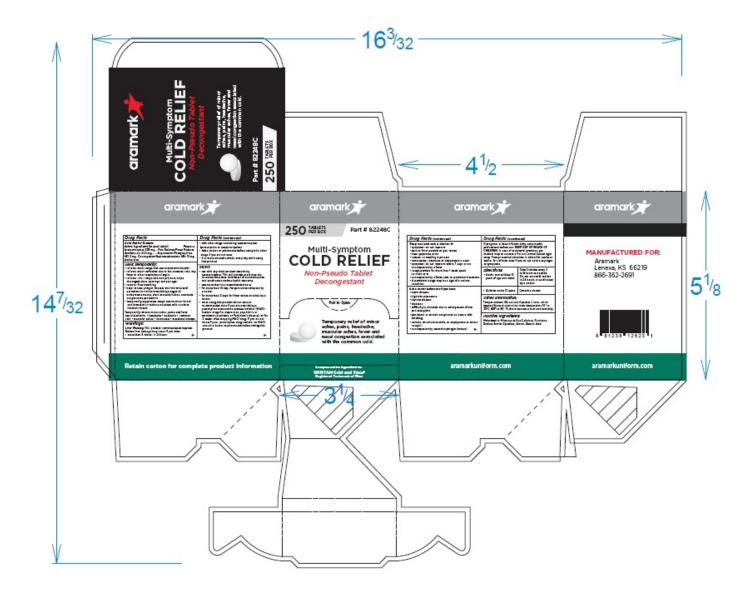
Aramark Lenexa, KS 66219 866-362-2691

aramarkuniform.com

100 Tablet Box



250 Tablet Box



2-Tablet Packet



Warnings (continued) which is the maximum daily amount with other drugs containing acetaminophen • 3 or more alcoholic drinks every day while using this product. Ask a doctor before use if you have • liver disease • heart disease high blood pressure • thyroid disease . diabetes or . difficulty in urination due to enlargement of the prostate gland. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Directions: Adults and children 12 years of age and older: 2 tablets every 4 to 6 hours, not to exceed 8 tablets in any 24 hour period. Children under 12: Consult a doctor. Other Information: Store at a controlled room temperature 15°-30° (59°-86°F). Tamper evident: Do not use packet if torn or cut.

Contact: Aramark Lenexa, KS 66219

REV 3/2021

Made in USA

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ARAMARK MULTI-SYMPTOM COLD RELIEF

acetaminophen, quaifenesin, phenylephrine hcl, dextromethorphan hbr tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81238-0107	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE	5 mg	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg	

Inactive Ingredients		
Ingredient Name	Strength	
MALTODEXTRIN (UNII: 7CVR7L4A2D)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
POVIDONE (UNII: FZ989GH94E)		

SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)
STARCH, CORN (UNII: O8232NY3SJ)

 Product Characteristics

 Color
 white
 Score
 no score

 Shape
 ROUND
 Size
 12mm

 Flavor
 Imprint Code
 FR12

 Contains

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:81238- 0107-1	50 in 1 BOX	05/14/2021		
1		2 in 1 PACKET; Type 0: Not a Combination Product			
2	NDC:81238- 0107-2	125 in 1 BOX	05/14/2021		
2		2 in 1 PACKET; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	05/14/2021		

Labeler - Western First Aid Safety DBA Aramark (043861524)

STEARIC ACID (UNII: 4ELV7Z65AP)

Registrant - Western First Aid Safety DBA Aramark (043861524)

EstablishmentNameAddressID/FEIBusiness OperationsULTRA SEAL CORPORATION085752004pack(81238-0107)

Establishment					
Na me	Address	ID/FEI	Business Operations		
Ultra Seal Corporation		944090448	manufacture(81238-0107)		

Revised: 6/2021 Western First Aid Safety DBA Aramark