MULTI SYMPTON COLD DAY NIGHT- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl
Kareway Product, Inc.

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.

Drug Facts

Active ingredients for Night(in each tablet)

Acetaminophen 325 mg

Chlorpheniramine maleate 2 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Active ingredients for Day(in each tablet)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose for Night

Pain reliever/fever reducer

Antihistamine

Cough suppressant

Nasal decongestant

Purpose for Day

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these common cold symptoms:
- minor aches and pains
- headache
- sore throat
- nasal congestion
- cough
- sneezing and runny nose (Night only)
- sinus congestion and pressure (Day only)

- helps clear nasal passages
- relieves cough to help you sleep (Night only)
- promotes nasal and sinus drainage (Day only)
- temporarily reduces fever

Warnings

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers or fever reducers. Acetaminophen may cause liver damage.**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other product containing acetaminophen
- 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 you prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma or emphysema
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis (Night only)
- glaucoma (Night only)

Ask a doctor or pharmacist before use if you are (Night only)

taking sedatives or tranquilizers (Night only)

When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children (Night only)
- marked drowsiness may occur (Night only)
- alcohol, sedatives and tranquilizers may increase drowsiness (Night only)
- avoid alcoholic drinks (Night only)
- be careful when driving a motor vehicle or operating machinery (Night only)

If pregnant or breastfeeding,

ask a health professional before use.

Keep out of reach of children.

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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.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

Directions

- do not take more than directed (see overdose warning)

adults and children 12 years and over	• take 2 tablets every 4 hours • swallow whole - do not crush, chew or dissolve • do not take more than 12 tablets in 24 hours
children under 12 years	Do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other information

- store between 20-25°C (68-77°F)
- do not use if carton is opened or if blister unit is broken
- see side panel for lot number and expiration date

Inactive ingredients

microcrystalline cellulose, lactose, hydroxypropyl cellulose, sodium starch glycolate, sillicon dioxide, magnesium stearate, hypromellose (Night only), bleu no.1 (Night only), titanium dioxide (Night only), polyethylene glycol (Night only), anhydrous citric acid, sodium citrate, ethanol, FDC Yellow no.5 (Day only),

Package label

MULTI SYMPTON COLD DAY NIGHT

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67510-0156

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:67510-0156-2	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BLISTER PACK	12
Part 2	1 BLISTER PACK	12

Part 1 of 2

MULTI SYMPTOM NIGHT

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl tablet

Product Information	
Item Code (Source)	NDC:67510-1156
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 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**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics			
Color	blue (light blue)	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	MS
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-1156-1	1 in 1 BOX		
1		12 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2012	

Part 2 of 2

MULTI SYMPTON DAY NON DROWSY

acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet

Product Information	
Item Code (Source)	NDC:67510-2156
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics			
Color	white (white)	Score	no score
Shape	ROUND	Size	9mm

Flavor		**Imprint Code**	MS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-2156-1	1 in 1 BOX		
1		12 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2012	

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OTC monograph final	part341	05/01/2012	

MULTI SYMPTON COLD DAY NIGHT

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67510-9156

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-9156-0	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	10
Part 2	1 BLISTER PACK	10

Part 1 of 2

MULTI SYMPTOM NIGHT

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl tablet

Product Information

Item Code (Source)	NDC:67510-3156
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

Color	blue (light blue)	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	MS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-3156-1	1 in 1 BOX		
1		10 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2012	

Part 2 of 2

MULTI SYMPTON DAY NON DROWSY

acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet

Product Information

Item Code (Source)	NDC:67510-4156
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
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HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

Color	white (white)	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	MS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-4156-1	1 in 1 BOX		
1		10 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2012	

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OTC monograph final	part341	05/01/2012	

Labeler - Kareway Product, Inc. (121840057)

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