

CAREONE DAY COLD AND FLU NIGHT COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, doxylamine succinate

American Sales Company

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.

American Sales Company Day Cold & Flu Night Cold & Flu Drug Facts

Active ingredients (in each liquid gel) DAY Cold & Flu

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purposes DAY Cold Flu

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Active ingredients (in each liquid gel) NIGHT Cold & Flu

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

Purposes NIGHT Cold & Flu

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
- sinus congestion and pressure
- cough
- minor aches and pains
- headache

- nasal congestion
- sore throat
- runny nose (**NIGHT only**)
- sneezing (**NIGHT only**)
- itching of the nose or throat (**NIGHT only**)
- itchy, watery eyes due to hay fever (**NIGHT only**)
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (**DAY only**)
- controls cough to help you get to sleep
- temporarily reduces fever

Warnings

Liver warning: These products contain acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using these products

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

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 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 these products.
- if you have ever had an allergic reaction to these products or any of their ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- glaucoma (**NIGHT only**)
- a breathing problem such as emphysema or chronic bronchitis (**NIGHT only**)

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (**NIGHT only**)

When using these products

- **do not use more than directed**
- 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**)

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.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: 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)**
- do not take more than 10 liquid gels in any 24-hour period
- adults and children 12 years of age and older: take 2 liquid gels every 4 hours
- children under 12 years of age: do not use

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients (DAY only)

edible ink*, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution

*may contain this ingredient

Inactive ingredients (NIGHT only)

D&C yellow #10, edible ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

COMBINATION PACK

Compare to the active ingredients in Mucinex[®] Fast-Max[®] Day Cold & Flu

DAY COLD & FLU

Pain Reliever/Fever Reducer – Acetaminophen

Cough Suppressant – Dextromethorphan HBr

Expectorant – Guaifenesin

Nasal Decongestant – Phenylephrine HCl

Maximum Strength

Sore Throat, Fever, Chest Congestion, Cough, Nasal Congestion, Sinus Congestion, Sinus Pressure, Headache, Body Pain

Fast Dissolving Liquid Gels

For Ages 12+

Gluten Free

Actual Size

OUR PHARMACISTS RECOMMEND

16 LIQUID GELS (Liquid Filled Capsules)

Compare to the active ingredients in Mucinex[®] Fast-Max[®] Night Cold & Flu

NIGHT COLD & FLU

Pain Reliever/Fever Reducer – Acetaminophen

Cough Suppressant – Dextromethorphan HBr

Antihistamine – Doxylamine Succinate

Nasal Decongestant – Phenylephrine HCl

Maximum Strength

Sore Throat, Fever, Itchy Throat, Cough, Nasal Congestion, Sneezing, Runny Nose, Headache, Body Pain

Fast Dissolving Liquid Gels

For Ages 12+

Gluten Free

Actual Size

OUR PHARMACISTS RECOMMEND

8 LIQUID GELS (Liquid Filled Capsules)

COMBINATION PACK

NDC 41520-820-90

CAREone®

Compare to the active ingredients in Mucinex® Fast-Max® Day Cold & Flu*

CAREone®

Compare to the active ingredients in Mucinex® Fast-Max® Night Cold & Flu*

DAY COLD & FLU

Pain Reliever/Fever Reducer - Acetaminophen
Cough Suppressant - Dextromethorphan HBr
Expectorant - Guaifenesin
Nasal Decongestant - Phenylephrine HCl

Maximum Strength**

Sore Throat, Fever, Chest Congestion, Cough, Nasal Congestion, Sinus Congestion, Sinus Pressure, Headache, Body Pain

Fast Dissolving Liquid Gels

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Actual Size



16
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(Liquid Filled Capsules)

NIGHT COLD & FLU

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Antihistamine - Doxylamine Succinate
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Maximum Strength**

Sore Throat, Fever, Itchy Throat, Cough, Nasal Congestion, Sneezing, Runny Nose, Headache, Body Pain

Fast Dissolving Liquid Gels

For Ages 12+

Gluten Free



Actual Size



8
LIQUID GELS
(Liquid Filled Capsules)

DISTRIBUTED BY
FOODHOLD U.S.A., LLC
LANDOVER, MD 20785
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1-877-846-9949
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Quality guaranteed or
your money back.

Do not use if blister unit is broken or torn

Drug Facts

Active ingredients (in each liquid gel) DAY Cold & Flu

Acetaminophen 325 mg.....Pain reliever/fever reducer
Dextromethorphan HBr 10 mg.....Cough suppressant
Guafenesin 200 mg.....Expectorant
Phenylephrine HCl 5 mg.....Nasal decongestant

Active ingredients (in each liquid gel) NIGHT Cold & Flu

Acetaminophen 325 mg.....Pain reliever/fever reducer
Dextromethorphan HBr 10 mg.....Cough suppressant
Doxylamine succinate 6.25 mg.....Antihistamine
Phenylephrine HCl 5 mg.....Nasal decongestant

Uses ■ temporarily relieves these common cold and flu symptoms:

- sinus congestion and pressure ■ nasal congestion
- minor aches and pains ■ cough ■ headache
- sore throat ■ runny nose (*NIGHT only*)
- sneezing (*NIGHT only*)
- itching of the nose or throat (*NIGHT only*)
- itchy, watery eyes due to hay fever (*NIGHT only*)
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (*DAY only*)
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- temporarily reduces fever

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■ 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 these products. ▶

Drug Facts (continued)

■ if you have ever had an allergic reaction to these products or any of their ingredients

Ask a doctor before use if you have

- liver disease ■ heart disease ■ diabetes
- high blood pressure ■ thyroid disease
- trouble urinating due to an enlarged prostate gland
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- fever gets worse or lasts more than 3 days
- redness or swelling is present ■ new symptoms occur
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Directions

- do not take more than directed (see Overdose warning)
- do not take more than 10 liquid gels in any 24-hour period
- adults and children 12 years of age and older: take 2 liquid gels every 4 hours
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Other information ■ store at 20-25°C (68-77°F) ▶

Drug Facts (continued)

Inactive ingredients (DAY only)

edible ink*, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution

*may contain this ingredient

Inactive ingredients (NIGHT only)

D&C yellow #10, edible ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution

Questions or comments?

1-800-719-9260

†These products are not manufactured or distributed by Reckitt Benckiser, distributor of Mucinex® Fast-Max® Day Cold & Flu & Night Cold & Flu.

**Per 4-hour dose, dose every 4 hours

Do not take DAY COLD & FLU and NIGHT COLD & FLU liquid gels at the same time. Always wait at least 4 hours before taking another dose. Do not take more than a total of 10 liquid gels in any 24-hour period.

Take only as directed

Keep carton for full information

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org



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CAREONE DAY COLD AND FLU NIGHT COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, doxylamine succinate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-820
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-820-90	1 in 1 KIT; Type 0: Not a Combination Product	07/23/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	8 BLISTER PACK	16
Part 2	4 BLISTER PACK	8

Part 1 of 2**CAREONE DAY COLD AND FLU**

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled

Product Information

Route of Administration	ORAL
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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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	OVAL	Size	25mm
Flavor		Imprint Code	7G0
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 in 1 CARTON		
1		2 in 1 BLISTER PACK; 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		

Part 2 of 2

CAREONE NIGHT COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

Product Information

Route of Administration	ORAL
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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

DOXYLAMINE SUCCINATE (UNII: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	345
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 CARTON		
1		2 in 1 BLISTER PACK; 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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/23/2019	

Labeler - American Sales Company (809183973)