

**MULTI SYMPTOM SEVERE COLD AND NIGHTTIME SEVERE COLD AND COUGH-
acetaminophen, dextromethorphan hbr, diphenhydramine hcl, phenylephrine
hcl
CVS Pharmacy, Inc.**

**CVS Health Multi Symptom Severe Cold and Nighttime Severe Cold and Cough
Value Pack**

Active ingredients (in each packet) - Multi Symptom Severe Cold

Acetaminophen 500 mg

Dextromethorphan hydrobromide 20 mg

Phenylephrine hydrochloride 10 mg

Active ingredients (in each packet) - Nighttime Severe Cold and Cough

Acetaminophen 650 mg

Diphenhydramine hydrochloride 25 mg

Phenylephrine hydrochloride 10 mg

Purpose - Multi Symptom Severe Cold

Pain reliever/fever reducer

Cough Suppressant

Nasal Decongestant

Purpose - Nighttime Severe Cold and Cough

Pain reliever/fever reducer

Antihistamine/cough suppressant

Nasal decongestant

Uses - Multi Symptom Severe Cold

- temporarily relieves these symptoms due to a cold:
- minor aches and pains
- minor sore throat pain
- headache
- nasal and sinus congestion
- cough due to minor throat and bronchial irritation
- temporarily reduces fever

Uses - Nighttime Severe Cold and Cough

- temporarily relieves these symptoms due to a cold:
- minor aches and pains
- minor sore throat pain
- headache
- nasal and sinus congestion
- runny nose
- sneezing
- itchy nose or throat
- itchy, watery eyes due to hay fever
- cough due to minor throat and bronchial irritation
- temporarily reduces fever

Warnings - Multi Symptom Severe Cold /Nighttime Severe Cold and Cough

Liver warning: This product contains 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 this product

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 - Multi Symptom Severe Cold

- in a child under 12 years of age
- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or a 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 this product.

Do not use - Nighttime Severe Cold and Cough

- in a child under 12 years of age
- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or a pharmacist.
- with any other product containing diphenhydramine, even one used on skin
- 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 this product.

Ask a doctor before use if you have - Multi Symptom Severe Cold

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, or emphysema

Ask a doctor before use if you have - Nighttime Severe Cold and Cough

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

Ask a doctor or pharmacist before use if you are - Multi Symptom Severe Cold

taking the blood thinning drug warfarin

Ask a doctor or pharmacist before use if you are - Nighttime Severe Cold and Cough

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product - Multi Symptom Severe Cold

do not exceed recommended dosage

When using this product - Nighttime Severe Cold and Cough

- **do not exceed recommended dosage**
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

- excitability may occur, especially in children

Stop use and ask a doctor if - Multi Symptom Severe Cold /Nighttime Severe Cold and Cough

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- symptoms do not get better or worsen
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- cough comes back or occurs with fever, 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). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions - Multi Symptom Severe Cold

- **do not use more than directed**
- take every 4 hours, while symptoms persist; Do not to take 6 packets in 24 hours or as directed by a doctor

1. Age	1. Dose
1. Adults and children 12 years of age	1. One packet
1. Children under 12 years of age	1. Do not use

Directions Nighttime Severe Cold and Cough

- **do not use more than directed**
- take every 4 hours while symptoms persist;; not to exceed 5 packets in 24 hours or as directed by a doctor

1. Age	1. Dose
1. Adults and children 12 years of age	1. One packet
1. Children under 12 years of age	1. Do not use

-
- Dissolve contents of one packet into 8 oz. hot water: sip while hot. Consume entire drink within 10-15 minutes
 - If using a microwave, add contents of one packet to 8 oz. of cool water: stir briskly before and after heating. Do not overheat.

Other information - Multi Symptom Severe Cold

- **each packet contains: potassium 6 mg**
- store at controlled room temperature. Protect from excessive heat and moisture.

Other information - Nighttime Severe Cold and Cough

- each packet contains: **potassium 6 mg**
- store at room temperature. Protect from excessive heat and moisture.

Inactive ingredients - Multi Symptom Severe Cold

anhydrous citric acid, caramel, flavors, maltodextrin, potassium citrate, silica, sucralose, sucrose

Inactive ingredients - Nighttime Severe Cold and Cough

citric acid, FD&C yellow #6, flavors, maltodextrin, potassium chloride, silica ,sucralose, sucrose.

Questions or comments?

1-866-467-2748

Package/Label Principal Display Panel

Multi Symptom Severe Cold 6 PACKETS + NIGHTTIME 6 PACKETS = 12 PACKETS TOTAL

Compare to the active ingredients in Theraflu® Multi Symptom Severe Cold* & Theraflu® Nighttime Severe Cold & Cough*

Multi Symptom

Severe Cold

ACETAMINOPHEN - Pain reliever; Fever reducer

DEXTROMETHORPHAN HBr - Cough suppressant

PHENYLEPHRINE HCl - Nasal decongestant

Relieves:

- Nasal congestion
- Sore throat pain
- Cough

- Headache
- Body ache
- Fever

Green Tea & Honey Lemon Flavors

6 PACKETS

NIGHTTIME

Severe Cold & Cough

ACETAMINOPHEN - Pain reliever; Fever reducer

DIPHENHYDRAMINE HCl - Antihistamine; Cough suppressant

PHENYLEPHRINE HCl - Nasal decongestant

Relieves:

- Nasal congestion
- Sore throat pain
- Cough
- Headache
- Body ache
- Fever
- Runny nose
- Sneezing

Honey Lemon Flavor Infused with Chamomile & White Tea Flavors

6 PACKETS

Distributed by:

CVS Pharmacy, Inc.

One CVS Drive

Woonsocket, RI 02895

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CVS.com®

1-800-SHOP CVS

Money Back Guarantee

*These products are not manufactured or distributed by GSK Consumer Healthcare, distributor of Theraflu® Multi-Symptom Severe Cold and Theraflu® Nighttime Severe Cold & Cough.

Part 1 of 2

CVS HEALTH MULTI SYMPTOM SEVERE COLD MULTI SYMPTOM SEVERE COLD

acetaminophen, dextromethorphan hbr, phenylephrine hcl powder, for solution

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARAMEL (UNII: T9D99G2B1R)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/21/2015	

Part 2 of 2

CVS HEALTH NIGHTTIME SEVERE COUGH AND COLD NIGHTTIME

SEVERE COLD AND COUGH

acetaminophen, diphenhydramine hcl, phenylephrine hcl powder, for solution

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/17/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/21/2015	

