

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

**CVS Pharmacy, 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.*

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**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

<b>Age</b>	<b>Dose</b>
Adults and children 12 years of age	One packet

Children under 12 years of age	Do not use
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### 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

Age	Dose
Adults and children 12 years of age	One packet
Children under 12 years of age	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.

**Multi-Symptom Severe Cold**  
ACETAMINOPHEN  
Pain reliever; Fever reducer  
DEXTROMETHORPHAN HBR  
Cough suppressant  
PHENYLEPHRINE HCl  
Nasal decongestant  
Dye, Aspartame & Sodium Free  
6 PACKETS

**Nighttime Severe Cold & Cough**  
ACETAMINOPHEN  
Pain reliever; Fever reducer  
DIPHENHYDRAMINE HCl  
Antihistamine; Cough suppressant  
PHENYLEPHRINE HCl  
Nasal decongestant  
Aspartame & Sodium Free  
6 PACKETS

**VALUE PACK**  
CVSHealth.  
Compare to the active ingredients in Theraflu® Multi-Symptom Severe Cold & Theraflu® Nighttime Severe Cold & Cough!  
Severe  
NDC: 5979-768-12

**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 aches  
• Fever  
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 aches  
• Fever  
• Runny nose  
• Sneezing  
6 PACKETS

**Drug Facts (in each packet)**

Active Ingredients	Purpose(s)
Acetaminophen 500 mg	Pain reliever/fever reducer
Dextromethorphan 10 mg	Cough suppressant
Phenylephrine HCl 10 mg	Nasal decongestant

**Directions**  
Take every 4 hours, with symptoms present. Do not take more than 6 packets in 24 hours unless directed by a doctor.  
Age: Adults and children 12 years of age and older (one packet)  
Children under 12 years of age: Do not use.

**Warnings**  
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours or with other drugs containing acetaminophen. Always alert acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, itches, hives, rash.

**Other information**  
Inactive ingredients: hydrochloric acid, caramel, flavors, maltodextrin, potassium chloride, silica, sucrose, sorbitol.

**Questions or comments? 1-800-467-2718**

**DO NOT TAKE BOTH PRODUCTS AT THE SAME TIME OR TAKE MORE THAN 6 DOSES IN ANY 24 HOUR PERIOD**  
READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE. KEEP CARTON FOR REFERENCE. DO NOT DISCARD.  
**DO NOT TAKE A DOSE OF THE NIGHTTIME PRODUCT SOONER THAN 10 HOURS AFTER THE LAST DOSE OF MULTI-SYMPTOM PRODUCT UNLESS DIRECTED BY A DOCTOR.**

## MULTI SYMPTOM SEVERE COLD AND NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, dextromethorphan hbr, diphenhydramine hcl, phenylephrine hcl kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-768
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-768-12	1 in 1 CARTON; Type 0: Not a Combination Product	09/21/2015	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 CARTON	6
Part 2	1 CARTON	6

## Part 1 of 2

### CVS HEALTH MULTI SYMPTOM SEVERE COLD MULTI SYMPTOM SEVERE COLD

acetaminophen, dextromethorphan hbr, phenylephrine hcl powder, for solution

## Product Information

<b>Route of Administration</b>	ORAL
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## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>CARAMEL</b> (UNII: T9D99G2B1R)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SUCROSE</b> (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 final	part341	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
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SUCROSE</b> (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 final	part341	08/17/2015	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/21/2015	

**Labeler** - CVS Pharmacy,Inc. (062312574)

Revised: 9/2023

CVS Pharmacy,Inc.