

**CVS PHARMACY DAYTIME NIGHTTIME SEVERE COLD AND COUGH KIT - acetaminophen, diphenhydramine hcl, phenylephrine hcl and dextromethorphan hbr
CVS Pharmacy**

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.

CVS Pharmacy Daytime Nighttime Severe Cold & Cough Kit

Active Ingredients for Nighttime

Active ingredients (in each packet)	Purpose
Acetaminophen 650 mg	Pain reliever/Fever reducer
Diphenhydramine hydrochloride 25 mg	Antihistamine/Cough suppressant
Phenylephrine hydrochloride 10 mg.....	Nasal decongestant.

Active Ingredients for Daytime

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Acetaminophen 650 mg	Pain reliever/Fever reducer
Dextromethorphan hydrobromide 20 mg	Cough suppressant
Phenylephrine hydrochloride 10 mg.....	Nasal decongestant.

Purpose Nighttime

Uses

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

Purpose Daytime

Uses

- Temporarily relieves:
- minor aches and pains - headache - minor sore throat pain
- nasal and sinus congestion - cough due to minor throat and bronchial irritation
- Temporarily reduces fever.

Nighttime Warnings

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take - more than 6 packets in 24 hours, which is the maximum daily amount - 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

- with any other drug containing acetaminophen (prescription and nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure.
- with any other product containing diphenhydramine, even one used on the 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 a MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease - heart disease - high blood pressure - thyroid disease - glaucoma - diabetes - trouble urinating due to an enlarged prostate gland - a breathing problem such as emphysema, asthma, 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

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

When using this product

- 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

- 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 care professional before use.

Keep out of reach of children.

In case of 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.

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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 and nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure.
- 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 a MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease - heart disease - high blood pressure - thyroid disease - diabetes - trouble urinating due to an enlarged prostate gland - a breathing problem such as emphysema, asthma, 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 taking the blood thinning drug warfarin.

When using this product

- do not exceed recommended dosage.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
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Nighttime Dosage & Administration

Directions

- do not use more than directed
- take every 4 hours; not to exceed 6 packets in 24 hours or as directed by a doctor.
- adults and children 12 years of age and over: dissolve contents of one packet into 8 oz. hot water; sip while hot. Consume entire drink within 10-15 minutes.
- children under 12 years of age: consult a doctor.
- if using a microwave, add contents of one packet to 8 oz. of cool water: stir briskly before and after heating. Do not overheat.

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heating. Do not overheat.

Nighttime Information for Patients

Other information

- each packet contains: potassium 7 mg, sodium 46 mg
- phenylketonurics: contains phenylalanine 13 mg per packet
- store at controlled room temperature 20-25C (68-77F). Protect from excessive heat and moisture.

Daytime Information for Patients

Other information

- each packet contains: potassium 8 mg, sodium 20 mg
- phenylketonurics: contains phenylalanine 14 mg per packet
- store at controlled room temperature 20-25C (68-77F). Protect from excessive heat and moisture.

Nighttime Inactive Ingredient

Acesulfame K, Aspartame, Caramel Color, Citric Acid, D and C Yellow 10, Maltodextrin, Natural Flavors, Sodium Citrate, Starch and Sugar.

Daytime Inactive Ingredient

Acesulfame K, Aspartame, Citric Acid, FD and C Blue No. 1, FD and C Red No. 40, Maltodextrin, Menthol, Natural Flavors, Sodium Citrate, Starch and Sugar.

<p>Nighttime Severe Cold & Cough</p> <p>Drug Facts</p> <p>Active ingredients (in each packet)</p> <p>Purpose</p> <p>Uses</p> <p>Warnings</p> <p>Do not use</p> <p>Ask a doctor before use if you have</p> <p>When using this product</p> <p>Do not exceed recommended dosage</p> <p>Stop use and ask a doctor if</p>	<p>Daytime Severe Cold & Cough</p> <p>Drug Facts</p> <p>Active ingredients (in each packet)</p> <p>Purpose</p> <p>Uses</p> <p>Warnings</p> <p>Do not use</p> <p>Ask a doctor before use if you have</p> <p>When using this product</p> <p>Do not exceed recommended dosage</p> <p>Stop use and ask a doctor if</p>	<p>Daytime</p> <p>Drug Facts (continued)</p> <p>Directions</p> <p>Other information</p> <p>Inactive ingredients:</p> <p>DO NOT USE IF SEALED PACKET IS TORN OR BROKEN.</p> <p>Distributed by: CVS Pharmacy, Inc.</p> <p>© 2013 CVS/Pharmacy</p> <p>Made in Canada</p> <p>CVS Quality</p>	<p>CVS pharmacy</p> <p>SEVERE COLD & COUGH DAYTIME</p> <p>CVS pharmacy</p> <p>SEVERE COLD & COUGH DAYTIME</p> <p>ACETAMINOPHEN - PAIN RELIEVER / FEVER REDUCER</p> <p>DEXTROMETHORPHAN HBR - COUGH SUPPRESSANT</p> <p>PHENYLEPHRINE HCl - NASAL DECONGESTANT</p> <p>Nasal & sinus congestion</p> <p>Sore throat pain</p> <p>Cough</p> <p>Body ache</p> <p>Headache</p> <p>Fever</p> <p>6 DAYTIME PACKETS</p> <p>SEEN NEW WARNINGS INFORMATION</p>	<p>CVS pharmacy</p> <p>SEVERE COLD & COUGH NIGHTTIME</p> <p>CVS pharmacy</p> <p>SEVERE COLD & COUGH NIGHTTIME</p> <p>ACETAMINOPHEN - PAIN RELIEVER / FEVER REDUCER</p> <p>DIPHENHYDRAMINE HCl - ANTIHISTAMINE / COUGH SUPPRESSANT</p> <p>PHENYLEPHRINE HCl - NASAL DECONGESTANT</p> <p>Nasal congestion</p> <p>Sore throat pain</p> <p>Cough</p> <p>Body ache</p> <p>Headache</p> <p>Fever</p> <p>Runny nose</p> <p>Sneezing</p> <p>6 NIGHTTIME PACKETS</p> <p>12 PACKETS TOTAL</p>	<p>Nighttime</p> <p>Drug Facts (continued)</p> <p>Directions</p> <p>Other information</p> <p>Inactive ingredients:</p> <p>DO NOT USE IF SEALED PACKET IS TORN OR BROKEN.</p> <p>*This product is not manufactured or distributed by Novartis Consumer Health, Inc., owner of the registered trademark Thermaflu.*</p>
<p># 942509</p> <p>0 50428 46926 2</p>					

CVS PHARMACY DAYTIME NIGHTTIME SEVERE COLD AND COUGH KIT

acetaminophen, diphenhydramine hcl, phenylephrine hcl and dextromethorphan hbr kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-661
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-661-12	1 in 1 BOX		

Quantity of Parts

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

Part 1 of 2

CVS PHARMACY NIGHTTIME SEVERE COLD AND COUGH HONEY LEMON INFUSED WITH CHAMOMILE AND WHITE TEA FLAVORS

acetaminophen, diphenhydramine hcl and phenylephrine hcl granule, for solution

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	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
ACESULFAME (UNII: MA3UYZ6K1H)	
ASPARTAME (UNII: Z0H242BBR1)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	yellow (Caramel color) , yellow (D and C Yellow 10)	Score	
Shape		Size	
Flavor	HONEY (Natural Honey and Lemon flavor) , LEMON (Natural Honey and Lemon flavor)	Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/25/2013	

Part 2 of 2**CVS PHARMACY DAYTIME SEVERE COLD AND COUGH BERRY INFUSED WITH MENTHOL AND GREEN TEA FLAVORS**

acetaminophen, dextromethorphan hbr and phenylephrine hcl granule, 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
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
ACESULFAME (UNII: MA3UYZ6K1H)	
ASPARTAME (UNII: Z0H242BBR1)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	red (FD and C Red No 40) , blue (FD and C Blue No 1)	Score	
Shape		Size	
Flavor	BERRY (Berry infused with menthol and green tea flavors) , MENTHOL (Menthol)	Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/19/2013	

Labeler - CVS Pharmacy (062312574)

Revised: 7/2013

CVS Pharmacy