#### CVS HEALTH MAXIMUM STRENGTH NON DROWSY DAY AND NIGHT COLD AND FLU MAX SOFTGELS MINIS- acetaminophen, dextrmethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride CVS Pharmacy

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CVS Health Maximum Strength Non Drowsy Day and Night Cold and Flu Max Softgels Minis

Do not take these products at the same time.

#### **Drug Facts**

CVS Health Non Drowsy Day Cold & Flu Max Softgels

## Active ingredients (in each capsule)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

## Purposes

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

## Uses

#### Uses

- $\cdot$  temporarily relieves these symptoms due to a cold or flu:
- · minor aches and pains · headache · cough
- $\cdot$  sore throat  $\cdot$  nasal and sinus congestion
- · temporarily reduces fever

## Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- $\cdot$  more than 4,000 mg of acetaminophen in 24 hours
- $\cdot$  with other drugs containing acetaminophen
- $\cdot$  3 or more alcoholic drinks every day while using this product

## Allergy alert: Acetaminophen may cause severe skin or severe

allergic reactions. Symptoms may include:

- $\cdot$  skin reddening  $\cdot$  blisters  $\cdot$  rash  $\cdot$  hives
- $\cdot$  facial swelling  $\cdot$  asthma (wheezing)  $\cdot$  shock

If a skin or general allergic 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 this product.

• if you have ever had an allergic reaction to this product or any of its ingredients

• in children under 12 years of age

# Ask a doctor before use if you have

- liver disease heart disease high blood pressure
- thyroid disease diabetes
- cough with excessive phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma,

or emphysema

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfa

# When using this product do not exceed recommended dosage

# Stop use and ask a doctor if

 $\cdot$  pain, cough, or nasal congestion gets worse or lasts more than

7 days

- $\cdot$  fever gets worse or lasts more than 3 days
- $\cdot$  redness or swelling is present
- · new symptoms occur
- $\cdot$  cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

· nervousness, dizziness, or sleeplessness occurs

IIf pregnant or breast-feeding, ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

## Directions

#### Directions

 $\cdot$  do not take more than the recommended dose

 $\cdot$  adults and children 12 years and over: take 2 capsules with water

every 4 hours. Do not exceed 10 capsules in 24 hours or as

directed by a doctor.

 $\cdot$  children under 12 years: do not use

## Other information

#### Other information

● store at room temperature. Avoid temperatures above 25°C (77°F).

## Inactive ingredients

FD&C yellow #6, gelatin, glycerin, pearlin silver, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol, titanium dioxide

## **Questions or comments?**

## Questions or comments? 1-888-333-9792

## CVS Health Maximum Strength Night Cold & Flu Softgels

## Active ingredients (in each capsule)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine hydrochloride 5 mg

## Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine Nasal decongestant

#### Uses

#### Uses

- $\cdot$  temporarily relieves these symptoms due to a cold or flu:
- $\cdot$  minor aches and pains  $\cdot$  headache
- $\cdot$  nasal and sinus congestion  $\cdot$  cough  $\cdot$  sore throat
- runny nose · sneezing
- $\cdot$  temporarily reduces fever

## Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- $\cdot$  more than 4,000 mg of acetaminophen in 24 hours
- $\cdot$  with other drugs containing acetaminophen
- $\cdot$  3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin or severe

allergic reactions. Symptoms may include:

 $\cdot$  skin reddening  $\cdot$  blisters  $\cdot$  rash  $\cdot$  hives

 $\cdot$  facial swelling  $\cdot$  asthma (wheezing)  $\cdot$  shock

If a skin or general allergic 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 to sedate children.

## 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 this product.

• if you have ever had an allergic reaction to this product or any of its ingredients

• in children under 12 years of age

# Ask a doctor before use if you have

- liver disease heart disease high blood pressure
- thyroid disease diabetes glaucoma
- cough with excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma,

or emphysema

# Ask a doctor or pharmacist before use if you are

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

# When using this product

- do not exceed recommended dosage
- may cause marked drowsiness
- avoid alcoholic drinks
- 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

- $\cdot$  pain, cough, or nasal congestion gets worse or lasts more than
- 7 days
- $\cdot$  fever gets worse or lasts more than 3 days
- $\cdot$  redness or swelling is present
- · new symptoms occur
- $\cdot$  cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

- $\cdot$  nervousness, dizziness, or sleeplessness occurs
- If pregnant or breast-feeding, ask a health professional before use.
- Keep out of reach of children. In case of overdose, get medical help

or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### Directions

#### Directions

 $\cdot$  do not take more than the recommended dose

 $\cdot$  adults and children 12 years and over: take 2 capsules with water

every 4 hours. Do not exceed 10 capsules in 24 hours or as

directed by a doctor.

· children under 12 years: do not use

# Other information

## Other information

● store at room temperature. Avoid temperatures above 25°C (77°F).

**Inactive ingredients** FD&C Blue #1, FD&C yellow #10, gelatin, glycerin, pearlin silver, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

## **Questions or comments?**

Questions or comments?1-888-333-9792

CVS Health

MAXIMUM STRENGTH

COLD & FIU MAX SOFTGELS

Compare to the active ingredients in

Alka-Seltzer PLUS® Maximum Strength Day

and Night Cold and Flu POWERMAX<sup>™</sup> GELS

DAY NON DROWSY

Acetaminophen / Pain Reliever-Fever Reducer

Dextromethorphan HBr / Cough Suppressant

Phenylephrine HCl / Nasal Decongestant

Relieves:

Nasal Congestion

Headache & Body Ache

Cough

Sore Throat

Sinus Pressure

16 SOFTGELS

NIGHT TIME

Acetaminophen / Pain Reliever-Fever Reducer

Dextromethorphan HBr / Cough Suppressant

Doxylamine Succinate / Antihistamine

Phenylephrine HCl / Nasal Decongestant

Nasal Congestion

Headache & Body Ache

Cough

Runny Nose

Sore Throat

8 SOFTGELS

24 SOFTGELS TOTAL

\*This product is not manufactured or distributed by Bayer

HealthCare LLC, owner of the registered trademark

Alka-Seltzer PLUS® POWERMAX™ GELS.

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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CVS.com® 1-800-SHOP CVS

Made in India

V-35249



## CVS HEALTH MAXIMUM STRENGTH NON DROWSY DAY AND NIGHT COLD AND FLU MAX SOFTGELS MINIS

acetaminophen, dextrmethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

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Product Information								
Product Type HUMAN OTC			HUMAN OTC DRUG	ltem Cod	e (Source)	NDC:69842-655		
Pa	Packaging							
# Item Code			Package Description		Marketing Start Date	Marketing End Date		
1	NDC:6 24	59842-655-	1 in 1 Produ	L CARTON; Type 0: Not a Comb uct	bination	06/06/2019		
Q	Quantity of Parts							
Part #			Pac	kage Quantity		Total Product Quantity		
Pa	rt 1	2 BLISTER	PACK		16			
Pa	rt 2	1 BLISTER	PACK		8 in 2			
Ρ	Part 1 of 2							
CVS HEALTH MAXIMUM STRENGTH NON DROWSY DAYTIME SOFTGELS								

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid

filled						
Product Information						
Route of Administration	ORAL					
Active Ingredient/Active	•				<b>.</b>	
-	edient Name		Basis of Stro	ength	Strength	
ACETAMINOPHEN (UNII: 36209IT			ACETAMINOPHEN		325 mg	
DEXTROMETHORPHAN HYDROE (DEXTROMETHORPHAN - UNII:7355			DEXTROMETHORPH HYDROBROMIDE	1AN	10 mg	
PHENYLEPHRINE HYDROCHLOR UNII:1WS297W6MV)	RIDE (UNII: 04JA59TNSJ) (PHEN	IYLEPHRINE -	PHENYLEPHRINE HYDROCHLORIDE		5 mg	
Inactive Ingredients						
	Ingredient Name			Str	ength	
GELATIN (UNII: 2G86QN327L)						
GLYCERIN (UNII: PDC6A3C0OX)						
POLYETHYLENE GLYCOL 400 (U	JNII: B697894SGQ)					
SORBITAN (UNII: 6092ICV9RU)						
SORBITOL (UNII: 506T60A25R)						
TITANIUM DIOXIDE (UNII: 15FIX9	V2JP)					
FD&C YELLOW NO. 6 (UNII: H77	VEI93A8)					
WATER (UNII: 059QF0KO0R)						
<b>POVIDONE</b> (UNII: FZ989GH94E)						
PROPYLENE GLYCOL (UNII: 6DCS	9Q167V3)					
<b>Product Characteristics</b>						
		Score		no scor	P	
			18mm			
Flavor			101			
Contains			101			
	contains					
Packaging						
# Item Pacl	kage Description	Mark	eting Start Date		ing End ate	
1 2 in 1 CARTON						
1 8 in 1 BLISTER PA Product	CK; Type 0: Not a Combinatio	on				
Marketing Information						
<b>_</b>	ation Number or Monog	raph Ma	rketing Start	Marke	ting End	
Category	Citation	pri 146	Date		ate	

# Part 2 of 2

# CVS HEALTH MAXIMUM STRENGTH NIGHT COLD AND FLU MAX SOFTGELS

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

#### **Product Information**

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg		
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients			
Ingredient Name	Strength		
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
SORBITOL (UNII: 506T60A25R)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
POVIDONE (UNII: FZ989GH94E)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
SORBITAN (UNII: 6092ICV9RU)			

Product Characteristics					
Color	green (opaque)	Score	no score		
Shape	OVAL (oblong)	Size	19mm		
Flavor		Imprint Code	102		
Contains					

	ckaging					
#	ltem Code	Package Descrip	tion Mai	rketing Start Date	Marketing End Date	
1	1	n 1 CARTON				
1 8 in 1 Produc		n 1 BLISTER PACK; Type 0: Not a oduct	Combination			
Ma	arketing	Information				
	Marketing Category	Application Number Citation		larketing Start Date	Marketing End Date	
отс	Monograph D	rug M012	06/	06/2019		
Ma	arketing	Information				
	Marketing Category	Application Number Citatio		larketing Start Date	Marketing End Date	

Labeler - CVS Pharmacy (062312574)

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CVS Pharmacy