

**ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, DEXTROMETHORPHAN HBR-  
acetaminophen, chlorpheniramine maleate, dextromethorphan hbr  
CVS Pharmacy, Inc**

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**6044-CVS**

**Daytime Flu Relief Maximum Strength**

***Drug Facts***

***Active ingredients (in each caplet)***

Acetaminophen 500 mg

Dextromethorphan HBr 15 mg

***Purposes***

Pain reliever/Fever reducer

Cough suppressant

***Uses***

- temporarily relieves these symptoms due to a common cold or flu:
  - headache
  - minor aches and pains
  - cough due to minor throat and bronchial irritation
  - minor sore throat pain
- temporarily reduces fever

**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

**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.

- 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 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.

- liver disease
- 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
  
- taking the blood thinning drug warfarin

**When using this product do not use more than directed.**

- pain 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 a rash or headache that lasts

These could be signs of a serious condition.

**If pregnant or breast-feeding,** ask a doctor before use.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- **do not use more than directed**
- **adults and children 12 years of age and over:** take 2 caplets every 6 hours, while symptoms persist
- do not take more than 6 caplets in 24 hours unless directed by a doctor
- **children under 12 years of age:** do not use

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Age	Dose
adults and children 12 years of age and over	2 caplets every 6 hours
children under 12 years of age	do not use

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**Other information**

Store in a dry place at 15° - 30°C (59° -86°F).

corn starch, crospovidone, FD&C blue #2 lake, FD&C red #40 lake, hypromellose, magnesium stearate, medium chain triglycerides, microcrystalline cellulose, mineral oil, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, talc, titanium dioxide.

1-800-231-4670

**Nighttime Flu Relief Maximum Strength**

**Drug facts**

### **Active ingredients (in each caplet)**

Acetaminophen 500 mg

Chlorpheniramine maleate 2 mg

Dextromethorphan HBr 15 mg

### **Purposes**

Pain reliever/Fever reducer

Antihistamine

Cough suppressant

### **Uses**

- temporarily relieves these symptoms due to a common cold or flu:
- headache
- minor aches and pains
- cough due to minor throat and bronchial irritation
- minor sore throat pain
- runny nose
- temporarily reduces fever

**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

**Allergy alert:** Acetaminophen may cause severe skin reactions.

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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.

- 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 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.
- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

- 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
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers
- 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
- pain 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 a rash or headache that lasts

These could be signs of a serious condition.

**If pregnant or breast-feeding,** ask a doctor before use.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### ***Directions***

- **do not use more than directed**
- **adults and children 12 years of age and over:** take 2 caplets every 6 hours, while symptoms persist
- do not take more than 6 caplets in 24 hours unless directed by a doctor
- **children under 12 years of age:** do not use

Age	Dose
adults and children 12 years of age and over	2 caplets every 6 hours
children under 12 years of age	do not use

### ***Other information***

Store in a dry place at 15° – 30°C (59° – 86°F).

corn starch, crospovidone, FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, titanium dioxide, triacetin.

1-800-231-4670

\*CVS™ is not affiliated with the owner of the registered trademark Theraflu® Flu Relief Max Strength Daytime & Nighttime.

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TAMPER EVIDENT FEATURE: FLU RELIEF MAX STRENGTH CAPLETS ARE SEALED IN BLISTER PACKETS. USE ONLY IF THE INDIVIDUAL SEAL IS UNBROKEN.

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 6 HOURS AFTER THE LAST DOSE OF THE DAYTIME PRODUCT UNLESS DIRECTED BY YOUR DOCTOR.

DO NOT TAKE THE DAYTIME AND NIGHTTIME PRODUCTS AT THE SAME TIME.  
DO NOT TAKE MORE THAN 3 DOSES IN TOTAL IN ANY 24 HOUR PERIOD.

CVS™

NDC 51316-984-03

Compare to Theraflu® Flu Relief Max Strength Daytime & Nighttime active ingredients\*

Maximum Strength†

DAYTIME FLU RELIEF

Acetaminophen

Pain Reliever, Fever Reducer

Dextromethorphan HBr

Cough Suppressant

Relieves: Fever, Body aches, Headache, Sore throat pain, Cough

20 DAYTIME CAPLETS

Maximum Strength†

NIGHTTIME FLU RELIEF

Acetaminophen

Pain Reliever, Fever Reducer

Chlorpheniramine Maleate,

Antihistamine

Dextromethorphan HBr

Cough Suppressant

Additional Nighttime Relief of: Runny nose

20 NIGHTTIME CAPLETS

40 TOTAL CAPLETS

†Maximum Strength per 6 hour dose under OTC monograph.



**Drug Facts (continued)**

**Save this 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**

- in a child under 12 years of age
- if you are allergic to 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.

**Ask a doctor before use if you have**

- liver disease • a breathing problem such as emphysema or chronic bronchitis • glaucoma • trouble urinating due to an enlarged prostate gland • 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
- taking sedatives or tranquilizers

**When using this product**

- 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

**Drug Facts (continued)**

**Save this 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**

- in a child under 12 years of age
- if you are allergic to acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
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**Ask a doctor before use if you have**

- liver disease • 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**

- taking the blood thinning drug warfarin

**When using this product do not use more than directed.**

**Stop use and ask a doctor if**

- pain or cough gets worse or lasts more than 7 days • fever present • new symptoms occur • cough comes back or occurs with a rash or headache that lasts

These could be signs of a serious condition.

**Nighttime Flu Relief Caplet (continued)**

**Daytime Flu Relief Caplet (continued)**

**Drug Facts**

**Active Ingredients (in each caplet)**

Acetaminophen 500 mg ..... Pain reliever/fever reducer  
 Chlorpheniramine maleate 2 mg ..... Antihistamine  
 Dextromethorphan Hbr 15 mg ..... Cough suppressant

**Uses**

- temporarily relieves these symptoms due to a common cold or flu: • headache • minor aches and pains • cough due to minor throat and bronchial irritation
- temporarily reduces fever

**Warnings**

- 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

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include: • skin redness • blisters • rash

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

**Drug Facts**

**Active Ingredients (in each caplet)**

Acetaminophen 500 mg ..... Pain reliever/fever reducer  
 Dextromethorphan Hbr 15 mg ..... Cough suppressant

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- temporarily reduces fever

**Warnings**

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- 3 or more alcoholic drinks every day while using this product

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

**Nighttime Flu Relief Caplet**

**Daytime Flu Relief Caplet**

**DO NOT TAKE THE DAYTIME AND NIGHTTIME PRODUCTS AT THE SAME TIME. DO NOT TAKE MORE THAN 3 DOSES IN TOTAL IN ANY 24 HOUR PERIOD.**

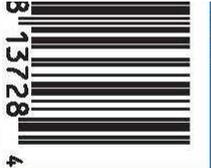
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**Maximum Strength!**  
**DAYTIME FLU RELIEF**  
**Acetaminophen**  
 Pain Reliever, Fever Reducer  
 Dextromethorphan HBr  
 Cough Suppressant

**Maximum Strength!**  
**NIGHTTIME FLU RELIEF**  
**Acetaminophen**  
 Pain Reliever, Fever Reducer  
 Chlorpheniramine Maleate, Antihistamine  
 Dextromethorphan HBr  
 Cough Suppressant

**Compare to Theraflu® Flu Relief Max Strength Daytime & Nighttime active ingredients\***

Relieves: Fever, Body aches, Headache, Sore throat pain, Cough

Additional Nighttime Relief of: Runny nose

**20 DAYTIME CAPLETS**  
**40 TOTAL CAPLETS**

**20 NIGHTTIME CAPLETS**  
 \*Maximum Strength per 8 hour dose under OTC monograph.

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 V-40056



**Questions? 1-800-231-4670**

**Drug Facts (continued)**

**Other Information**  
 Store in a dry place at 15° – 30°C (59° – 86°F).

**Inactive ingredients** corn starch, croscopolone, FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, polyethylene glycol, polydioxane, sodium starch glycolate, stearic acid, titanium dioxide, Tracellin.

\*CVS® is not affiliated with the owner of the registered trademark Theraflu® Flu Relief Max Strength Daytime & Nighttime.

**Questions? 1-800-231-4670**

**Drug Facts (continued)**

**Daytime Flu Relief Caplet (continued)**

**Directions**

- do not use more than directed
- adults and children 12 years of age and over: take 2 caplets every 6 hours, while symptoms persist
- do not take more than 6 caplets in 24 hours unless directed by a doctor
- children under 12 years of age: do not use

**Drug Facts (continued)**

**Other Information**

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

If pregnant or breast-feeding, ask a doctor before use. These could be signs of a serious condition:

- fever gets worse or lasts more than 3 days
- redness or swelling is present
- cough comes back or occurs with a rash or headache that lasts

Stop use and ask a doctor if:

- pain or cough gets worse or lasts more than 7 days
- new symptoms occur

**Drug Facts (continued)**

Age	Dose
adults and children 12 years of age and over	2 caplets every 6 hours
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**Directions**

- do not use more than directed
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**Drug Facts (continued)**

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- redness or swelling is present
- cough comes back or occurs with a rash or headache that lasts

Stop use and ask a doctor if:

- pain or cough gets worse or lasts more than 7 days
- new symptoms occur

**Drug Facts (continued)**

Age	Dose
adults and children 12 years of age and over	2 caplets every 6 hours
children under 12 years of age	do not use

**ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, DEXTROMETHORPHAN HBR**  
 acetaminophen, chlorpheniramine maleate, dextromethorphan hbr kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-984
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-984-03	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	07/10/2024	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	20 in 40
Part 2	2 BLISTER PACK	20 in 40

### Part 1 of 2

## ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, DEXTROMETHORPHAN HBR

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr tablet, film coated

### Product Information

Item Code (Source)	NDC:51316-451
Route of Administration	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSPROVIDONE</b> (UNII: 2S7830E561)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>FD&amp;C BLUE NO. 2 ALUMINUM LAKE</b> (UNII: 4AQJ3LG584)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>TRACETIN</b> (UNII: XHX3C3X673)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	

## Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	C451
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-451-01	10 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 Drug	M012	07/10/2024	

## Part 2 of 2

### ACETAMINOPHEN, DEXTROMETHORPHAN HBR

acetaminophen, dextromethorphan hbr tablet, film coated

## Product Information

Item Code (Source)	NDC:51316-983
Route of Administration	ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FD&amp;C BLUE NO. 2 ALUMINUM LAKE</b> (UNII: 4AQJ3LG584)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	

<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>FD&amp;C RED NO. 40 ALUMINUM LAKE</b> (UNII: 6T47AS764T)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	C642
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-983-01	10 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 Drug	M012	07/10/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/10/2024	

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