ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, DEXTROMETHORPHAN HBRacetaminophen, chlorpheniramine maleate, dextromethorphan hbr CVS Pharmacy, Inc

6044-CVS

Day Time 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 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, 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 Maximu 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.

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
- 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 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

† These products are not manufactured or distributed by Haleon, distributor of Theraflu.

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One CVS Drive, Woonsocket, RI 02895
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CVS.com® 1-800-SHOP CVS

*Maximum Strength per 6 hour dose.

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 Health

Compare to the active ingredients in Theraflu Flu Relief Maximum Strength Daytime & Nighttime caplets†

Multi-Symptom

DAYTIME

MAXIMUM STRENGTH*

Flu Relief

ACETAMINOPHEN

Pain reliever: Fever reducer

DEXTROMETHORPHAN HBr

Cough suppressant

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

20 CAPLETS

NIGHTTIME

MAXIMUM STRENGTH*

Flu Relief

ACETAMINOPHEN

Pain reliever; Fever reducer

CHLORPHENIRAMINE MALEATE

Antihistamine

DEXTROMETHORPHAN HBr

Cough suppressant

20 CAPLETS

40 TOTAL CAPLETS

Flu Relief Maximum Strength Daytime Caplets

Drug Facts (continued)

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

- of not use more than directed

 adults and children 12 years 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).

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

Flu Relief Maximum Strength Daytime Caplets (continued)

Drug Facts (continued)

Questions? 1-800-231-4570

Flu Relief Maximum Strength Nighttime Caplets (continued)

Drug Facts (continued)

- Stop use and ask a doctor if

- surp use and ask a loctor in pain or could jest 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. Respond 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

- DIFOCIONS

 do not use more than directed

 adults and children 12 years 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	

Flu Relief Maximum Strength Nighttime Caplets (continued)

Drug Facts (continued)

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

Inactive Ingredients com 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.

Questions? 1-800-231-4670

†These products are not manufactured or distributed by Haleor distributor of Theraflu.



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40 TOTAL CAPLETS **20 CAPLETS**

Actual Size

Bunny nose Additional relief of:

Cough suppressant

ТЕХТВОМЕТНОВРНАИ НВ

CHLORPHENIRAMINE MALEATE

NECETAMINOPHEN

Tella Relief

MAXIMUM STRENGTH*

NIGHTTIME

SO CAPLETS

DEXTROMETHORPHAN HBr

ACETAMINOPHEN

Flu Relief

MAXIMUM STRENGTH*

DAYTIME

Multi-Symptom

Maximum Strength Daytime & Nighttime caplets † Compare to the active ingredients in Theraffu Flu Relief





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

THE LAST DOSE OF THE DAYTIME PRODUCT UNLESS DIRECTED BY YOUR DOCTOR. DO NOT TAKE A DOSE OF THE NIGHTTIME PRODUCT SOONER THAN 6 HOURS AFTER

> KEEP CARTON FOR REFERENCE. DO NOT DISCARD. READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE.

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

*Maximum Strength per 6 hour dose.

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.

USE AS DIRECTED

Flu Relief Maximum Strength Daytime Caplets

Flu Relief Maximum Strength Nighttime Caplets

Drug Facts

Active ingredients (In each caplet)

Purposes

Acetaminophen 500 mg Pain reliever/Fever reduce Dextromethorphan HBr 15 mg Cough suppressant

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- 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

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
• with other drugs containing acetaminophen
• 3 or more alcoholic drinks every day while using this product

Allergy elert: Acetaminophen may cause severe skin reactions. Symptoms may include: • skin reddening • bilsters • rash If a skin reaction occurs, stop use and seek medical help right away.

Drug Facts

Active ingredients (In each caplet)

Purposes

Acetaminophen 500 mg.. Pain reliever/f Chlorpheniramine maleate 2 mg ... Antihistamine Dextromethorphan HBr 15 mg .. . Cough suppressant

- *emporarily 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

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
- 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

Flu Relief Maximum Strength Daytime Caplets

Drug Facts (continued)

Sore threat 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
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- you are now taking a prescription monoamine oxidase nyou are now taxing a prescription monoamine oxidase inhibitor (MAOI) (cartain 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

 Niver 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

Aften using this product do not use more than directed.

op use and ask a doctor if

 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.

Flu Relief Maximum Strength Nighttime Caplets (continued)

Drug Facts (continued)

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

- 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
- 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

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ilver 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, astima or emphysema

- Ask a dector 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 drowsine
- be careful when driving a motor vehicle or operating machinery
 excitability may occur, especially in children

ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, **DEXTROMETHORPHAN HBR**

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr kit

Product Information

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

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	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

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

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg		
CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - UNII: 3U6I01965U)	CHLORPHENIRAMINE MALEATE	2 mg		

Inactive Ingredients			
Ingredient Name	Strength		
CROSPOVIDONE (UNII: 2S7830E561)			
FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
STARCH, CORN (UNII: O8232NY3SJ)			

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TRIACETIN (UNII: XHX3C3X673)	
MINERAL OIL (UNII: T5L8T28FGP)	
POVIDONE (UNII: FZ989GH94E)	

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

l	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		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg		

Inactive Ingredients				
Ingredient Name	Strength			

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ 989GH94E)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)	
MINERAL OIL (UNII: T5L8T28FGP)	
CROSPOVIDONE (UNII: 2S7830E561)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics				
Color	red	Score	no score	
Shape	OVAL	Size	18mm	
Flavor		Imprint Code	C642	
Contains				

l	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 In	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)

Revised: 3/2025 CVS Pharmacy, Inc