COLD AND FLU SEVERE DAYTIME AND NIGHTTIME- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride CHAIN DRUG MARKETING ASSOCIATION INC.

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1186 - QCH - 2019-0103

Cold + Flu Severe Day

**Drug Facts** 

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever
Acetaininophen 323 mg	reducer
Dextromethorphan HBr 10 mg	Cough
Dextromethorphan fibril 10 mg	suppressant
Guaifenesin 200 mg	Expectorant
Dhanylanhrina UCLE ma	Nasal
Phenylephrine HCl 5 mg	decongestant

#### Uses

- for the temporary relief of the following cold/flu symptoms:
  - minor aches and pain
  - headache
  - sore throat
  - nasal congestion
  - cough
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

## **Warnings**

## Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. 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.

#### 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

## 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
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

# 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 occur
- pain, nasal congestion, 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 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). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### **Directions**

do not take more than directed (see overdose warning)

adults and children 12 years and over	<ul> <li>take 2 caplets every 4 hours</li> <li>swallow whole - do not crush, chew, or dissolve</li> <li>do not take more than 10 caplets in 24 hours</li> </ul>
children under 12 years	■ ask a doctor

#### Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information and warnings

## **Inactive ingredients**

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #2 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

## Cold + Flu Severe Night Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever
	reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

#### Uses

- for the temporary relief of the following cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion

- cough
- sinus congestion and pressure
- sneezing and runny nose
- helps clear nasal passages
- relieves cough to help you sleep
- temporarily reduces fever

## Warnings

## Liver warning

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

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- skin reddening
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- rash

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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 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

# 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
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

## 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
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

## Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
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# Keep out of reach of children.

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children under 12 years	<ul><li>ask a doctor</li></ul>

#### Other information

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- retain carton for complete product information and warnings

## **Inactive ingredients**

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

#### PRINCIPAL DISPLAY PANEL

Quality Choice®

NDC 63868-238-16

Cold + Flu Severe for Adults

Daytime + Nighttime

Pain Reliever | Fever Reducer, Cough Suppressant,

Nasal Decongestant, Expectorant

Day | Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl, Guaifenesin

For Relief of: Head + Body Aches

Fever + Sore Throat

Cough, Nasal Congestion

Mucus + Chest Congestion

Pain Reliever | Fever Reducer, Antihistamine, Cough Suppressant,

Nasal Decongestant

Night | Acetaminophen, Chlorpheniramine Maleate, Dextromethorphan HBr, Phenylephrine HCl

For Relief of: Head + Body Aches

Fever + Sore Throat

Cough, Nasal Congestion

Runny Nose

**Total 24 Cool Taste Caplets** 

16 Day Caplets / 8 Night Caplets



comprescription), if you are not sure whether a drug contains acetaminophen, Do not use with any other drug containing acetan incohen brescription or occompanied or followed by tever, headache, rash, nausea, or vominng, consun

Sore Unroal warning: If sore throat is severe, persists for more than 2 days, is g a skiju reaction occurs, stop use and seek medical help right away.

Allergy alert. Acetaminophen may cause severe skin reactions. Symptoms may include: a skin reddening a blisters a rash

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

more than 4,000 mg of acetaminophen in 24 hours

Severe liver damage may occur it you take dose of this product is 10 capiets (3,250 mg sostaminophen) in 24 hours. Liver warming: This product contains acetaminophen. The maximum daily Varnings

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Drug Facts (continued)

COLO + FLU SEVERE NIGHT

Dextomethorphan HSr 10 mg.

Chlorpheniramine maleate 2 mg.

Phenylephrine HOLS mg.

Drug Facts

femborarily reduces fever

Warnings

a doctor promptly.

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Drug Facts (continued)

Massa decongestant

Cough suppressent

Just segmoso lessi Phenylephrine HCl 5 mg. Cough suppressant Considence in 200 mg

Dextromethorphan HBr 10 mg. Active ingredients (in each day caplet)

Drug Facts

SEVERE DAY COLD + FLU

sp in a 24-hour pariod. Take only as dredled. Read all product information before using. Keep this carbon for complete product information and wamings.

NDC 63868-238-16

Active ingredients (in each night caplet)

\*Compare to the active ingredients in TYLENOL\* Cold + Flu Severe Day and Night

# Cold + Flu Severe For Adults Daytime + Nighttime

#### DAY | Acetaminophen,

Dextromethorphan HBr, Phenylephrine HCl, Guaifenesin

Head + Body Aches Fever + Sore Throat

Cough, Nasal Congestion Mucus + Chest Congestion

scesnisme potassium, colloidal alicon

#### NIGHT | Acetaminophen,

Chlorpheniramine Maleate, Dextromethorphan HBr, Phenylephrine HCI For Relief of:

Head + Body Aches Fever + Sore Throat Cough, Nasal Congestion Runny Nose

## 16 DAY CAPLETS / 8 NIGHT CAPLETS

pregelatinized starch, propylene glycol, stearic acid, talc, titanium doxide

lake, FD&C blue #2 shuminum lake, flavor, magnesium stearale, marbodextrin, microcrystalline cellulose, polyethylene glycol, polyninyl alcohol, poundone,

dioxide, croscamellose sodium, crospovidone, D&C yellow #10 aluminum

bregelatinized starch, propylene glycol, stearic acid, talc, ttanium dioxide microcrystaline cellulose, polyetrytene glycol, polyvinyl alcohol, povidone, croscarmellose sodium, FO&C blue #1 aluminum lake, flavor, magnesium stearate oceangame potassium, colloidal silicon dioxide, Inactive ingredients

 retain carton for complete product information and warmings Other information = store between 20-25°C (68-77°F) in a dry place

Drug Facts (continued)

adults and children

COLO + FLU SEVERE DAY

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Drug Facts (continued)

■ qo uot pays more than 10 caplets in 24 hours swallow whole - do not areh, chew, or desolve Jano Due Sjeaf, 21 ■ paye 5 cablets every 4 hours neadiffs and children

DILECTIONS • do not take more than directed (see overdose warming)

adults as weil as for children even I you do not notice any signs or symptoms. Overdose warning in case of overdose, get medical halp or contact a Poleon Combot Center right away (1-800-222-1222). Ouick medical attendonis cribical for

Keep out of reach of children. If pregnant or breast-feeding, ask a health professional before use.

These could be signs of a serious condition.

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 ■ CONTROLLES OCCITES MELLI USER OCCITES MELLI USER OCCITES DE DESTRESSE lever gets worse or lasts more than 3 days
 redness or swelling is present Stop use and ask a doctor if a nerrousness, dzaness, or sleeplessness occur a pain, nasal congestion, or cough gets worse or lasts more than 7 days

When using this product do not exceed recommended dosage

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 avoid alcoholic drinks exclability may occur, especially in children
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†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenof® Cold + Flu Severe Day and Night. 8 AR OT USE IF BLISTER UNITS TORN OR BROKEN



Overdose warming: in case of overdose, get medical help or contact a Poison

COLD WATER IN Ask a doctor or pharmacist before use if you are taking the blood thinning ■ condu gust occurs with too much philosom (mucus) bronchitis, or emphysema

 persidert or chronic cough such as occurs with smoking, astlima, chronic ■ trouble unimating due to an eniarged prostate gland sapgap a esseed blongs = Ask a doctor before use if you have in liver disease in heart disease

**Drug Facts** (continued)

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 Lisking the blood thinning drug warfarin

 Ask a doctor or pharmacist before use if you are

 a breathing problem such as emphysems or chronic bronchitte persistent or chronic cough such as occurs with smoking, asthma, or emphysema bineby statement begreinen ne of sub brotherin sidoot = seaseb hash = seaseb hash = seaseb hash = seaseb broth if = Drug Facts (continued)



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COLD + FLU SEVERE DAY

#### COLD AND FLU SEVERE DAYTIME AND NIGHTTIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride kit

#### **Product Information**

**Product Type** HUMAN OTC DRUG Item Code (Source) NDC:63868-238

#### **Packaging**

# Item Code	Package Description	Marketing Start Date	Marketing End Date
<b>1</b> NDC:63868-238-16	1 in 1 CARTON	09/01/2017	06/30/2026

#### **Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	16
Part 2	1 BLISTER PACK	8

#### Part 1 of 2

# ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, **GUAIFENESIN, AND PHENYLEPHRINE HYDROCHLORIDE**

acetaminophen, dextromethorphan hydrobromide, quaifenesin, and phenylephrine hydrochloride tablet, coated

#### **Product Information**

**Route of Administration ORAL** 

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII: 7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients				
Ingredient Name	Strength			
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)				
CROSPOVIDONE (UNII: 2S7830E561)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
ALUMINUM OXIDE (UNII: LMI26O6933)				
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL (UNII: 532B59J990)				
POVIDONE (UNII: FZ989GH94E)				
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				

Product Characteristics				
Color	yellow	Score	no score	
Shape	OVAL	Size	19mm	
Flavor	MINT	Imprint Code	AAA;1136	
Contains				

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		8 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			

# Part 2 of 2

# ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, DEXTROMETHORPHAN HYDROBROMIDE, AND PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated

## **Product Information**

Route of Administration ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - UNII: 3U6I01965U)	CHLORPHENIRAMINE MALEATE	2 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients		
Ingredient Name	Strength	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
ALUMINUM OXIDE (UNII: LMI26O6933)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
POVIDONE (UNII: FZ989GH94E)		
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	blue	Score	no score
Shape	OVAL	Size	17mm
Flavor	MINT	Imprint Code	AAA;1139
Contains			

Packaging				
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/01/2017	06/30/2026

**Labeler -** CHAIN DRUG MARKETING ASSOCIATION INC. (011920774)

Revised: 10/2024 CHAIN DRUG MARKETING ASSOCIATION INC.