

**HEALTH MART DAY TIME COLD AND FLU NIGHT TIME COLD AND FLU-
acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl
Strategic Sourcing Services LLC**

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.

**McKesson Day Time Cold & Flu Night Time Cold
& Flu Drug Facts**

Active ingredients (in each softgel) – Nighttime Cold & Flu

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Active ingredients (in each softgel) – Daytime Cold & Flu

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose – Nighttime Cold & Flu

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Purpose – Daytime Cold & Flu

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses – Nighttime Cold & Flu

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

Uses – Daytime Cold & Flu

temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- 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 right away.

Sore throat warning: If sore throat is severe, lasts 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 – Nighttime Cold & Flu

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- trouble urinating due to an enlarged prostate gland

Ask a doctor before use if you have – Daytime Cold & Flu

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are – Nighttime Cold & Flu

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

Ask a doctor or pharmacist before use if you are – Daytime Cold & Flu

taking the blood thinning drug warfarin

When using this product – Nighttime Cold & Flu

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

When using the product – Daytime Cold & Flu

do not use more than directed

Stop use and ask a doctor if – Nighttime Cold & Flu

- 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 rash or headache that lasts. These could be signs of a serious condition.

Stop use and ask a doctor if – Daytime Cold & Flu

- you get nervous, dizzy or sleepless
- 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 – Nighttime Cold & Flu

- take only as directed – see overdose warning
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	2 softgels with water every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Directions – Daytime Cold & Flu

- take only as directed – see overdose warning
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	2 softgels with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients – Nighttime Cold & Flu

D&C yellow no. 10, edible ink*, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution *may contain this ingredient

Inactive ingredients – Daytime Cold & Flu

edible ink*, FD&C red no. 40, FD&C yellow no. 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution *may contain this ingredient

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to Vicks® DayQuil® Cold & Flu active ingredients

DAYTIME RELIEF

DayTime Cold & Flu

Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl

Pain Reliever/Fever Reducer, Cough Suppressant, Nasal Decongestant

For Relief of:

Aches/Fever/Sore Throat

Nasal Congestion – Cough

Alcohol Free

Antihistamine Free

Gluten Free

Actual Size

32 Softgels

Compare to Vicks® NyQuil® Cold & Flu active ingredients

NIGHTTIME RELIEF

NightTime Cold & Flu

Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate

Pain Reliever/Fever Reducer, Cough Suppressant, Antihistamine

For Relief of:

Aches/Fever/Sore Throat

Sneezing/Runny Nose – Cough

Alcohol Free

Gluten Free

Actual Size

16 Softgels

NDC #2011-0437-1



HealthMart.

Compare to Vicks® DayQuil®
Cold & Flu active ingredients**

DAYTIME RELIEF

DayTime Cold & Flu

Acetaminophen, Dextromethorphan HBr,
Phenylephrine HCl

Pain Reliever/Fever Reducer,
Cough Suppressant, Nasal Decongestant

For Relief of:

- Aches/Fever/Sore Throat
- Nasal Congestion • Cough



Actual Size

Alcohol Free
Antihistamine Free
Gluten Free

32 Softgels



HealthMart.

Compare to Vicks® NyQuil®
Cold & Flu active ingredients**

NIGHTTIME RELIEF

NightTime Cold & Flu

Acetaminophen, Dextromethorphan HBr,
Doxylamine Succinate

Pain Reliever/Fever Reducer,
Cough Suppressant, Antihistamine

For Relief of:

- Aches/Fever/Sore Throat
- Sneezing/Runny Nose • Cough

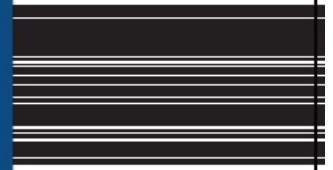
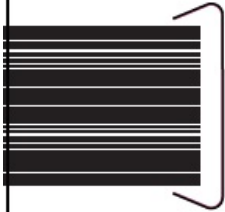


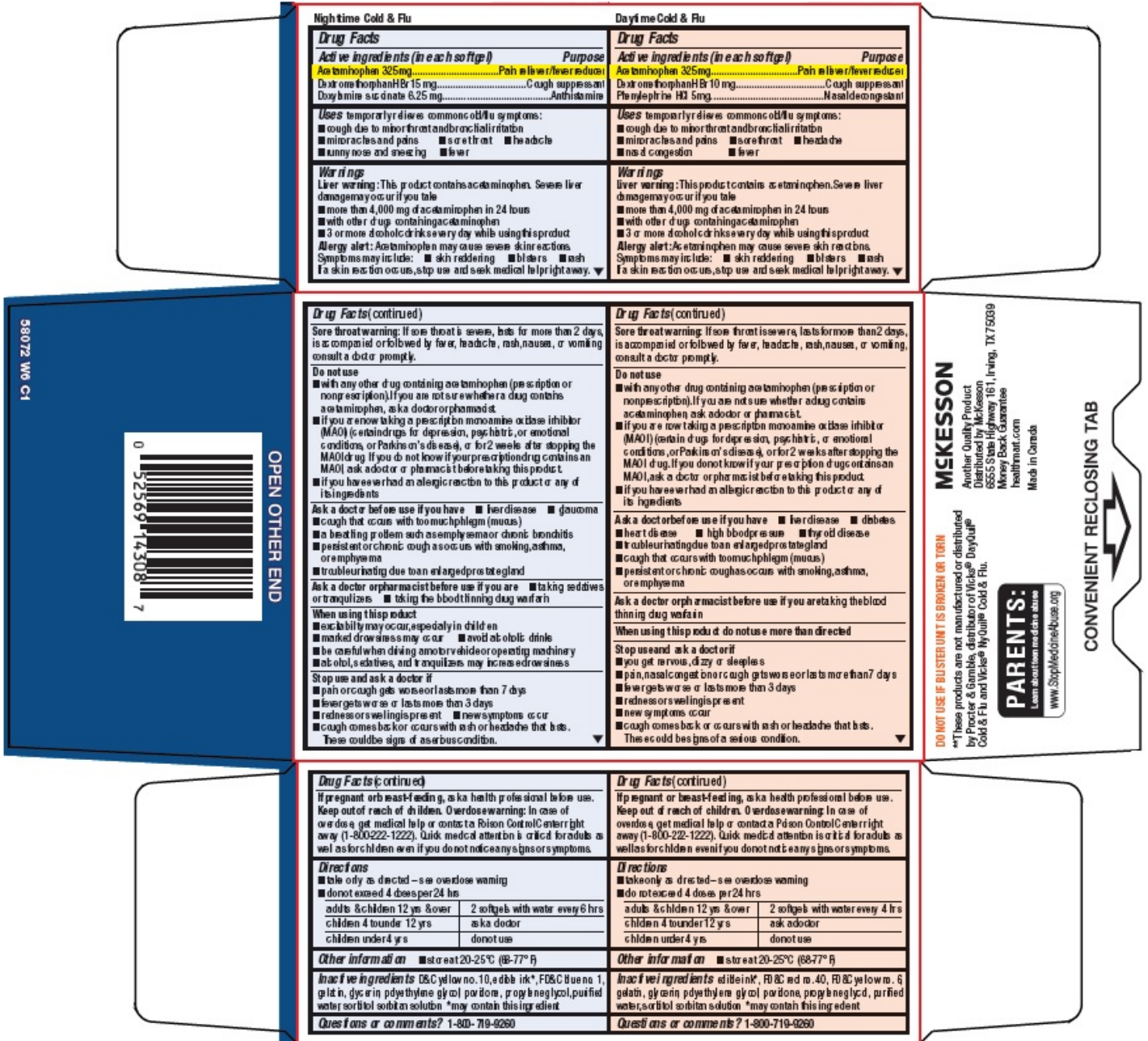
Actual Size

Alcohol Free
Gluten Free

16 Softgels

VISIBLE PRINT AREA





HEALTH MART DAY TIME COLD AND FLU NIGHT TIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:620 11-0437
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:620 11-0437-1	1 in 1 CARTON; Type 0: Not a Combination Product	01/22/2020	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity

Part 1	8 BLISTER PACK	16
Part 2	16 BLISTER PACK	32

Part 1 of 2

HEALTH MART NIGHT TIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	GREEN (clear)	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	056
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 in 1 CARTON		
1		2 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 final	part341		

Part 2 of 2

HEALTH MART DAY TIME COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

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	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	L994
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		16 in 1 CARTON		
1		2 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 final	part341			
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	01/22/2020		

Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 1/2020

Strategic Sourcing Services LLC