DAYTIME NITETIME- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride
Publix Super Markets Inc

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.

Publix Super Markets, Inc. Daytime Nitetime Drug Facts

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

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

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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

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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

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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

Package/Label Principal Display Panel

daytime

ACETAMINOPHEN

DEXTROMETHORPHAN HBr

PHENYLEPHRINE HCl

Pain reliever
Fever reducer
Cough suppressant
Nasal decongestant
MULTI-SYMPTOM
COLD & FLU RELIEF
ACTUAL SIZE
32 SOFTGELS
Compare to the active ingredients in Vicks® DayQuil® Cold & Flu
nitetime
ACETAMINOPHEN
DEXTROMETHORPHAN HBr
DOXYLAMINE SUCCINATE
Pain reliever
Fever reducer
Cough suppressant
Antihistamine
MULTI-SYMPTOM
COLD & FLU RELIEF
ACTUAL SIZE
16 SOFTGELS
Compare to the active ingredients in Vicks® NyQuil® Cold & Flu

Nighttime Cold & Flu

Drug Facts

Active Ingredients (in each softgel)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine

Uses temporarily relieves common cold/flu symptoms:
- cough due to minor throat and bronchial irritation
- minor aches and pains
- sore throat
- headache
- runny nose and sneezing
- fever

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

Daytime Cold & Flu

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NDC 56062-717-72

nitetime

ACETAMINOPHEN
DEXTROMETHORPHAN HBr
DOXYLAMINE SUCCINATE

Pain reliever
Fever reducer
Cough suppressant
Antihistamine

MULTI-SYMPTOM
COLD & FLU RELIEF

ACTUAL SIZE

16 SOFTGELS

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

daytime

ACETAMINOPHEN
DEXTROMETHORPHAN HBr
PHENYLEPHRINE HCl

Pain reliever
Fever reducer
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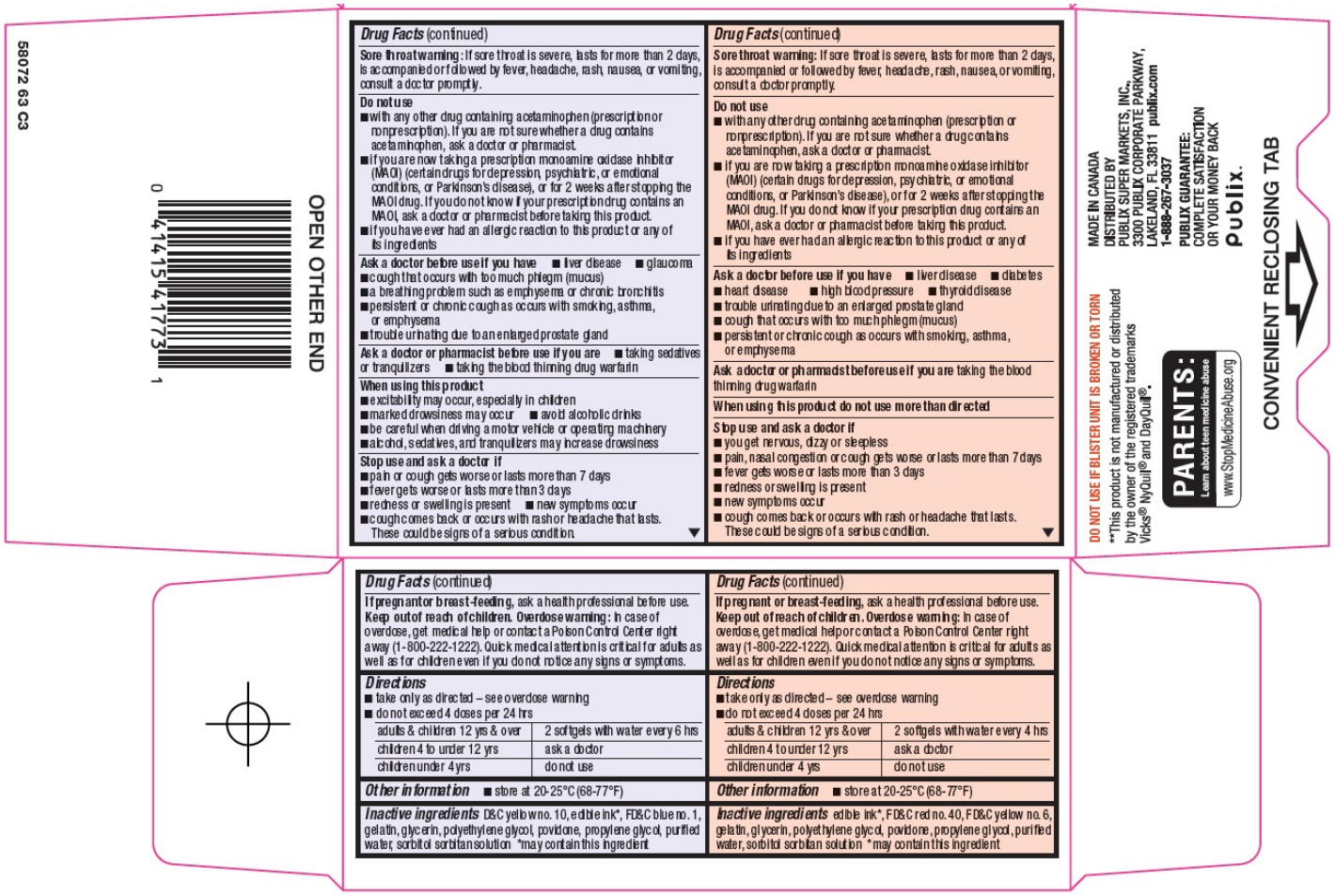
MULTI-SYMPTOM
COLD & FLU RELIEF

ACTUAL SIZE

32 SOFTGELS

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



DAYTIME NITETIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:56062-717

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:56062-717-72	1 in 1 CARTON; Type 0: Not a Combination Product	09/25/2018	

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

NITETIME

acetaminophen, dextromethorphan hydrobromide, 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: H3R47K3TBD)	
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		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

DAYTIME

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride 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	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		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		

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/25/2018	

Labeler - Publix Super Markets Inc (006922009)

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