

DAYTIME PE NITETIME- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl

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 PE Nitetime 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 these products.
- if you have ever had an allergic reaction to these products or any of their 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

Principal Display Panel - Daytime

See New Warning

NON-DROWSY

daytime PE

ACETAMINOPHEN – ACHES, FEVER

DEXTROMETHORPHAN HBr – COUGH

PHENYLEPHRINE HCl – NASAL CONGESTION

PAIN RELIEVER, FEVER REDUCER

COUGH SUPPRESSANT
NASAL DECONGESTANT
MULTI-SYMPPTOM
COLD/FLU RELIEF

Compare to Active Ingredients in Vicks® DayQuil®

ACTUAL SIZE
32 SOFTGELS

Principal Display Panel - Nighttime

See New Warnings

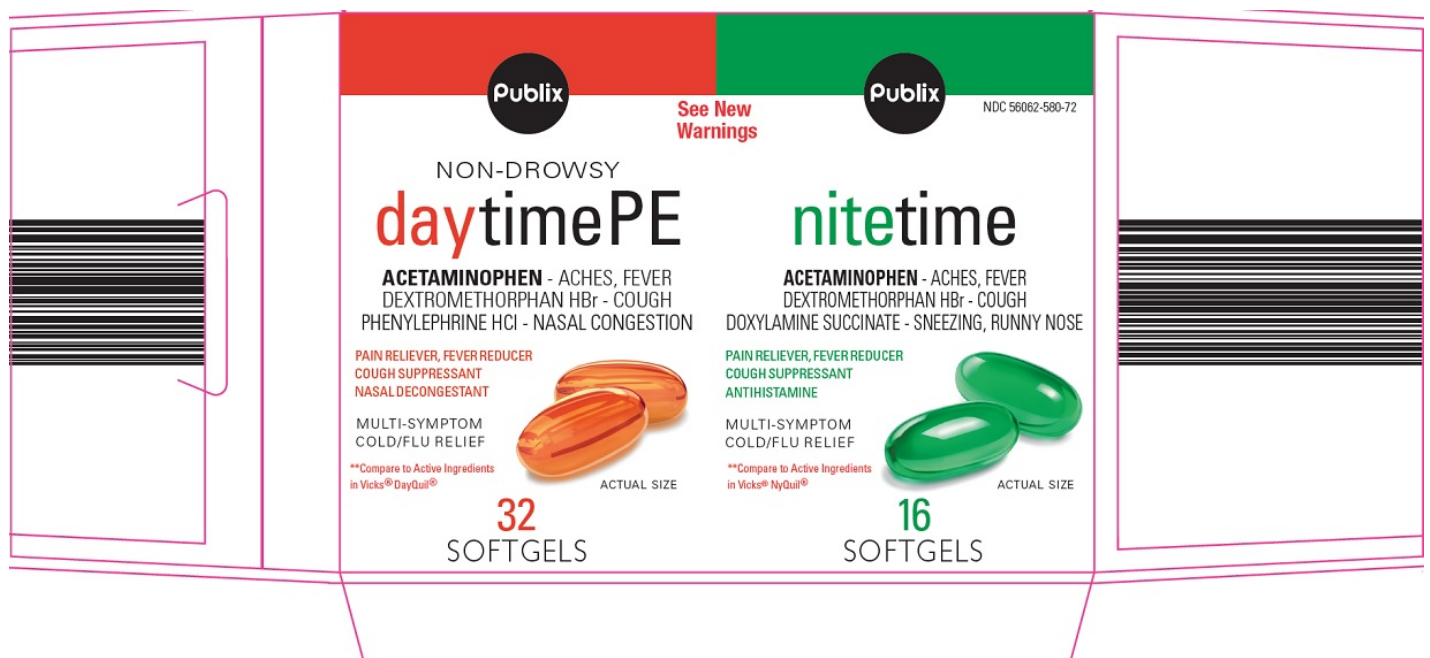
nitetime



ACETAMINOPHEN – ACHES, FEVER
DEXTROMETHORPHAN HBr – COUGH
DOXYLAMINE SUCCINATE – SNEEZING, RUNNY NOSE
PAIN RELIEVER, FEVER REDUCER
COUGH SUPPRESSANT

ANTIHISTAMINE
MULTI-SYMPPTOM
COLD/FLU RELIEF

Compare to Active Ingredients in Vicks® NyQuil®

ACTUAL SIZE
16 SOFTGELS



: 56072 63 C2 0 4 14 15 4 1773 1 OPEN OTHER END	Nighttime Cold & Flu Drug Facts Active ingredients (in each softgel) 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 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 redness ■ blisters ■ rash If a skin reaction occurs, stop use and seek medical help right away. ▼	Daytime Cold & Flu Drug Facts Active ingredients (in each softgel) Acetaminophen 325 mg.....Pain reliever/fever reducer Dextromethorphan HBr 10 mg.....Cough suppressant Phenylephrine HCl 5 mg.....Nasal decongestant Uses temporarily relieves common cold/flu symptoms: ■ cough due to minor throat and bronchial irritation ■ minor aches and pains ■ sore throat ■ headache ■ nasal congestion ■ 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 redness ■ blisters ■ rash If a skin reaction occurs, stop use and seek medical help right away. ▼	 Made in Canada DISTRIBUTED BY PUBLIX SUPER MARKETS, INC. 3300 PUBLIX CORPORATE PARKWAY LAKELAND, FL 33811 publix.com PARENTS: Learn about teen medicine abuse www.StopMedicineAbuse.org CONVENIENT RECLOSING TAB											
	Drug Facts (continued) 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 ■ 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 or pharmacist before use if you are ■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin When using this product ■ 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 Stop 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 rash or headache that lasts. These could be signs of a serious condition. ▼	Drug Facts (continued) 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 ■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ 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 ■ diabetes 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 ■ 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. ▼												
	Drug Facts (continued) 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 ■ take only as directed - see overdose warning ■ do not exceed 4 doses per 24 hrs <table border="1"> <tr> <td>adults & children 12 yrs & over</td> <td>2 softgels with water every 6 hrs</td> </tr> <tr> <td>children 4 to under 12 yrs</td> <td>ask a doctor</td> </tr> <tr> <td>children under 4 yrs</td> <td>do not use</td> </tr> </table> Other information ■ store at 20-25°C (68-77°F) Inactive ingredients 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	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	Drug Facts (continued) 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 ■ take only as directed - see overdose warning ■ do not exceed 4 doses per 24 hrs <table border="1"> <tr> <td>adults & children 12 yrs & over</td> <td>2 softgels with water every 4 hrs</td> </tr> <tr> <td>children 4 to under 12 yrs</td> <td>ask a doctor</td> </tr> <tr> <td>children under 4 yrs</td> <td>do not use</td> </tr> </table> Other information ■ store at 20-25°C (68-77°F) Inactive ingredients 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	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
	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													
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													

DAYTIME PE NITETIME				
acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-580	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-580-72	1 in 1 CARTON; Type 0: Not a Combination Product	07/07/2014	
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 hbr, doxylamine succinate capsule, gelatin coated

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 (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	GREEN (clear)	Score	no score
Shape	CAPSULE	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	02/17/2014	

Part 2 of 2

DAYTIME PE

acetaminophen, dextromethorphan hbr, phenylephrine hcl 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 (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	CAPSULE	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	11/02/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/07/2014	

Labeler - Publix Super Markets Inc (006922009)

Revised: 12/2018

Publix Super Markets Inc