# DAY TIME NON DROWSY- acetaminophen, dextromethorphan hbr, phenylephrine hcl solution 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.

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# Publix Super Markets, Inc. DayTime Drug Facts

## Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

## **Purpose**

Pain reliever/fever reducer Cough suppressant Nasal decongestant

#### Uses

- temporarily relieves common cold/flu symptoms:
- cough due to minor throat and bronchial irritation
- nasal congestion
- minor aches and pains
- sore throat
- headache
- fever

# Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

# 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 5 days (children) or 7 days (adults)
- 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**

- take only as directed see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

#### Other information

- each 15 mL contains: sodium 7 mg
- store at 68-77°F (20-25°C)

# Inactive ingredients

butylated hydroxyanisole, edetate disodium, FD&C yellow no. 6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

# **Principal Display Panel**

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daytime

**ACETAMINOPHEN** 

**DEXTROMETHORPHAN HBr** 

PHENYLEPHRINE HCI

MULTI-SYMPTOM COLD & FLU RELIEF

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Nasal Decongestant

ALCOHOL FREE Compare to active ingredients in Vicks  $^{\circledR}$  DayQuil  $^{\circledR}$  Cold & Flu 12 FL OZ (355 mL)



# daytime

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12 FL OZ (355 mL)

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#### Drug Facts (continued)

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> PUBLIX GUARANTEE: COMPLETE SATISFACTION OR YOUR MONEY BACK

## Publix.

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

# PARENTS

www.StopMedicineAbuse.org

#### Drug Facts

cetaminophen

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Purpose

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■ blisters ■ rash If a skin reaction occurs, stop use and seek medical help right away.

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#### Drug Facts (continued)

Stop use and ask a doctor if you get nervous, dizzy or sleepless ■ pain, nasal congestion or cough gets worse or lasts more than 5 days (children) or 7 days (adults) ■ 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.

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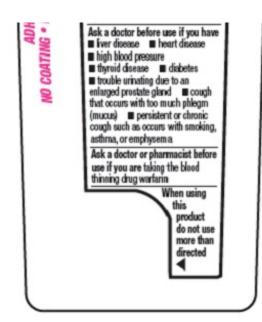
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adults & children 30 mL every 4hrs 12yrs&over children 6 to under 12 yrs 15 mL every 4 hrs

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# **DAY TIME NON DROWSY**

acetaminophen, dextromethorphan hbr, phenylephrine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-656
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg in 15 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL	

Inactive Ingredients		
Ingredient Name	Strength	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GLYCERIN (UNII: PDC6A3C0OX)		
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)		
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SUCROSE (UNII: C151H8M554)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	ORANGE (clear)	Score	
Shape		Size	
Flavor	MENTHOL (with fruit)	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:56062-656-	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2006	05/16/2013
NDC:56062-656- 40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/08/2006	

# Labeler - Publix Super Markets Inc (006922009)

Revised: 2/2023 Publix Super Markets Inc