**DAYTIME- acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled**
**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 softgel)**

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:

- 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**

- 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**

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.

**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

| | |
|---|---|
| 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

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

P

daytime

ACETAMINOPHEN

DEXTROMETHORPHAN HBr

PHENYLEPHRINE HCl

Pain reliever

Fever reducer

Cough suppressant

Nasal decongestant

MULTI-SYMPTOM COLD & FLU RELIEF

ACTUAL SIZE

24 SOFTGELS

Compare to the active ingredients in Vicks® Day Quil® Cold & Flu

CONVENIENT RECLOSING TAB

## Drug Facts

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

| Active ingredients (in each softgel) | Purpose |
|---|---|
| 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
- nasal congestion
- sore throat
- headache
- fever

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take
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- 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**
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- trouble urinating due to an enlarged prostate gland
- liver disease
- heart disease
- high blood pressure
- thyroid disease
- 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
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| children 4 to under 12 yrs | ask a doctor |
| children under 4 yrs | do not use |

▲

**Drug Facts** (continued)

**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

**This product is not manufactured or distributed by the owner of the registered trademarks Vicks® DayQuil®.

OPEN OTHER END

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NDC 56062-417-62

# daytime

## ACETAMINOPHEN
## DEXTROMETHORPHAN HBr
## PHENYLEPHRINE HCl

Pain reliever
Fever reducer
Cough suppressant
Nasal decongestant

MULTI-SYMPTOM
COLD & FLU RELIEF

ACTUAL SIZE

24 SOFTGELS

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

# DAYTIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:56062-417 |
| **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: 3WQ0SDW1A) | |
| **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** | NDC:56062-417-62 | 12 in 1 CARTON | 08/30/2018 | |
| **1** | | 2 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

| | | | | |
|---|---|---|---|---|
| **2** | NDC:56062-417-73 | 8 in 1 CARTON | 11/18/2022 | |
| **2** | | 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 | 08/30/2018 | |

## Labeler - Publix Super Markets Inc (006922009)

Revised: 11/2022 Publix Super Markets Inc