**SEVERE COLD AND FLU- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, coated**
**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. Severe Cold & Flu Drug Facts**

**Active ingredients (in each caplet)**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

**Purpose**

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

**Uses**

- for the temporary relief of the following cold/flu symptoms:
- minor aches and pains
- headache
- sore throat
- nasal congestion
- cough
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces 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, 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
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)

**Ask a doctor or pharmacist before use if you are**

taking the blood thinning drug warfarin

**When using this product**

**do not exceed recommended dosage**

**Stop use and ask a doctor if**

- nervousness, dizziness or sleeplessness occur
- 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**

- **do not take more than directed (see overdose warning)**

| | |
|---|---|
| adults and children 12 years and over | • take 2 caplets every 4 hours<br>• swallow whole – do not crush, chew or dissolve<br>• do not take more than 10 caplets in 24 hours |
| children under 12 years | ask a doctor |

**Other information**

- **each caplet contains:** sodium 3 mg
- store at 20-25°C (68-77°F)

**Inactive ingredients**

acesulfame potassium, carnauba wax, croscarmellose sodium, crospovidone, D&C yellow #10 aluminum lake, flavor, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

**Principal Display Panel**

severe cold & flu

ACETAMINOPHEN – PAIN RELIEVER/FEVER REDUCER

PHENYLEPHRINE HCl – NASAL DECONGESTANT

DEXTROMETHORPHAN HBr – COUGH SUPPRESSANT

GUAIFENESIN – EXPECTORANT

Headache/Fever/Sore Throat

Nasal Congestion/Cough

Chest Congestion/Clears Out Mucus

For Adults

ACTUAL SIZE

24 CAPLETS

Compare to the Active Ingredients in Tylenol® Cold + Flu Severe

Publix

NDC 56062-319-62

# severecold&flu

**ACETAMINOPHEN** - PAIN RELIEVER/FEVER REDUCER
PHENYLEPHRINE HCl - NASAL DECONGESTANT
DEXTROMETHORPHAN HBr - COUGH SUPPRESSANT
GUAIFENESIN - EXPECTORANT

• Headache/Fever/Sore Throat • Nasal Congestion/Cough • Chest Congestion/Clears Out Mucus

For Adults

ACTUAL SIZE

*Compare to the Active Ingredients in Tylenol® Cold + Flu Severe

24 CAPLETS

# SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:56062-319 |
| **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 |
| **GUAIFENESIN** (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 200 mg |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **ACESULFAME POTASSIUM** (UNII: 23OV73Q5G9) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **CROSPOVIDONE (15 MPA.S AT 5%)** (UNII: 68401960MK) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POLYVINYL ALCOHOL, UNSPECIFIED** (UNII: 532B59J990) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | YELLOW | **Score** | no score |
| **Shape** | OVAL | **Size** | 20mm |
| **Flavor** | | **Imprint Code** | L234 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:56062-319-62 | 12 in 1 CARTON | 04/08/2015 | |

| | | | | |
|---|---|---|---|---|
| **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 | 04/08/2015 | |

## Labeler - Publix Super Markets Inc (006922009)

Revised: 11/2020 Publix Super Markets Inc