

COLD RELIEF MULTI SYMPTOM- acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet, film 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.

Publix Super Markets, Inc. Multi-Symptom Cold Relief Drug Facts

Active ingredients (in each caplet)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these common cold/flu symptoms:
- minor aches and pains
- headache
- sore throat
- nasal congestion
- cough
- sinus congestion and pressure
- helps clear nasal passages
- promotes nasal and sinus drainage
- 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, 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 | <ul style="list-style-type: none">• take 2 caplets every 4 hours• swallow whole – do not crush, chew or dissolve• do not take more than 10 caplets in 24 hours |
| children under 12 years | ask a doctor |

Inactive ingredients

acesulfame potassium, carnauba wax, crospovidone, flavor, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Principal Display Panel

MULTI-SYMPTOM

cold relief

ACETAMINOPHEN – FEVER/HEADACHE/SORE THROAT

PHENYLEPHRINE HCl – NASAL CONGESTION

DEXTROMETHORPHAN HBr – COUGHING

pain reliever/fever reducer – nasal decongestant – cough suppressant

For Adults

24 CAPLETS

ACTUAL SIZE

Compare to the Active Ingredients in Tylenol® Cold Max

Publix

NDC 56062-371-62

MULTI-SYMPTOM cold relief

ACETAMINOPHEN - FEVER/HEADACHE/SORE THROAT
PHENYLEPHRINE HCl - NASAL CONGESTION
DEXTROMETHORPHAN HBr - COUGHING

- pain reliever/fever reducer • nasal decongestant • cough suppressant

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24 CAPLETS

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

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PUBLIX GUARANTEE:
COMPLETE SATISFACTION OR YOUR MONEY BACK

Important Read all product information before using. Keep this box for important information.

Drug Facts

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Drug Facts (continued)

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Drug Facts (continued)

Inactive ingredients acesulfame potassium, carnauba wax, croscavidone, flavor, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Store at 20-25°C (68-77°F).

37162 63 C2



SEALED IN BLISTER UNIT FOR YOUR PROTECTION.
IF BROKEN OR TORN RETURN TO STORE.

*This product is not manufactured or distributed by the owner of the registered trademark Tylenol®.

COLD RELIEF MULTI SYMPTOM

acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:56062-371 |
| 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 |
|---|----------|
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|---------------------|---------------------|----------|
| Color | WHITE | Score | no score |
| Shape | CAPSULE (caplet) | Size | 17mm |
| Flavor | VANILLA ((menthol)) | Imprint Code | L371 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:56062-371-62 | 12 in 1 CARTON | 09/21/2015 | |
| 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 | 09/21/2015 | |

