

**DOLOMAX COLD COUGH- acetaminophen, dextromethorphan hydrobromide,  
guaifenesin, phenylephrine hydrochloride tablet  
BENARD INDUSTRIES INC**

-----  
**DoloMax® Cold Cough**

***Drug Facts***

***Active ingredients (in each tablet)***

Acetaminophen 325 mg  
Dextromethorphan HBr 10 mg  
Guaifenesin 200 mg  
Phenylephrine HCl 5 mg

***Purpose***

Pain Reliever  
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.

The maximum daily dose of this product is 10 tablets (3,250 mg acetaminophen) in 24 hours.

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**

- liver 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 blood thinning drug warfarin

**When using this product do not exceed recommended dose**

**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<br>12 years and over | <ul style="list-style-type: none"> <li>• take 2 tablets every 4 hours</li> <li>• swallow whole; do not crush, chew or dissolve</li> <li>• do not take more than 10 tablets in 24 hours</li> </ul> |
| children under 12<br>years               | ask a doctor  |

**Other information**

- **each tablet contains:** sodium 2 mg
- store at 20°-25°C (68°-77°C)

## ***Inactive ingredients***

croscarmellose sodium, D&C Yellow #10 aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, pregelatinized starch, silicon dioxide, sodium starch glycolate, stearic acid, titanium dioxide, triacetin

## ***Questions or comments?***

**1.800.595.0480 Mon-Fri: 9 AM to 4 PM**

## **SEE NEW WARNINGS INFORMATION & DIRECTIONS**

### **Cold/Cough Medicine**

### **OTC EXCELLENCE IN NUTRITION™**

- > **Head & Body Aches**
- > **Nasal Congestion**
- > **Fever**
- > **Sore Throat**
- > **Cough**
- > **Sinus Pain**

**READ AND KEEP CARTON FOR NEW WARNINGS INFORMATION & DIRECTIONS.**

**SEE ACETAMINOPHEN WARNINGS**

**RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION**

**TAMPER EVIDENT: DO NOT USE IF BLISTER IS CUT OR BROKEN**

**Distributed by**

**OTC Pharmaceutical Products**

10860 Nw 27th St , Doral , FL 33172

**[www.otcpharmausa.com](http://www.otcpharmausa.com)**

## **Packaging**





Distributed by  
**OTC**  
 Pharmaceutical Products  
 10660 NW 27th St., Dept. J1  
 www.otcpharmusa.com

**RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION**  
**TAMPER EVIDENT: DO NOT USE IF BLISTER IS CUT OR BROKEN**  
 Questions or comments? 1-800-555-0460 Mon-Fri: 9 AM to 4 PM

**Drug Facts (continued)**

**Warnings**  
 Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 tablets (3,250 mg acetaminophen) in 24 hours. 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 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**  
 ■ liver disease ■ high blood pressure ■ thyroid disease

**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

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

**Adults and children 12 years and over**  
 ■ take 2 tablets every 4 hours  
 ■ swallow whole; do not crush, chew or

**Other information**  
 Each tablet contains: sodium 2 mg ■ store at 20°-25°C (68°-77°F)

**Keep out of reach of children.**  
 If pregnant or breast-feeding, ask a health professional before use.  
 These could be signs of a serious condition.  
 ■ back or occurs with rash or headache that lasts  
 ■ 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  
 ■ 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

**When using this product do not exceed recommended dose**  
 Ask a doctor or pharmacist before use if you are taking blood thinning drug warfarin

**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

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

**Adults and children 12 years and over**  
 ■ take 2 tablets every 4 hours  
 ■ swallow whole; do not crush, chew or

**Drug Facts (continued)**

**Active ingredients (in each tablet)**  
 Acetaminophen 325 mg ■ Pain Reliever  
 Dextromethorphan HBr 10 mg ■ Cough suppressant  
 Guaifenesin 200 mg ■ Expectorant  
 Phenylephrine HCl 5 mg ■ Nasal decongestant

**Purpose**  
 Pain Reliever  
 Cough suppressant  
 Expectorant  
 Nasal decongestant

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

**Adults and children 12 years and over**  
 ■ take 2 tablets every 4 hours  
 ■ swallow whole; do not crush, chew or

# DRUG FACTS LABEL

**Drug Facts**

**Active ingredients (in each tablet)**

| Active ingredients (in each tablet) | Purpose            |
|-------------------------------------|--------------------|
| Acetaminophen 325 mg                | Pain Reliever      |
| Dextromethorphan HBr 10 mg          | Cough suppressant  |
| Guaifenesin 200 mg                  | Expectorant        |
| Phenylephrine HCl 5 mg              | 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. The maximum daily dose of this product is 10 tablets (3,250 mg acetaminophen) in 24 hours. 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,

**Drug Facts (continued)**

**Ask a doctor before use if**  
 ■ liver 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 blood thinning drug warfarin**

**When using this product do not exceed recommended dose**

**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 tablets every 4 hours  
 ■ swallow whole; do not crush, chew or

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**

- liver disease ■ high blood pressure ■ thyroid disease ➤

children 12 years and over ■ swallow whole, do not crush, chew or dissolve ■ do not take more than 10 tablets in 24 hours

children under 12 years ask a doctor

**Other information**

■ each tablet contains: sodium 2 mg ■ store at 20°-25°C (68°-77°C)

**Inactive ingredients** croscarmellose sodium, D&C Yellow #10 aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, pregelatinized starch, silicon dioxide, sodium starch glycolate, stearic acid, titanium dioxide, triacetin

**Drug Facts (continued)**

Questions or comments?

1.800.595.0480 Mon-Fri: 9 AM to 4 PM

**DOLOMAX COLD COUGH**

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:55959-133 |
| <b>Route of Administration</b> | ORAL           |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength             | Strength |
|--|-------------------------------|----------|
| <b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)                    | ACETAMINOPHEN                 | 325 mg   |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg    |
| <b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)                        | GUAIFENESIN                   | 200 mg   |
| <b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)      | PHENYLEPHRINE HYDROCHLORIDE   | 5 mg     |

**Inactive Ingredients**

| Ingredient Name   | Strength |
|---|----------|
| <b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)               |          |
| <b>D&amp;C YELLOW NO. 10 ALUMINUM LAKE</b> (UNII: CQ3XH3DET6) |          |
| <b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)           |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)                  |          |
| <b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)                        |          |
| <b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)          |          |
| <b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)               |          |
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)                        |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                     |          |
| <b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)      |          |

|  |  |
|--|--|
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)     |  |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) |  |
| <b>TRIACETIN</b> (UNII: XHX3C3X673)        |  |

### Product Characteristics

|                 |                       |                     |          |
|-----------------|-----------------------|---------------------|----------|
| <b>Color</b>    | yellow (light yellow) | <b>Score</b>        | no score |
| <b>Shape</b>    | capsule               | <b>Size</b>         | 19mm     |
| <b>Flavor</b>   |                       | <b>Imprint Code</b> |          |
| <b>Contains</b> |                       |                     |          |

### Packaging

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:55959-133-01 | 1 in 1 BOX  | 07/05/2021           |                    |
| 1 |                  | 12 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 Drug | M012                                     | 07/05/2021           |                    |

**Labeler** - BENARD INDUSTRIES INC (106700321)

Revised: 10/2024

BENARD INDUSTRIES INC