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

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 12 years and over	• take 2 tablets every 4 hours • 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

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

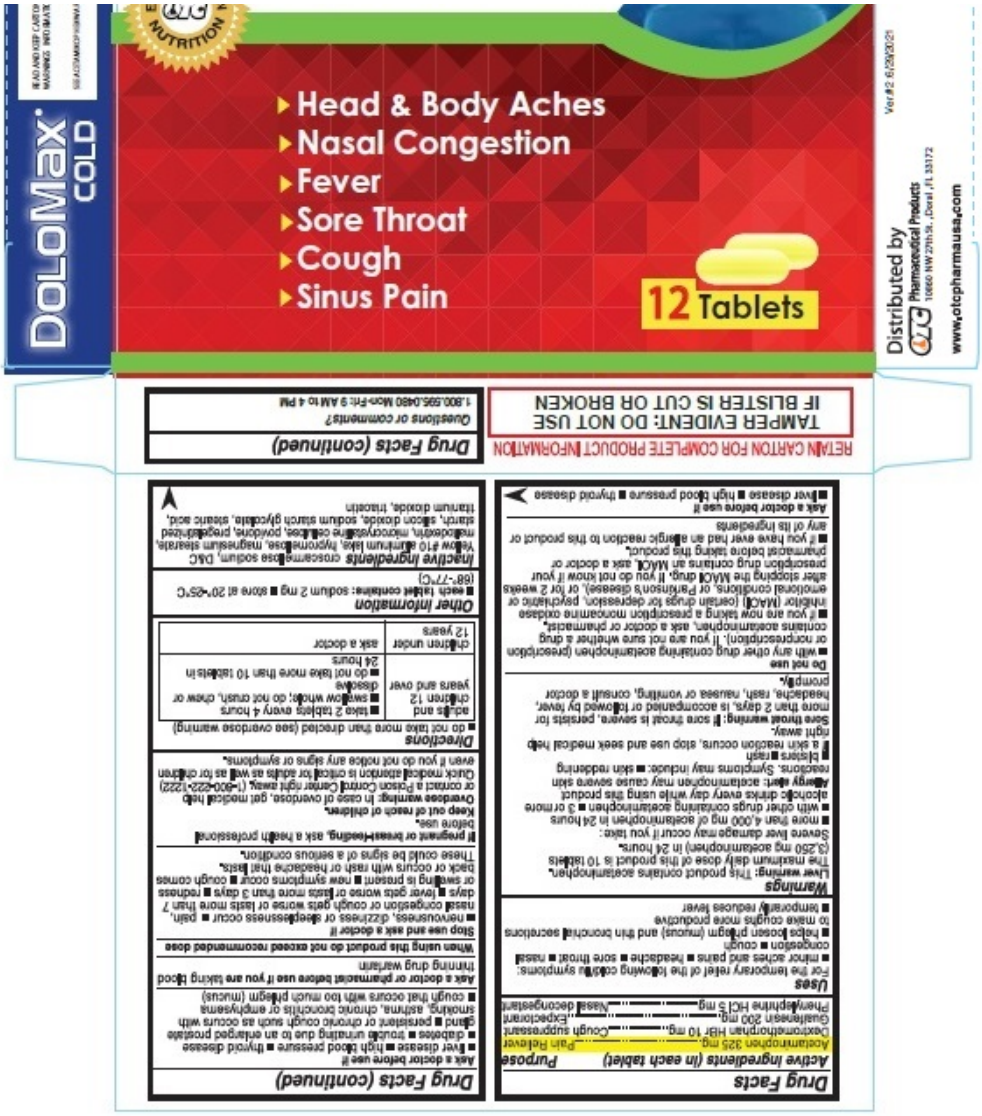
RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

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

Packaging



DRUG FACTS LABEL

Drug Facts

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

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)

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

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 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			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55959-133
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	yellow (light yellow)	**Score**	no score
Shape	capsule	**Size**	19mm
Flavor		**Imprint Code**	
Contains			

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 final	part341	07/05/2021	

Labeler - BENARD INDUSTRIES INC (106700321)

Revised: 7/2021 BENARD INDUSTRIES INC