

**DOLOMAX COLD COUGH- acetaminophen, guaifenesin, phenylephrine hcl,
dextromethorphan 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

Uses:

temporarily relieves these symptoms due to the common cold:

- nasal congestion
- headache
- minor aches and pains chest congestion
- cough
- sore throat
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and makes coughs more productive
- temporarily reduces fever

Active Ingredients

Active Ingredient (in each tablet)

Purpose

Acetaminophen 325 mg	Pain Reliever/Fever Reducer
Guaifenesin 200mg	Expectorant
Phenylephrine HCl 5mg	Decongestant
Dextromethorphan HBr 15mg	Antitussive

Warnings

Liver Warning: this product contains acetaminophen. The maximum daily dose of this product is 8 tablets (2,600 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

Sore throat warning: if sore throat is severe, persists more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consults a doctor promptly.

Do not use

- with any other drugs containing acetaminophen (prescription or non prescription) 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 ie emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription contains MAOI, ask a doctor or

pharmacist before taking this product.

- if you have ever had an allergic reactions 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 sedatives, tranquilizers or the blood thinning drug warfarin.

When using this product do not exceed recommended dose.

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occurs
- pain, cough, or nasal congestion gets worse or last more than 7 days
- fever gets worse or lasts for more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache. 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 immediately (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 use more than directed (see overdose warning)

Adults and children 12 years and over	☐ take 2 tablets every 6-8 hours. ☐ do not take more than 8 tablets in 24 hours
Children under 12 years	consult a doctor

Other Information

do not use if blister package is torn, cut or open

☐ store at room temperature ☐ avoid excessive heat and humidity

Inactive Ingredients: Maltodextrin, Microcrystalline Cellulose, Povidone, Sodium Starch Glycolate, Starch, Stearic Acid.

Questions / COmments: (305)594-0480

KEEP OUT OF REACH OF CHILDREN

INDICATIONS & USAGE

- temporarily relieves these symptoms due to the common cold:
- nasal congestion
- headache
- minor aches and pains chest congestion
- cough
- sore throat
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- temporarily reduces fever

<p>Drug Facts (continued)</p> <p>Uses: • temporarily relieves these symptoms due to the common cold: • nasal congestion • headache • minor aches and pains chest congestion • cough • sore throat • help loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive • temporarily reduces fever</p> <p>Warnings: Liver Warnings: This product contains acetaminophen. The maximum daily dose of this product is 3 tablets (3,600 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take more than 3,600 mg of acetaminophen in 24 hours. • If other drugs containing acetaminophen • 3 or more alcoholic drinks every day will add to this product. Severe liver warning: If you feel it is worse, persists more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.</p> <p>Do not use: • with any other drugs containing acetaminophen (prescription or non-prescription) • 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 anti-anxiety conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains a 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.</p> <p>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)</p> <p>Ask a doctor or pharmacist before use if you are taking sedatives, tranquilizers or the blood thinning drug warfarin.</p> <p>When using this product do not exceed recommended dose.</p> <p>Stop use and ask a doctor if: • nervousness, dizziness or sleeplessness occur • pain, cough or nasal congestion gets worse or lasts for more than 7 days • fever gets worse or lasts for more than 3 days • redness or swelling in ear area • new symptoms occur • cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.</p> <p>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 immediately at 1-800-222-1222. Child medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p>Directions • do not use more than directed (see overdose warnings). Adults and children 12 years and over: • take 2 tablets every 6-8 hours. • do not take more than 3 tablets in 24 hours. Children under 12 years: consult a doctor.</p> <p>Other Information do not use if blister package is torn, cut or creased • store at room temperature • avoid excessive heat and humidity</p>	<p>Datos del medicamento (continuación)</p> <p>Usos: • Alivia temporal de los síntomas del resfriado común: • congestión nasal • congestión de pecho • tos • dolor de garganta • dolores menores • dolor de cabeza • secreciones bronquiales • reduce temporalmente la fiebre</p> <p>Advertencias: Advertencia de Hígado: Este producto contiene acetaminofén (la dosis máxima permitida es de 3 tabletas (3,600 mg de acetaminofén) en 24 hrs. Puede causar daño severo al hígado si toma más de 3,600 mg de acetaminofén en 24 horas. • Si toma con otros medicamentos que contengan acetaminofén • con 3 o más bebidas alcohólicas por día mientras se consume este producto. Advertencia sobre dolor de garganta: Si el dolor de garganta persiste más de 2 días y está acompañado de fiebre, dolor de cabeza, sarpullido, náuseas o vómitos consulte a su médico de inmediato.</p> <p>NO USE: • con otros productos que contengan acetaminofén (prescritos o de venta libre) si no está seguro si un producto contiene acetaminofén consulte a su médico o farmacéutico • si toma inhibidores de la monoaminoxidasa (IMAO), ciertos medicamentos para la depresión o condiciones emocionales o psicológicas o enfermedad de Parkinson, o si está seguro de que su receta contiene un IMAO, consulte a un profesional de la salud antes de tomar este producto. Si usted alguna vez tuvo alguna reacción alérgica a este producto o alguno de sus ingredientes.</p> <p>Pregunte a su doctor antes de usar si Uds. tiene: • enfermedad hepática • enfermedad del corazón • presión alta • problemas de riñón • problemas para orinar debido al agrandamiento de la próstata • los acompañados de fiebre excesiva (muchedumbre) • lo hipertensión o crónica (como la de los fumadores), asma, bronquitis crónica o emfisema</p> <p>Pregunte a su doctor o farmacéutico antes de usar si Ud. toma tranquilizantes o el anti-coagulante warfarin</p> <p>Cuando use este producto no tome más de lo indicado</p> <p>Día de usarlo y consulte a su doctor si: • aparecen mareos o somnolencia • el dolor, tos o congestión nasal empeora o dura más de 7 días • la fiebre sube o dura más de 3 días • el agrandamiento de la glándula se presenta en la oreja • sueño excesivo • tos persiste más de 7 días, regresa acompañada de fiebre, infección o dolor de cabeza persistente. Estos pueden ser síntomas de una condición más seria.</p> <p>Si está embarazada o lactando, consulte a su médico antes de usar este producto. Mantenga fuera del alcance de los niños. En caso de verse embarazada consulte a su médico o contacte al Centro de Control de Venenos en español (1-800-222-1222). La atención médica inmediata es necesaria para niños (trato como para adultos hasta cuando no se presentan síntomas de envenenamiento).</p> <p>Indicaciones: No utilizar más de lo indicado (vea advertencias de sobredosis)</p> <p>Miembros y adultos 12 años y más: • tome 2 tabletas cada 6-8 hrs. • no exceda 3 tabletas en 24 hrs.</p> <p>Miembros menores de 12 años: consulte a su médico</p> <p>Otra información: no utilizar en caso que el blister este roto, cortado o abollado • guardar a temperatura ambiente • evitar exceso de humedad</p>
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<p>Drug Facts (continued)</p> <p>Inactive Ingredients: Methylparaben, Microcrystalline Cellulose, Povidone, Sodium Starch Glycolate, Starch, Stearic Acid.</p> <p>Questions / Comments: (202) 594-0482</p>	<p>Datos del medicamento (continuación)</p> <p>Ingredientes Inactivos: Metilparabeno, Celulosa Microcristalina, Povidona, Almidón Sódico Glicolato, Almidón, Ácido Estéarico.</p> <p>Preguntas / Comentarios: (202) 594-0482</p>
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LEA NUEVAS INFORMACIONES
ADVERTENCIAS Y DIRECCIONES

SEE NEW WARNINGS
INFORMATION & DIRECTIONS

DOLO-Max

COLD GRIPE

Cold/Cough Medicine Gripe y Tos



- ▶ Headaches & Body Aches
- ▶ Nasal Congestion
- ▶ Fever and Sore Throat
- ▶ Coughing
- ▶ Sinus Pain

- ▶ Dolor de Cuerpo y Cabeza
- ▶ Congestión/ Secreción Nasal
- ▶ Fiebre y Dolor de Garganta
- ▶ Tos



12 Tablets / Tablet as

DOLO-Max

COLD / GRIPE

LEA NUEVAS INFORMACIONES
ADVERTENCIAS Y DIRECCIONES

SEE NEW WARNINGS
INFORMATION & DIRECTIONS

Distributed by

 ATC Pharmaceutical Products
 1445713201

Drugs Facts		Datos del medicamento	
Active Ingredient (in each tablet)	Pain Reliever/Fever Reducer	Ingredientes Activos (por tableta)	Propósito
Acetaminophen 325 mg	Relieve del dolor y reduce la fiebre	Acetaminofén 325 mg	Alivia el dolor y reduce la fiebre
Guafenesin 200 mg	Expectorant	Guafenesina 200 mg	Expectorante
Phenylephrine HCl 5mg	Decongestant	Fenilefrina HCl 5mg	Descongestionante
Dextromethorphan HBr 15mg	Antitussive	Dextrometorfán HBr 15mg	Supresor de la tos

DOLOMAX COLD COUGH
 acetaminophen, guaifenesin, phenylephrine hcl, dextromethorphan tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55959-132
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

Inactive Ingredients

Ingredient Name	Strength
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
povidone (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	capsule	Size	6mm
Flavor	grape	Imprint Code	FR12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55959-132-01	1 in 1 BOX	12/01/2017	
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	12/01/2017	

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

Name	Address	ID/FEI	Business Operations
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BENARD INDUSTRIES INC		106700321	label(55959-132)
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Establishment

Name	Address	ID/FEI	Business Operations
ULTRAtab Laboratories, Inc		151051757	manufacture(55959-132)

Revised: 12/2017

BENARD INDUSTRIES INC