

**NEXT NIGHT TIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan,
doxylamine succinate capsule, liquid filled
Genomma Lab USA**

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.

Drug Facts

Active ingredient

Acetaminophen 325 mg
Dextromethorphan HBr 15 mg
Doxylamine succinate 6.25 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Antihistamine

Uses

temporarily relieves common cold and flu symptoms: cough due to minor throat and bronchial irritation
sore throat headache minor aches and pains fever, runny nose and sneezing

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take more than 4 doses in 24 hours, which is the maximum daily amount for this product 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 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 products 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 drugs. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product to make a child sleep

Ask a doctor before use if you have

liver disease glaucoma cough that occurs with too much phlegm (mucus) a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema trouble urinating due to enlarged prostate gland

When using this product

do not exceed recommended dosage excitability may occur, especially in children marked drowsiness may occur avoid alcoholic drink be careful when driving a motor vehicle or operating machinery alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

pain or cough gets worse or lasts more than 7 days fever gets worse or last 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

In case of accidental overdose, contact a doctor or Poison Control Center immediately (1-800-222-1222). Taking more than the recommended dose can cause serious health problems. Quick medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

Directions

- take only as recommended (see Warnings)
 - do not exceed 4 doses per 24 hours
- Adults and children 12 years and over: ■ take 2 softgels with water every 6 hours
Children 4 to under 12 years: ■ Ask a doctor
Children under 4 years: ■ Do not use

Other information

store at room temperature do not use if blister is torn or open

Inactive Ingredients

FD&C Green #3, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol. May also contain FD&C Blue #1, D&C Yellow Yellow #10, titanium dioxide.

Questions or comments

Call toll free 1-877-99-GENOM (43666)

Package/Label Principal Display Panel

The product is not manufactured or distributed by Procter & Gamble, distributor of Next.[®]
 Next[®] Cold & Flu Softgels
¿Preguntas o comentarios? Llame al 1-877-99-GENOM (43666) Lunes a Viernes de 8 am a 6 pm
Ingredientes activos (In each softgel)
 Acetaminophen 325 mg, Dextromethorphan HBr 15 mg, Doxylamine succinate 6.25 mg
 Distribuido por / Distributed by: Genomina Lab USA, Inc. Houston, TX 77027
 LBI3671
 R1014

NEXT[®]

NIGHTTIME COLD & FLU RELIEF

ALIVIO DEL RESFRIADO Y GRIPE PARA LA NOCHE

Acetaminophen / Dextromethorphan HBr / Doxylamine succinate
Paracetamol / Dextrometorfano HBr / Succinato de Doxilamina

⚡ Aches/Dolor

⚡ Sneezing/Estornudo

⚡ Runny Nose/Flujo Nasal

⚡ Fever/Fiebre

⚡ Cough/Tos

⚡ Sore Throat/Dolor de Garganta

10 Softgels / Cápsulas blandas

Genomina Lab[®]



Drug Facts	Información del Medicamento												
<p>Active ingredient (in each softgel)</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Acetaminophen 325 mg</td> <td style="width: 40%;">Pain reliever/fever reducer</td> </tr> <tr> <td>Dextromethorphan HBr 15 mg</td> <td>Cough suppressant</td> </tr> <tr> <td>Doxylamine succinate 6.25 mg</td> <td>Antihistamine</td> </tr> </table> <p>Uses Temporarily relieves common cold and flu symptoms: ■ cough due to minor throat and bronchial irritation ■ sore throat ■ headache ■ minor aches and pains ■ fever ■ runny nose and sneezing</p>	Acetaminophen 325 mg	Pain reliever/fever reducer	Dextromethorphan HBr 15 mg	Cough suppressant	Doxylamine succinate 6.25 mg	Antihistamine	<p>Ingredientes activos (en cada cápsula)</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Paracetamol 325 mg</td> <td style="width: 40%;">Analgésico / Antipirético</td> </tr> <tr> <td>Dextrometorfano HBr 15 mg</td> <td>Antitusivo</td> </tr> <tr> <td>Succinato de Doxilamina 6.25 mg</td> <td>Antihistamínico</td> </tr> </table> <p>Usos Alivia temporalmente los síntomas comunes del resfriado y de la gripe: ■ los debida a irritación menor de la garganta y bronquial ■ dolor de garganta ■ dolor de cabeza ■ dolores menores y dolencias ■ fiebre ■ dolores menores y dolencias</p>	Paracetamol 325 mg	Analgésico / Antipirético	Dextrometorfano HBr 15 mg	Antitusivo	Succinato de Doxilamina 6.25 mg	Antihistamínico
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Drug Facts (continued)	Información del Medicamento (cont.)
<p>Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4000 mg in 24 hours, which is the maximum daily amount for this product with other drugs containing acetaminophen or 3 or more alcoholic drinks every day while using this product.</p> <p>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.</p> <p>Do not use with any other products 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 drugs. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product to make a child sleep.</p> <p>Ask a doctor before use if you have liver disease ■ glaucoma ■ cough that occurs with too much phlegm (mucus) ■ a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ trouble urinating due to enlarged prostate gland</p> <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin</p> <p>When using this product do not exceed recommended dosage ■ excitability may occur, especially in children ■ marked drowsiness may occur ■ avoid alcoholic drink ■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives, and tranquilizers may increase drowsiness</p> <p>Stop use and ask a doctor if pain or cough gets worse or lasts more than 7 days ■ fever gets worse or last 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.</p> <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of accidental overdose, contact a doctor or Poison Control Center immediately (1-800-222-1222). Taking more than the recommended dose can cause serious health problems. Quick medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.</p> <p>Directions ■ take only as recommended (see Warnings) ■ do not exceed 4 doses per 24 hours ■ Adults and children 12 years and over: take 2 softgels with water every 6 hours ■ Children 4 to under 12 years: ask a doctor ■ Children under 4 years: do not use</p> <p>Other information ■ store at room temperature 20-25°C (68-77°F) ■ do not use if blister is torn or open</p> <p>Inactive ingredients FD&G Green #3, gelatin, glycerin, polyethylene glycol 400, polydextrose, propylene glycol, purified water, sorbitol. May also contain FD&G Blue #1, D&G Yellow #10, titanium dioxide.</p> <p>Questions or comments? Call toll free 1-877-99-GENOM (43666)</p>	<p>Advertencias Advertencia Hepática: Este producto contiene paracetamol. Puede presentarse daño hepático severo si usted toma más de 4000 mg en 24 horas, la cual es la cantidad máxima diaria para este producto en conjunto con otros medicamentos que contienen paracetamol o 3 o más bebidas alcohólicas al día mientras usa este producto.</p> <p>Advertencia sobre el dolor de garganta: Si el dolor de garganta es severo, persiste por más de 2 días, está acompañado o seguido por fiebre, dolor de cabeza, erupción, náusea, o vómito, consulte inmediatamente a su médico.</p> <p>No lo utilice con cualquier otro producto que contenga paracetamol (con o sin prescripción). Si usted no está seguro si un medicamento contiene paracetamol, pregunte a su médico o al farmacéutico. Si actualmente está tomando algún inhibidor de la monoaminooxidasa (MAOI) de prescripción (ciertos medicamentos para la depresión, condiciones psiquiátricas o emocionales, o para la enfermedad de Parkinson) o durante 2 semanas luego de interrumpir los medicamentos MAOI. Si usted no sabe si su medicamento de prescripción contiene un MAOI, consulte a su médico o farmacéutico antes de tomar este producto para hacer dormir a un niño.</p> <p>Consulte a su médico antes de utilizarlo si usted tiene enfermedad hepática ■ glaucoma ■ tos que se presenta con demasiada flema (mucoosidad) ■ problemas respiratorios o los crónica persistente o que se presenta con tabaquismo, asma, bronquitis crónica o enfisema ■ dificultad para orinar debido a dilatación de la glándula prostática</p> <p>Consulte a su médico o farmacéutico antes de utilizarlo si usted está tomando sedantes o tranquilizantes ■ tomando el medicamento anticoagulante warfarina</p> <p>Cuando use este product no exceda la dosis recomendada ■ no exceda la dosis recomendada ■ puede presentarse excitabilidad, especialmente en niños ■ puede presentarse somnolencia marcada ■ evite las bebidas alcohólicas mientras sea cuidadoso cuando conduzca un vehículo o en la operación de maquinaria ■ el alcohol, sedantes y tranquilizantes pueden incrementar la somnolencia</p> <p>Suspenda su uso y consulte a su médico si el dolor o la tos empeoran o duran más de 7 días ■ la fiebre empeora o dura más de 3 días ■ se presentan enrojecimiento o hinchazón ■ se presentan síntomas nuevos ■ regresa la tos, o se presenta con erupción o dolor de cabeza persistente. Estos podrían ser signos de una condición grave.</p> <p>En caso de embarazo o lactancia, pregunte a un profesional médico antes de utilizarlo. Manténgase fuera del alcance de los niños. En caso de sobredosis accidental, contacte inmediatamente a su médico o al Centro de Control de Envenenamiento. El tomar más de la dosis recomendada (sobredosis) puede ocasionar daño hepático. La atención médica inmediata es crítica para adultos al igual que para niños, incluso si usted no nota ningún signo o síntoma.</p> <p>Indicaciones ■ tomar únicamente como se indica (ver Advertencias) ■ no exceder de 4 dosis en 24 horas ■ Adultos y niños de 12 años y mayores: tomar 2 cápsulas blandas con agua cada 4 horas ■ Niños de 4 y menores de 12 años: consulte a su médico ■ Niños menores de 4 años: no administrar</p> <p>Información adicional ■ mantener a temperatura ambiente 20-25 °C (68-77 °F)</p>

Lot:
Exp:

2FNNTCBUEW1A

acetaminophen, dextromethorphan, doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-357
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	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONES (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
May contain	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
May contain	D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
May contain	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-357-09	10 in 1 BOX; Type 0: Not a Combination Product	01/21/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/21/2015	

Labeler - Genomma Lab USA (832323534)

Registrant - Genomma Lab USA (832323534)

Revised: 1/2015

Genomma Lab USA