

**NEXT DAY TIME NON DROWSY COLD AND FLUE- acetaminophen 325 mg,  
dextromethorphan hbr 10 mg, phenylephrine hci 5 mg 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.*

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**Drug Facts**

**Active ingredient**

Acetaminophen 325 mg  
Dextromethorphan HBr 10 mg  
Phenylephrine HCl 5 mg

**Purpose**

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 loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive temporarily reduces fever

**Warnings**

**Liver warning:**

This product contains acetaminophen. Severe liver damage may occur if you take more than 12 caplets in 24 hours, which is the maximum daily amount 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.

**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**

In case of accidental overdose, contact a doctor or Poison Control Center immediately (1-800-222-1222). Taking more than the recommended dose (overdose) may cause liver damage. 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 **Warnings**)

Adults and children 12 years and over: ■ take 2 caplets every 4 hours ■ do not take more than a total of 12 caplets in 24 hours

Children under 12 years: Do not use this adult product in children under 12 years of age. This will provide more than the recommended dose (overdose) and may cause liver damage.

**Other information**

store between 15-30°C (59-86°F) do not use if blister is torn or open

**Inactive Ingredients**

colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, silicone dioxide, stearic acid, titanium dioxide

**Questions or comments?**

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

**Package/Label Principal Display Panel**

DO NOT USE IF BLISTER IS TORN OR OPEN  
NO USAR SI LOS BLISTERS ESTÁN  
ROTOS O ABIERTOS

**Información del Medicamento (cont.)**  
**Ingredientes Inactivos** FD&C Rojo #40, gelatina, glicerina, polietilenglicol 400, povidona, propilenglicol, agua purificada, sorbitol.  
**¿Preguntas o comentarios?** Llame al 1-877-99-GENOM (43666) Lunes a Viernes de 8 am a 6 pm

**Non Drowsy/Sin Somnolencia**

# NEXT<sup>®</sup>

**DAYTIME**  
**COLD & FLU RELIEF**  
**ALIVIO DEL RESFRIADO**  
**Y GRIPE DE DÍA**

**Acetaminophen / Dextromethorphan HBr / Phenylephrine HCl**  
**Paracetamol / Dextromethorfan HBr / Fenilefrina HCl**

➤ Aches/Dolor ➤ Fever/Fiebre  
➤ Nasal Congestion/ ➤ Cough/Tos  
Congestión Nasal ➤ Sore Throat/Dolor de Garganta



**10 Softgels / Cápsulas blandas**



#### Drug Facts

Active ingredient (in each softgel)	Purposes
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses** temporarily relieves common cold and flu symptoms: ■ nasal congestion ■ cough due to minor throat and bronchial irritation ■ sore throat ■ headache ■ minor aches and pains ■ fever

#### Información del Medicamento

Ingredientes activos (en cada cápsula)	Propósito
Paracetamol 325 mg	Analgésico / Antipirético
Dextrometorfano HBr 10 mg	Antitusivo
Fenilefrina HCl 5 mg	Descongestionante Nasal

**Usos** Alivio temporal de los síntomas comunes del resfriado y de la gripe: ■ congestión nasal ■ tos debida a irritación menor de garganta y bronquial ■ dolor de garganta ■ dolor de cabeza ■ dolores menores y dolencias ■ fiebre

#### Drug Facts (continued)

##### 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 ■ 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.

**Ask a doctor before use if you have** ■ liver disease ■ heart disease ■ thyroid disease ■ diabetes ■ high blood pressure ■ trouble urinating due to enlarged prostate gland ■ cough that occurs with too much phlegm (mucus) ■ persistent or chronic cough as occurs with smoking, asthma, or emphysema

**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** ■ you get nervous, dizzy or sleepless ■ symptoms get worse or last more than 5 days (children) or 7 days (adults) ■ 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.** In case of accidental overdose, contact a doctor or Poison Control Center immediately (1-800-222-1222). Taking more than the recommended dose (overdose) may cause liver damage. 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 directed (see Warnings)

■ do not exceed 4 doses per 24 hours

**Adults and children 12 years and over:** take 2 softgels with water every 4 hours

**Children 4 to under 12 years:** Ask a doctor **Children under 4 years:** Do not use

**Other information** ■ store at room temperature 20-25°C (68-77°F)

■ do not use if blister is torn or open

**Inactive ingredients** FD&C Red #40, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol. May also contain FD&C Yellow #6, titanium dioxide.

**Questions or comments?** Call toll free 1-877-99-GENOM (43666)

Distributed by / Distribuido por:  
Genomma Lab USA, Inc.  
Houston, TX 77027

LB1356  
R0414

#### Información del Medicamento (cont.)

##### 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 contengan paracetamol ■ 3 o más bebidas alcohólicas al día mientras usa este producto.

**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.

**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.

**Consulte a su médico antes de utilizarlo si usted está** ■ tomando el medicamento anticoagulante warfarina

**Cuando use este producto** ■ no exceda la dosis recomendada

**Consulte a su médico antes de utilizarlo si usted tiene** ■ enfermedad hepática ■ enfermedad cardíaca ■ diabetes ■ hipertensión ■ dificultad al orinar debido a dilatación de la glándula prostática ■ los que se presenta con demasiada flema (mucosidad) ■ enfermedad de tiroides ■ tos persistente o crónica como ocurre con el tabaquismo, el asma o el enfisema

**Suspenda su uso y consulte a su médico si** ■ se siente nervioso, mareado o insomne ■ los síntomas empeoran o duran más de 7 días (adultos) ■ la fiebre empeora o dura más de 3 días ■ se presenta 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.

**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.

##### 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

##### Información adicional

■ mantener a temperatura ambiente 20-25°C (68-77°F)

■ no usar si los blisters están rotos o abiertos



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Exp: Lot:

NEXT DAY TIME NON DROWSY COLD AND FLUE

acetaminophen 325 mg, dextromethorphan hbr 10 mg, phenylephrine hci 5 mg capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-356
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOLYMER (UNII: 68401960MK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVIDONES (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	ORANGE	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-356-09	10 in 1 BOX; Type 0: Not a Combination Product	01/19/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/19/2015	

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**Labeler** - Genomma Lab USA (832323534)

**Registrant** - Genomma Lab USA (832323534)

Revised: 1/2015

Genomma Lab USA