

**NEXT SEVERE COLD, FLU AND SORE THROATE NIGHT MAX STRENGTH -
acetaminophen, dextromethorphan hbr, doxylamine succinate, and phenylephrine hcl solution
Genomma Lab USA 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.

Drug Facts

***Active ingredients
(in each 30 mL dose cup)***

Acetaminophen USP 650 mg
Dextromethorphan HBr USP 20 mg
Doxylamine succinate USP 12.5 mg
Phenylephrine HCl USP 10 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Antihistamine
Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- minor aches & pains
- headache
- fever
- sore throat
- runny nose & sneezing
- promotes nasal and/or sinus drainage

Warnings

Liver warning: This product contains acetaminophen.

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.
- to make a child sleep

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- 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: Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt 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 Overdose warning
- use dose cup or tablespoon (TBSP)
- do not exceed 4 doses per 24 hours
- mL = milliliter; TBSP = tablespoon

adults & children 12 years & over	30 mL (2 TBSP) every 4 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

- **when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing**

Other information

- **each 30 mL dose cup contains:** sodium 95 mg
- store at 20° to 25°C (68° to 77°F)
- keep carton for future reference

Inactive ingredients

anhydrous citric acid, flavors, FD&C Blue no. 1, FD&C Red no. 40, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose, xanthan gum

Questions or Comments?

call 1 877 99 GENOM (43666) (Monday - Friday 8:30 AM to 5:00 PM EST)

Distributed by:

Genoma Laba USA Inc.,
Houston, TX 77027

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 6 FL OZ (177 mL Carton Label)

MAX STRENGTH

NEXT

Night

**Severe
Cold, Flu &**

Sore Throat

- Fever, Aches & Pains
- Runny Nose, Nasal Congestion & Sinus Pressure
- Cough

Acetaminophen

Pain Reliever - Fever Reducer

Dextromethorphan HBr

Cough suppressant

Doxylamine succinate Antihistamine

Phenylephrine HCl Nasal decongestant

Berry Flavor

6 FL OZ (177 mL)

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS MISSING OR BROKEN / EVIDENCIA DE MANIPULACION: NO USAR SI EL IMPRESO DE SEGURIDAD DEL SELLO DEBAJO DE LA TAPA ESTA ROTO O FALTA

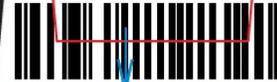
Failure to follow these warnings could result in serious consequences.



Night · Noche

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Información del medicamento (continuación)

durante 2 semanas después de interrumpir el fármaco IMAO. Si no sabe si el fármaco recetado que toma contiene un IMAO, preguntar a un médico o farmacéutico antes de usar este producto.

Consultar a un médico antes de usar si usted tiene: enfermedad hepática; enfermedad cardíaca; presión arterial alta; enfermedad tiroidea; diabetes; glaucoma; los con demencia flama (inco); un problema respiratorio o los crónica persistente que ocurre como con el tabaquismo, asma, bronquitis crónica o enfisema; dificultad para orinar a causa del agrandamiento de la glándula prostática; una dieta restringida en sodio

Consultar a un médico o farmacéutico antes de usar si usted está: tomando sedantes o tranquilizantes; tomando el fármaco anticoagulante llamado warfarina.

Al utilizar este producto: No usar más de lo indicado. Puede ocurrir excitabilidad, especialmente en los niños. Puede ocurrir mucha somnolencia. Evitar las bebidas alcohólicas. Tener precaución al conducir un automóvil o al operar maquinaria. El alcohol, los sedantes y los tranquilizantes pueden incrementar la somnolencia.

Suspender el uso y preguntar a un médico si: Experimenta nerviosismo, mareos o insomnio; el dolor, la congestión nasal o la tos empeoran o duran más de 7 días; la fiebre empeora o dura más de 3 días; presenta enrojecimiento o hinchazón; aparecen nuevos síntomas; reaparece la tos o va acompañada de sarpullido o dolor de cabeza persistente. Estos podrían ser signos de una afección grave.

Si está embarazada o en período de lactancia, consulte a un profesional de la salud antes de usarlo.

Mantener fuera del alcance de los niños.

Advertencia de sobredosis: Tomar más de lo indicado puede causar serios problemas de salud. En caso de sobredosis, buscar ayuda médica o comunicarse con un centro de toxicología de inmediato. (1-800-222-1222) La atención médica rápida es fundamental para los adultos, así como para los niños, aunque no se adviertan signos ni síntomas.

Instrucciones

Tomar únicamente según las recomendaciones. Consulte las Advertencias de Sobredosis. Utilizar vaso dosificador o cucharada (cda.). No exceder 4 dosis por cada 24 horas. ml = milliliter, cda. = cucharada

Table with 2 columns: Age group, Dosage. Rows: Adults y niños de 12 años o más (30 mL (2cda.) cada 4 horas); Niños de 4 a menos de 12 años (Consultar a un médico); Niños menores de 4 años (No usar)

Quando tome algún otro producto de Día o de Noche, los cuidadosamente los legales para asegurar la dosis correcta.

Otra información Cada recipiente dosificador de 30 mL contiene 95 mg de sodio. Conservar a 20° a 25°C (68° a 77°F). Mantener cartón para futuras consultas

Ingredientes Inactivos Ácido cítrico, saborizante, FD&C azul #1, FD&C rojo #40, Glicerina, Propilenglicol, Agua purificada, Sacarina de sodio, Benzoato de sodio, Cloruro de sodio, Citrato de sodio sorbitol, Sucralosa, Goma de xantano

¿Preguntas? Llame 1-877-99-GENOM (43666) (L-V 8:30 a.m. a 5:00 p.m. EST)

PARENTS: Learn about teen medicine abuse

www.StopMedicineAbuse.org

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

MAX STRENGTH



Night · Noche

Severe Cold, Flu & Sore Throat Resfriado, Gripe y Dolor de garganta

- Fever, Aches & Pains; Runny Nose, Nasal Congestion & Sinus Pressure; Cough; Fiebre y Dolores; Flujo y Congestión Nasal; Tos

Acetaminophen Pain Reliever - Fever Reducer; Dextromethorphan HBr Cough Suppressant; Doxylamine succinate Antihistamine; Phenylephrine HCl Nasal Decongestant; Paracetamol Alivia Fiebre y Dolores; Dextrometorfano HBr Reduce la tos; Succinato de Doxilamina Antihistamínico; Fenilfrina HCl Descongestionante; BERRY FLAVOR Sabor Mora; 6 FL OZ (177 mL)

Drug Facts

Table with 2 columns: Active ingredients (in each 30 mL dose cup) and Purpose. Rows: Acetaminophen USP 650 mg (Pain reliever/fever reducer); Dextromethorphan HBr USP 20 mg (Cough suppressant); Doxylamine succinate USP 12.5 mg (Antihistamine); Phenylephrine HCl USP 10 mg (Nasal decongestant)

Uses temporarily relieves common cold/flu symptoms: nasal congestion; sinus congestion & pressure; cough due to minor throat & bronchial irritation; minor aches & pains; headache; fever; sore throat; runny nose & sneezing; promotes nasal and/or sinus drainage

Warnings: 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; itches; 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. To make a child sleep

Ask a doctor before use if you have: liver disease; heart disease; high blood pressure; thyroid disease; diabetes; 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; a sodium-restricted diet

Ask a doctor or pharmacist before use if you are: taking sedatives or tranquilizers; taking the blood thinning drug warfarin

When using this product: do not use more than directed; excitability may occur, especially in children; marked drowsiness may occur; avoid alcoholic drinks

Stop use and ask a doctor if you get nervous, dizzy or sleepless; 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: Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Drug Facts (continued)

Directions: take only as directed - see Overdose warning; use dose cup or tablespoon (TBS)P; do not exceed 4 doses per 24 hours; mL = milliliter, TBS = tablespoon

Table with 2 columns: Age group, Dose. Rows: adults & children 12 years & over (30 mL (2 TBS) every 4 hours); children 4 to under 12 years (ask a doctor); children under 4 years (do not use)

when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing

Other information

each 30 mL dose cup contains: sodium 95 mg; store at 20° to 25°C (68° to 77°F); keep carton for future reference

Inactive ingredients: anhydrous citric acid, flavors, FD&C Blue no. 1, FD&C Red no. 40, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose, xanthan gum

Questions or comments? call 1 877 99 GENOM (43666) (Monday - Friday 8:30 AM to 5:00 PM EST)

Información del medicamento

Ingredientes activos Propósito

Table with 2 columns: Active ingredients and Purpose. Rows: Paracetamol 650 mg (Analgésico/antipirético); Dextrometorfano HBr 20 mg (Antitusígeno); Succinato de doxilamina 12.5 mg (Antihistamínico); Fenilfrina HCl 10 mg (Descongestionante nasal)

Usos Alivia temporalmente los síntomas del resfriado y la gripe común; Congestión nasal; Congestión y presión sinusal; Tos debida a irritación leve de los bronquios y la garganta; Dolores y molestias leves; Dolor de cabeza; Fiebre; Dolor de garganta; Secreción nasal y estornudos; Promueve el drenaje nasal o sinusal

Precauciones

Advertencia acerca del hígado: este producto contiene paracetamol. Puede producirse daño hepático grave si toma más de 4,000 mg de paracetamol en 24 horas; lo toma con otros fármacos que contengan paracetamol; toma 3 o más bebidas alcohólicas por día mientras usa este producto.

Alerta sobre alergia: el paracetamol puede provocar reacciones graves en la piel. Los síntomas pueden incluir: enrojecimiento de la piel; ampollas; sarpullido. Si se produce una reacción en la piel, suspender el uso y buscar ayuda médica de inmediato. Advertencia acerca del dolor de garganta: si el dolor de garganta es intenso, persiste por más de 2 días, está acompañado de fiebre, dolor de cabeza, sarpullido, náuseas o vómitos, consultar a un médico de inmediato.

No usar: con ningún otro fármaco que contenga paracetamol (recetado o de venta libre). Si no se está seguro si un fármaco contiene paracetamol, preguntar a un médico o farmacéutico. Si usted toma actualmente un inhibidor de la monoaminoxidasa (IMAO) recetado (ciertos fármacos para la depresión, afecciones psiquiátricas o emocionales, o la enfermedad de Parkinson) o



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LOT: EXP:



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NEXT SEVERE COLD, FLU AND SORE THROATE NIGHT MAX STRENGTH acetaminophen, dextromethorphan hbr, doxylamine succinate, and phenylephrine hcl solution

Table with 4 columns: Product Information, Product Type (HUMAN OTC DRUG), Item Code (Source), NDC:50066-926

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	BERRY (Prosweet) , MENTHOL	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-926-18	1 in 1 CARTON	06/21/2018	
1		177 mL in 1 BOTTLE; 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	06/21/2018	

Labeler - Genomma Lab USA Inc (832323534)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurohealth LLC		078728447	MANUFACTURE(50066-926)

Revised: 12/2019

Genomma Lab USA Inc