

**NEXT COLD AND FLU NIGHTTIME- acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, gelatin coated
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.

NEXT Nighttime Cold & Flu - 603

Drug Facts

**Active ingredients
(in each softgel)**

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
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists 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 an MAOI drug. If you do not know if 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

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 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 lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts
- a skin reaction occurs. 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.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away. 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 6 hours

- Children 4 to under 12 years: Ask a doctor

Children under 4 years: Do not use

- When using Day Time or Night Time products, carefully read each label to ensure correct dosing

Other information

- store at room temperature 20-25°C (68-77°F)

Inactive Ingredients

FD&C Blue # 1, D&C Yellow # 10, Gelatin, Glycerin, Polyethylene glycol, Povidone, Propylene glycol, Purified water, Sorbitol sorbitan solution, Titanium dioxide.

Questions?

Call 1-877-99-Genom (43666)

Weekdays from 8am to 6 pm

NEXT COLD & FLU NIGHTTIME product label

NEXT

COLD & FLU

NIGHTTIME RELIEF

- Fever
- Sneezing
- Sore Throat
- Aches
- Runny Nose
- Cough

Acetaminophen/

Dextromethorphan HBr / Doxylamine succinate

Tamper evident: Do not use if blisters are torn or open

Distributed by:

Genomma Lab USA, Inc.

Houston, TX 77027

Made in India

BX-056

NEXT[®]
COLD & FLU
RESFRIADO Y GRIPE

NEXT[®]
COLD & FLU
RESFRIADO Y GRIPE

NIGHTTIME RELIEF
ALIVIO DE NOCHE

NIGHTTIME RELIEF
ALIVIO DE NOCHE

- Fever/Fiebre
- Sneezing/Estornudo
- Sore Throat/Dolor de Garganta
- Aches/Dolor
- Runny Nose/Flujo nasal
- Cough/Tos

Acetaminophen /
Dextromethorphan HBr / Doxylamine succinate

Paracetamol /
Dextrometorfano HBr / Succinato de Doxilamina

24 Softgels
Cápsulas blandas

Tamper Evident: Do not use if blisters are torn or open
Evidencia de Manipulación: No usar si los blísters están rotos o abiertos

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

Made in / Hecho en: India

8X-056

NIGHTTIME RELIEF
ALIVIO DE NOCHE

NEXT[®]
COLD & FLU
RESFRIADO Y GRIPE

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Drug Facts		Drug Facts (continued)
Active ingredients	Purpose	When using this product • do not exceed recommended dosage • excitability may occur, especially in children • marked drowsiness may occur
Acetaminophen 325 mg... Pain reliever/fever reducer		• avoid alcoholic drinks • be careful when driving a motor vehicle or operating machinery • alcohol, sedatives, and tranquilizers may increase drowsiness
Dextromethorphan HBr 15 mg... Cough suppressant		
Doxylamine succinate 6.25 mg... Antihistamine		
Uses		Stop use and ask a doctor if • pain 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 • a skin reaction occurs. These could be signs of a serious condition.
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		Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.
Liver warnings: 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 • 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 redness/itching or hives. If skin reaction occurs, stop use and seek medical help right away. Save throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, hoarseness, or vomiting, consult a doctor promptly.		Other information • store at room temperature 20-25°C (68-77°F)
Do not use • with any other products containing acetaminophen (prescription or nonprescription), 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 (MAI) sleep		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 6 hours Children 4 to under 12 years: Ask a doctor Children under 4 years: Do not use • When using Day Time or Night Time products, carefully read each label to ensure correct dosing.
Ask a doctor before use if you have • liver disease • glaucoma • tough 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		Inactive ingredients FD&C Blue #1, GSC Yellow #10, Gelatin, Glycerin, Polyethylene glycol, Povidone, Propylene Glycol, Purified water, Sorbitol sorbitan solution, Titanium dioxide
Ask a doctor or pharmacist before use if you are • taking sedatives or tranquilizers • taking the blood thinning drug warfarin		Questions? Call 1-877-96-GENOM (43666) Weekdays from 8 am to 8 pm

NEXT[®]

Nighttime Cold & Flu relief
Alivio del resfriado y gripe para la noche

Each softgel contains:

Acetaminophen-325 mg
Dextromethorphan HBr-15 mg
Doxylamine succinate-6.25 mg

Made in/ Hecho en: India
Distributed by / Distribuido por:
Genomma Lab USA, Inc., Houston, TX 77027

LOT/LOTE: TC160020 EXP: 02/18

Use only if blisters are intact
Usar sólo si los blísters están intactos

NEXT[®]

Nighttime Cold & Flu relief
Alivio del resfriado y gripe para la noche

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NEXT COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-603
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: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
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:50066-603-03	24 in 1 BOX	05/03/2016	
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	05/03/2016	

Labeler - Genomma Lab USA, Inc. (832323534)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(50066-603) , relabel(50066-603) , repack(50066-603)