

**NITECIN- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled**  
**OPMX LLC**

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**Nitecin Night-Time Relief**

***Drug Facts***

<b><i>Active ingredients (in each Softgels)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine

**Uses**

Temporarily relieves common cold/flu symptoms:

- Cough due to minor throat & bronchial irritation
- Sore throat
- Headache
- Minor aches & pains
- Fever
- Runny nose & sneezing

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4 doses in 24 hrs, which is the maximum daily amount for this product
- 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 a skin reaction occurs, stop use and seek medical help right away

**Sore throat warning**

If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see 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.

### **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 doctor or pharmacist before use if you are**

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

### **When using this product**

- 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, & 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. 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 right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

### **Directions**

- Take only as directed
  - Do not exceed 4 doses per 24 hrs
-

Adults & children 12 yrs & over	2 softgels with water every 6 hrs
Children 4 to under 12 yrs	Ask a doctor
Children under 4 yrs	Do not use

### **Other information**

- Store at room temperature

### **Inactive ingredients**

D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, titanium dioxide

### **Questions?**

Call toll free 619-600-5632 Monday through Friday 9AM - 5PM EST

### **Made for:**

**RRX**

### **Exclusively distributed by:**

**OPMX**

**Chula Vista, CA 91910**

### **PRINCIPAL DISPLAY PANEL**

NDC 69729-054-10

Cough & Flu/ Tos y Gripe

Nitecin

Night-ttmeRelief

Multi-Symptom Relief

*Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate*

- Headache/ Dolor de cabeza
- Fever/ Fiebre
- Sore Throat/ Dolor de Garganta
- Sneezing/ Estornudos
- Runny Nose/ Secreción Nasal
- Cough/ Tos

10 Softgels/ 10 Cápsulas Blandas de Gel



NDC 69729-054-10

**COUGH & FLU  
TOS Y GRIPE**

# Nitecin

Night-time Relief

Multi-Symptom Relief  
Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate

- Headaches / Dolor de Cabeza
- Fever / Fiebre
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- Cough / Tos



\*Capsules, Liquid-Filled / \*Cápsulas rellenas de líquido **10 Softgels\*  
10 Cápsulas Blandas de Gel\***

Lot:  
Exp:

8 10053 18045 7  
REV/06/2022 ITEM# RRBX1110

**Drug Facts (continued)**

**Ask a doctor or pharmacist before use if you are:** taking sedatives or tranquilizers • taking the blood thinning drug warfarin • taking Doxylamine succinate 6.25 mg • taking Dextromethorphan HBr 15 mg • taking Doxylamine succinate 6.25 mg

**When using this product:** • Excitability may occur especially in children • Motor drowsiness may occur • Avoid alcoholic drinks • Do not drink alcohol while taking this product • Avoid alcohol while taking this product • Avoid alcohol while taking this product

**Stop use and ask a doctor if:** • Alcohol, sedatives, & tranquilizers may increase drowsiness • You have had an allergic reaction to any of the ingredients • You have had an allergic reaction to any of the ingredients • You have had an allergic reaction to any of the ingredients

**Keep out of reach of children.** • New symptoms occur, these could be signs of a serious condition. • New symptoms occur, these could be signs of a serious condition. • New symptoms occur, these could be signs of a serious condition.

**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. 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. • Do not exceed 4 doses per 24 hours. • Adults & children 12 yrs & over: 2 softgels with water every 6 hrs. • Children 4 to under 12 yrs: Ask a doctor. • Children under 4 yrs: Do not use.

**Other information:** • Store at room temperature. • Store at room temperature. • Store at room temperature.

**Inactive ingredients:** DSC Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol, powder, propylene glycol, purified water, sorbitol, titanium dioxide.

**Questions?** Call toll free 619-600-5632 Monday through Friday 9AM - 5PM EST

**Drug Facts**

**Active ingredients (in each Softgel) Purpose**  
Acetaminophen 325 mg: Pain reliever/Fever reducer  
Dextromethorphan HBr 15 mg: Cough suppressant  
Doxylamine succinate 6.25 mg: Antihistamine

**Uses**  
Temporarily relieves common cold/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 hrs, which is the maximum daily amount for this product. • 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 redness • Blisters • Rash  
**If a skin reaction occurs:** Stop use and seek medical help right away. • If a skin reaction occurs, stop use and seek medical help right away.  
**Sore throat warning:** If sore throat is severe, lasts 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 Parkinson's disease), or 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.

**Ask a doctor before use if you have:** • Liver disease • Glaucoma • Problem or chronic cough that lasts or occurs with smoking. • Cough that occurs with too much phlegm (mucus). • A breathing problem or chronic bronchitis or emphysema.

Made for:

Exclusively distributed by:

Chula Vista, CA 91910  
Phone: 619-600-5632

**TAMPER EVIDENT:**  
Do not use if package is opened or if blister unit is torn, broken or shows any sign of tampering.

**NITECIN**  
acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69729-054
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

## Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	AP02
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69729-054-10	1 in 1 CARTON	05/23/2022	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M012	05/23/2022	

**Labeler** - OPMX LLC (029918743)

## Establishment

Name	Address	ID/FEI	Business Operations
OCEAN HEALTHCARE PVT. LTD.		873673519	manufacture(69729-054)

Revised: 7/2025

OPMX LLC