

NITE-TIME COLD/FLU ORIGINAL- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid
Salado Sales, Inc.

Nite Time 501

Drug Facts Active ingredients (in each 30 mL dose cup)

Acetaminophen 650 mg Dextromethorphan HBr 30 mg Doxylamine Succinate 12.5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Keep Out Of Reach Of Children

Keep out of reach of children.

Uses

temporarily relieves cold/flu symptoms:

- sore throat
- minor aches and pain
- runny nose and sneezing
- cough due to minor sore throat and bronchial irritation
- headache
- fever

Warnings

Failure to follow these warnings could result in serious consequences

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
- 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.

Ask a doctor before use if you have

- a sodium restricted diet
- 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
- if you are taking the blood thinning drug warfarin

When Using This Product

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

Stop Use And Ask A Doctor If

- redness or swelling is present
- symptoms do not get better within 7 days or are accompanied by a fever
- fever gets worse or lasts more than 3 days
- new symptoms occur
- cough lasts more than 7 days, comes back, or occurs with fever, rash, headache that lasts

Pregnant Or Breast-Feeding

ask a health professional before use.

Overdose Warning

Taking more than the recommended dose 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 recommended-see Overdose warnings
- Use dose cup or tablespoon (TBSP)
- do not exceed 4 doses per 24 hours
- If taking Nite Time at night and Day Time during the day, limit total to 4 doses per 24 hours

adults & children 12 years and over	30 mL (2 TBSP) every 6 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

Other Information

- **each 30 mL dose cup contains:**
- sodium 45 mg
- store at room temperature

Inactive ingredients

citric acid, D and C yellow No. 10, FD and C Green No. 3, FD and C Yellow No. 6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose

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 sleepy

Product Label

Compare to VICKS® NYQUIL® active ingredients CVP CONSUMER VALUE PRODUCTS

Nite-Time COLD/FLU Medicine

Multi-Symptom ORIGINAL FLAVOR

AcetaminophenAches, Fever and Sore Throat

DextromethorphanCough

Doxylamine SuccinateSneezing, Runny nose

6 FL OZ (177 mL)

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN

*This product is not manufactured or distributed by Proctor and Gamble, distributor of Vicks® Nyquil® LR-002

Questions? Call weekdays from 9:30am to 4:30pm EST 1-877-795-5944

Distributed by: Salado Sales, Inc. P.O. Box 6115 Temple, TX 76503
www.saladosales.com

LOT: EXP:

Peel Here DRUG FACTS CONTINUED ON BACK

ORIGINAL FLAVOR Nite-Time Multi-Symptom COLD/FLU Medicine

- Antihistamine
- Cough Suppressant
- Pain Reliever
- Fever Reducer

NITE TIME

MULTI-SYMPOM
COLD/FLU MEDICINE

ORIGINAL FLAVOR

- ANTIHISTAMINE
- COUGH SUPPRESSANT
- PAIN RELIEVER
- FEVER REDUCER

Drug Facts (continued)

Sore throat warning: If sore throat is severe, persists for more than two 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 sleepy

Ask a doctor before use if you have • a sodium restricted diet • 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 • if you are taking the blood thinning drug warfarin

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

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN



*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® NyQuil®.

Questions? Call weekdays from 9:30am to 4:30pm EST at 1-877-798-5944

LN-002 Rev 01

Distributed by:
Salado Sales, Inc
P.O. Box 6115
Temple, TX 76503
www.saladoales.com

EXP:

LOT:

Drug Facts

Failure to follow these warnings could result in serious consequences

Active ingredients (in each 30 mL dose cup) Purpose
Acetaminophen 650 mg Pain reliever/fever reducer
Dextromethorphan HBr 30 mg Cough suppressant
Doxylamine Succinate 12.5 mg Antihistamine

Uses temporarily relieves cold/flu symptoms:
• sore throat • headache
• minor aches and pain • fever
• runny nose and sneezing
• cough due to minor throat and bronchial irritation

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take • more than 4,000mg 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.

Peel Here

COMPARE TO
"VICKS" NYQUIL®
ACTIVE INGREDIENTS



NITE TIME

MULTI-SYMPOM COLD/FLU MEDICINE

ORIGINAL FLAVOR

- ACETAMINOPHEN - ACHES, FEVER & SORE THROAT
- DEXTROMETHORPHAN HBr - COUGH SUPPRESSANT
- DOXYLAMINE SUCCINATE - SNEEZING, RUNNY NOSE

6 FL OZ (177 mL)

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN



*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® NyQuil®.

Questions? Call weekdays from 9:30am to 4:30pm EST at 1-877-798-5944

LN-002 Rev 01

Distributed by:
Salado Sales, Inc
P.O. Box 6115
Temple, TX 76503
www.saladoales.com

EXP:

LOT:

Drug Facts (continued)

Stop use and ask a doctor if • redness or swelling is present • symptoms do not get better within 7 days or are accompanied by a fever • fever gets worse or lasts more than 3 days • new symptoms occur • cough lasts more than 7 days, comes back, or occurs with fever, 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 the recommended dose 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 recommended-see Overdose warning • Use dose cup or tablespoon (TBS) • do not exceed 4 doses per 24 hours

Drug Facts (continued)

adults & children 12 years and over	30 mL (2 TBS) every 6 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

• If taking Nite Time at night and Day Time during the day, limit total to 4 doses per 24 hours.

Other information • each 30 mL dose cup contains: sodium 45mg • store at room temperature

Inactive ingredients citric acid, D&C yellow # 10, FD&C Green No. 3, FD&C Yellow No. 6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose

NITE TIME

MULTI-SYMPOM COLD/FLU MEDICINE

ORIGINAL FLAVOR

- ANTIHISTAMINE
- COUGH SUPPRESSANT
- PAIN RELIEVER
- FEVER REDUCER

Drug Facts (continued)

Sore throat warning: If sore throat is severe, persists for more than two 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 sleepy

Ask a doctor before use if you have • a sodium restricted diet • 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 • if you are taking the blood thinning drug warfarin

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

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN

7 61706 16003 9

*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® NyQuil®.

Questions? Call weekdays from 9:30am to 4:30pm EST at 1-877-798-5944

LR-002 Rev 01

Distributed by:
Salado Sales, Inc
P.O. Box 6115
Temple, TX 76503
www.saladoales.com

EXP: _____
LOT: _____

Drug Facts Failure to follow these warnings could result in serious consequences

Active ingredients (in each 30 mL dose cup) Purpose

Acetaminophen 650 mg Pain reliever/fever reducer
Dextromethorphan HBr 30 mg Cough suppressant
Doxylamine Succinate 12.5 mg Antihistamine

Uses temporarily relieves cold/flu symptoms:
• sore throat • headache
• minor aches and pain • fever
• runny nose and sneezing
• cough due to minor throat and bronchial irritation

Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take • more than 4,000mg 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.

Peel Here

DRUG FACTS CONTINUED ON BACK

COMPARE TO VICKS' NYQUIL ACTIVE INGREDIENTS

NITE TIME

MULTI-SYMPOM COLD/FLU MEDICINE

ORIGINAL FLAVOR

- ACETAMINOPHEN - ACHES, FEVER & SORE THROAT
- DEXTROMETHORPHAN HBr - COUGH SUPPRESSANT
- DOXYLAMINE SUCCINATE - SNEEZING, RUNNY NOSE

6 FL OZ (177 mL)

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN

7 61706 16003 9

*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® NyQuil®.

Questions? Call weekdays from 9:30am to 4:30pm EST at 1-877-798-5944

LR-002 Rev 01

Distributed by:
Salado Sales, Inc
P.O. Box 6115
Temple, TX 76503
www.saladoales.com

EXP: _____
LOT: _____

Drug Facts (continued)

Stop use and ask a doctor if • redness or swelling is present • symptoms do not get better within 7 days or are accompanied by a fever • fever gets worse or lasts more than 3 days • new symptoms occur • cough lasts more than 7 days, comes back, or occurs with fever, 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 the recommended dose 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 recommended-see Overdose warning • Use dose cup or tablespoon (TBS) • do not exceed 4 doses per 24 hours

Drug Facts (continued)

adults & children 12 years and over	30 mL (2 TBS) every 6 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

• If taking Nite Time at night and Day Time during the day, limit total to 4 doses per 24 hours.

Other information • each 30 mL dose cup contains: sodium 45mg • store at room temperature

Inactive ingredients citric acid, D&C yellow # 10, FD&C Green No. 3, FD&C Yellow No. 6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose

res

NITE-TIME COLD/FLU ORIGINAL			
acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57243-501
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	30 mg in 30 mL	
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE -	DOXYLAMINE SUCCINATE	12.5 mg	

UNII:95QB77JKPL)

DOXYLAMINE SUCCINATE

in 30 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57243-501-25	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/16/2012	

Labeler - Salado Sales, Inc. (009830555)**Registrant** - AptaPharma Inc. (790523323)**Establishment**

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(57243-501)

Revised: 12/2023

Salado Sales, Inc.