

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

Night Time Cherry 502

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 4,000 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 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

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

These could be signs of a serious condition.

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

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

- 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 45 mg
- store at room temperature

Inactive ingredients

citric acid, FD and C Blue No. 1, FD&C Red No. 40, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose

Nite Time Cherry product label

Compare to VICKS® NYQUIL® active ingredients

CVP® CONSUMER VALUE PRODUCTS

Nite-Time COLD/FLU Medicine

Multi-Symptom CHERRY FLAVOR

Acetaminophen • Aches, Fever & Sore Throat

Dextromethorphan • Cough

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 Proctor and Gamble, distributor of Vicks® Nyquil® LR-003

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57243-502
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: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY (CHERRY FLAVOR)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57243-502-25	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/31/2012	

Registrant - AptaPharma Inc. (790523323)**Establishment**

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(57243-502)

Revised: 4/2017

Salado Sales, Inc.