

DAYTIME NON-DROWSY COLD/FLU- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride 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.

Drug Facts Active Ingredients
(in each 15 mL, 1 tablespoon)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCL 5 mg

Purpose

Purpose

Pain reliever/fever reducer
Cough suppressant
Nasal decongestant

Keep out of reach of children

Keep this and all drugs out of the reach of children.

Uses

Uses

- temporarily relieves these common cold/flu symptoms:
- minor aches and pains
- headache
- sore throat
- fever
- nasal congestion
- cough due to minor throat and bronchial irritation

Warnings

Warnings

Liver warning:

This product contains acetaminophen. Severe liver damage may occur if adult/child takes

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks everyday 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

Do not use

- 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 two weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or a pharmacist before taking this product
- with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacists.

Ask a doctor before use if you have Ask a doctor or pharmacist

Ask a doctor before use if you have

- liver disease
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough accompanied by excessive phlegm (mucus)

Ask a doctor or pharmacist before use

if the user is taking the blood thinning drug warfarin

When using this product

When using this product

- do not use more than directed (see overdose warning)
- avoid alcoholic drinks

Stop use and ask a doctor if

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- new symptoms occur
- fever gets worse or lasts more than 3 days

- pain or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- redness or swelling is present
- 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.

Overdose Warning:

Taking more than the recommended dose (overdose) could cause serious health problems, including liver damage. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

Directions

- take only as recommended (see overdose warning)
- use dosage cup or tablespoon (TBSP)
- do not exceed 4 doses per 24 hours

age	dose
adults and children 12 years and over	30 mL (2 TBSP) every 4 hours
children 6 years to under 12 years	15 mL (1 TBSP) every 4 hours
children 4 years to under 6 years	ask a doctor
children under 4 years	do not use
<ul style="list-style-type: none"> • When using Day Time and Night Time products, carefully read each label to ensure correct dosing. 	

Other information

Other information

- sodium content per tablespoon: 10 mg
- store at room temperature

Inactive ingredients

citric acid, FD&C Yellow #6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sucrose

Questions?

Call weekdays from 9:30 AM to 4:30 PM EST at

1-877-798-5944

Day Time product label

*COMPARE TO THE ACTIVE INGREDIENTS IN VICKS®
DAYQUIL®

CVP

CONSUMER VALUE PRODUCTS

DAYTIME

NON-DROWSY COLD/FLU RELIEF

Acetaminophen.....Pain Reliever/Fever Reducer

Dextromethorphan HBr.....Cough Suppressant

Phenylephrine HCL Nasal Decongestant

6 FL OZ (177 mL)

Failure to follow these warnings could result in serious consequences

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN

*This product is not manufactured or distributed by Proctor and Gamble, owner of the registered trademark Vicks® Dayquil®.

LR-038 Rev 02

Distributed by:

Salado Sales, Inc.

P.O. Box 6115

Temple, Tx 76503

www.saladosales.com

LOT: EXP:

DAY TIME

NON-DROWSY COLD/FLU RELIEF

- NASAL DECONGESTANT
- COUGH SUPPRESSANT
- PAIN RELIEVER
- FEVER REDUCER

Drug Facts (continued)

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 • 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 two weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or a pharmacist before taking this product.

• with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have • liver disease • heart disease • thyroid disease • diabetes • high blood pressure • trouble urinating due to enlarged prostate gland • persistent or chronic cough such as occurs with smoking, asthma, or emphysema • cough accompanied by excessive phlegm (mucus)

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin

When using this product • do not use more than directed (see overdose warning)

• avoid alcoholic drinks

Stop use and ask a doctor if • you get nervous, dizzy or sleepless • new symptoms occur • fever gets worse or lasts more than 3 days

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LR-038 Rev 02

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P.O. Box 6115
Temple, TX 76603
www.saladosales.com

EXP:

LOT:

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

Active Ingredients (in each 15 mL, 1 tablespoon)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses temporarily relieves these common cold/flu symptoms:
• minor aches and pains • headache • sore throat • fever
• nasal congestion • cough due to minor throat and bronchial irritation

Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if • adult takes more than 4,000 mg of acetaminophen in 24 hours • child takes more than 5 doses in 24 hours • taken with other drugs containing acetaminophen • adult has 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® DAYQUIL® ACTIVE INGREDIENTS

DAY TIME

NON-DROWSY COLD/FLU RELIEF

- ACETAMINOPHEN - PAIN RELIEVER/FEVER REDUCER
- DEXTROMETHORPHAN HBR - COUGH SUPPRESSANT
- PHENYLEPHRINE HCl - NASAL DECONGESTANT

6 FL OZ (177 mL)

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EXP:

LOT:

Drug Facts (continued)	Drug Facts (continued)										
<p>• pain or cough gets worse or lasts more than 5 days (children) or 7 days (adults) • redness or swelling is present</p> <p>• cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding ask a health professional before use. Keep this and all drugs out of the reach of children.</p> <p>Overdose Warning: Taking more than the recommended dose (overdose) could cause serious health problems, including liver damage. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p>Directions • take only as recommended (see overdose warning)</p> <p>• use dosage cup or tablespoon (TBSP)</p> <p>• do not exceed 4 doses per 24 hours</p>	<table border="1"> <thead> <tr> <th>age</th> <th>dose</th> </tr> </thead> <tbody> <tr> <td>adults and children 12 years and over</td> <td>30 mL (2 TBSP) every 4 hours</td> </tr> <tr> <td>children 6 years to under 12 years</td> <td>15 mL (1 TBSP) every 4 hours</td> </tr> <tr> <td>children 4 years to under 6 years</td> <td>ask a doctor</td> </tr> <tr> <td>children under 4 years</td> <td>do not use</td> </tr> </tbody> </table> <p>• When using Day Time and Night Time products, carefully read each label to ensure correct dosing.</p> <p>Other information</p> <p>• sodium content per tablespoon: 10 mg</p> <p>• store at room temperature</p> <p>Inactive ingredients</p> <p>citric acid, FD&C Yellow # 6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sucrose</p>	age	dose	adults and children 12 years and over	30 mL (2 TBSP) every 4 hours	children 6 years to under 12 years	15 mL (1 TBSP) every 4 hours	children 4 years to under 6 years	ask a doctor	children under 4 years	do not use
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DAYTIME NON-DROWSY COLD/FLU

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57243-506
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57243-506-25	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/05/2012	

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

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(57243-506)

Revised: 4/2017

Salado Sales, Inc.