

**NIGHT TIME COLD AND FLU RELIEF LIQUID FILLED SOFTGELS-
acetaminophen,dextromethrophan hbr,doxylamine succinate capsule, liquid
filled
AptaPharma Inc.**

AP SAFE Night-Time Cold/Flu SoftGels

Drug Facts

Active ingredients

(in each Softgel)

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 & pain
- 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 hours, 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, 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 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 use more than directed.• 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, 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. 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.

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 Warning)
- do not exceed 4 doses per 24 hours

Adults & Children 12 years & over: 2 soft gels with water every 6 hours

Children 4 to under 12 years: Ask a doctor

Children under 4 years: Do not use

•When using other Daytime or Nighttime products, carefully read each label to ensure correct dosing.

Other information

- Store at room temperature 20-25°C (68-77°F)
- avoid excessive heat

Inactive ingredients

D&C Yellow # 10, FD&C Blue # 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, Sorbitol sorbitan solution, Titanium dioxide.

Questions? Call Weekdays from 9:30 AM to 4:30 PM EST at 1-877-798-5944

Product Label: AP SAFE Night time cold/flu Softgels

AP SAFE® Nighttime
the active ingredients

*Compare to

Cold/Flu Relief
Nyquil™ Cold & Flu Nighttime

In Vicks®

LiquiCaps™

Relief

Acetaminophen

Dextromethorphan HBr/Doxylamine Succinate

24 Softgels

Manufactured by AptaPharma Inc.,

1533 Union Ave., Pennsauken, NJ 08110

• This product is not manufactured or distributed by Procter & Gamble, owner of the registered

trademark Vicks® Nyquil™ Liquicaps™

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

KEEP OUTER CARTON FOR COMPLETE WARNING AND PRODUCT INFORMATION.

Drug Facts
Active ingredients (in each softgel)
Acetaminophen 325 mg Pain reliever/fever reducer
Doxylamine succinate 6.25 mg Antihistamine
Purpose
Pain reliever/fever reducer
Cough suppressant
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 redness, 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, 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

Drug Facts (continued)
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 use more than directed, 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. 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 children, even if you do not notice any signs or symptoms.

Drug Facts (continued)
Directions
Take only as directed (see Warnings)
do not exceed 4 doses per 24 hrs
adults & children 12 yrs & over 2 softgels with water every 6 hours
children 4 to under 12 yrs ask a doctor
children under 4 yrs do not use
When using other Daytime or Nighttime products, carefully read each label to ensure correct dosing
Store at room temperature 20-25°C (68-77°F)
avoid excessive heat

Other Information
Store at room temperature 20-25°C (68-77°F)
avoid excessive heat

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

Questions?
Call weekdays from 9:30 AM to 4:30 PM EST at 1-877-739-5944

This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® Nyquil™ LiquiCaps™.

AP SAFE®
Nighttime
Cold/Flu Relief
Acetaminophen
Dextromethorphan HBr/ Doxylamine Succinate
Nighttime
Cold/Flu Relief
• Aches, Fever & Sore Throat
• Sneezing, Runny Nose
• Cough
Actual Size
24 Softgels

NDC 76281-603-03

*Compare to the active ingredients in Vicks® Nyquil™ Cold & Flu Nighttime Relief LiquiCaps™

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.
Failure to follow these warnings could result in serious consequences.

Manufactured by: AptaPharma Inc.,
1533 Union Ave., Pennsauken, NJ 08110

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3 76281 60303 3

NIGHT TIME COLD AND FLU RELIEF LIQUID FILLED SOFTGELS

acetaminophen,dextromethrophan hbr,doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76281-603
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: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	603
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-603-03	2 in 1 CARTON	01/01/2026	
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 Drug	M012	01/01/2026	

Labeler - AptaPharma Inc. (790523323)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(76281-603)

Revised: 5/2026

AptaPharma Inc.