

NITE-TIME COLD/FLU MEDICINE CHERRY- acetaminophen liquid
AptaPharma Inc.

Active Ingredients

Drug facts

Active ingredients (in each 30 mL dose cup)

Acetaminophen 650 mg Dextromethorphan HBr 30 mg Doxylamine Succinate 12.5 mg

Purpose

Purpose

Pain reliever/fever reducer Cough suppressant Antihistamine

Keep Out Of Reach Of Children

Keep out of reach of children.

Uses

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

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take ● more than 4 doses (30 mL each) in 24 hours, which is the maximum daily amount for this product ● with other drugs containing acetaminophen ● 3 or more alcoholic drinks everyday while using this product.

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

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

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

When using this product

- do not use more than directed
- avoid alcohol 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, or headache that lasts

These could be signs of a serious condition.

Pregnancy Or Breast-Feeding

If pregnant or breast-feeding, ask a health professional before use.

Overdose Warning

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 (TBSP)
- do not exceed 4 doses per 24 hours

adults and 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

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

Do Not Use

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

Package Label - Night Time Multi-Symptom Cherry Flavor

NDC 76281-502-28

AP SAFE

***COMPARE TO
the active ingredients in
VICKS® NYQUIL®**

Night Time

**Acetaminophen - Pain Reliever/Fever Reducer
Dextromethorphan HBr - Cough Suppressant
Doxylamine Succinate - Antihistamine**

**Multi-Symptom
Cold & Flu Relief**

Cherry Flavor

12 FL OZ (354 mL)

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN

Failure to follow these warnings could result in serious consequences

Questions? Call weekdays 1-877-798-5944

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

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

12 oz

Drug Facts (continued)

- 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, 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 (overdose) may cause liver damage. In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt 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 (TBSF) do not exceed 4 doses per 24 hours
- If taking Night 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 TBSF) 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

Made in USA
AP-LR-09 REV 01

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

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Cold & Flu Relief**

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12 FL OZ (354 mL)

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Drug Facts

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 doses (30 mL each) in 24 hours, which is the maximum daily amount for this product, 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 redness, 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 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 for more than 10 days for pain unless directed by a doctor for more than 3 days for fever unless directed by a doctor.

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.

6 oz

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN
Failure to follow these warnings could result in serious consequences

Drug Facts

Active ingredients (in each 30 mL dose cup) Purpose
Acetaminophen 650 mg Pain reliever/fever reducer
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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:** The product contains acetaminophen. Severe liver damage may occur if you take ■ more than 4 doses (30 mL each) in 24 hours, which is the maximum daily amount for this product ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using the 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, persists for more than two



NDC 76281-502-25

***COMPARE TO
the active ingredients in
VICKS® NYQUIL®**

Night Time

Acetaminophen - Pain Reliever/Fever Reducer
Dextromethorphan HBr - Cough Suppressant
Doxylamine Succinate - Antihistamine

**Multi-Symptom
Cold & Flu Relief**

Cherry Flavor



6 FL OZ (177 mL)

Drug Facts (continued)

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
■ for more than 10 days for pain unless directed by a doctor
■ for more than 3 days for fever unless directed by a doctor
■ 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

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Manufactured by: AptaPharma Inc., Made in USA
1533 Union Ave. AP-UR-16
Pennsauken, NJ 08110



PEEL HERE

EXP.

LOT.

Drug Facts (continued)

■ cough that occurs with too much phlegm (mucus)
■ a breathing problem or chronic cough that lasts or is accompanied by fever, 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, or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding ask a health professional before use. **Keep this and all drugs out of the reach of children.**

Overdose Warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt 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 ■ If taking Night 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 years 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, FD&C Blue No. 1, FD&C Red No. 40, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose

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

res

NITE-TIME COLD/FLU MEDICINE CHERRY

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76281-502
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: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
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:76281-502-28	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2018	
2	NDC:76281-502-25	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/01/2018	

Labeler - AptaPharma Inc. (790523323)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(76281-502)

Revised: 12/2023

AptaPharma Inc.