DAY-TIME COLD/FLU RELIEF- acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid
AptaPharma Inc.

Day Time Cold & Flu Relief

Drug Facts

Active Ingredients
(in each 15 mL, 1 tablespoon)

Acetaminophen	325 mg
Dextromethorphan HBr	10 mg
Phenylephrine HCl	5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
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/child takes: ■ 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 everyday while usina 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

■ 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. ■ for

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

■ liver disease ■ heart disease ■ thyroid disease ■ diabetes
■ high blood pressure ■ trouble urinating due to enlarged prostrate 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 you are 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
■ 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 couldbe 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 dosage cup or tablespoon (TBSP)
■ do not exceed 4 doses per 24 hours

age	dose
adults & children 12 years and over	30 mL (2 TBSP) every 4 hours
children 6 to under 12 years	15 mL (1 TBSP) every 4 hours
children 4 to under 6 years	ask a doctor
children under 4 years	do not use

When using Day Time and Night Time products, carefully read each label to ensure correct dosing.

Other information

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

Inactive Ingredients

citric acid, FD&C Yellow # 6, Made in USA 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**

Product Package Label - Day Time Cold & Flu Relief

AP SAFE

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

Day Time

Acetaminophen – Pain Reliever/Fever Reducer
Dextromethorphan HBr – Cough Suppressant
Phenylephrine HCl – Nasal Decongestant

Cold & Flu Relief

Multi-Symptom Relief

12 FL OZ (354 mL)

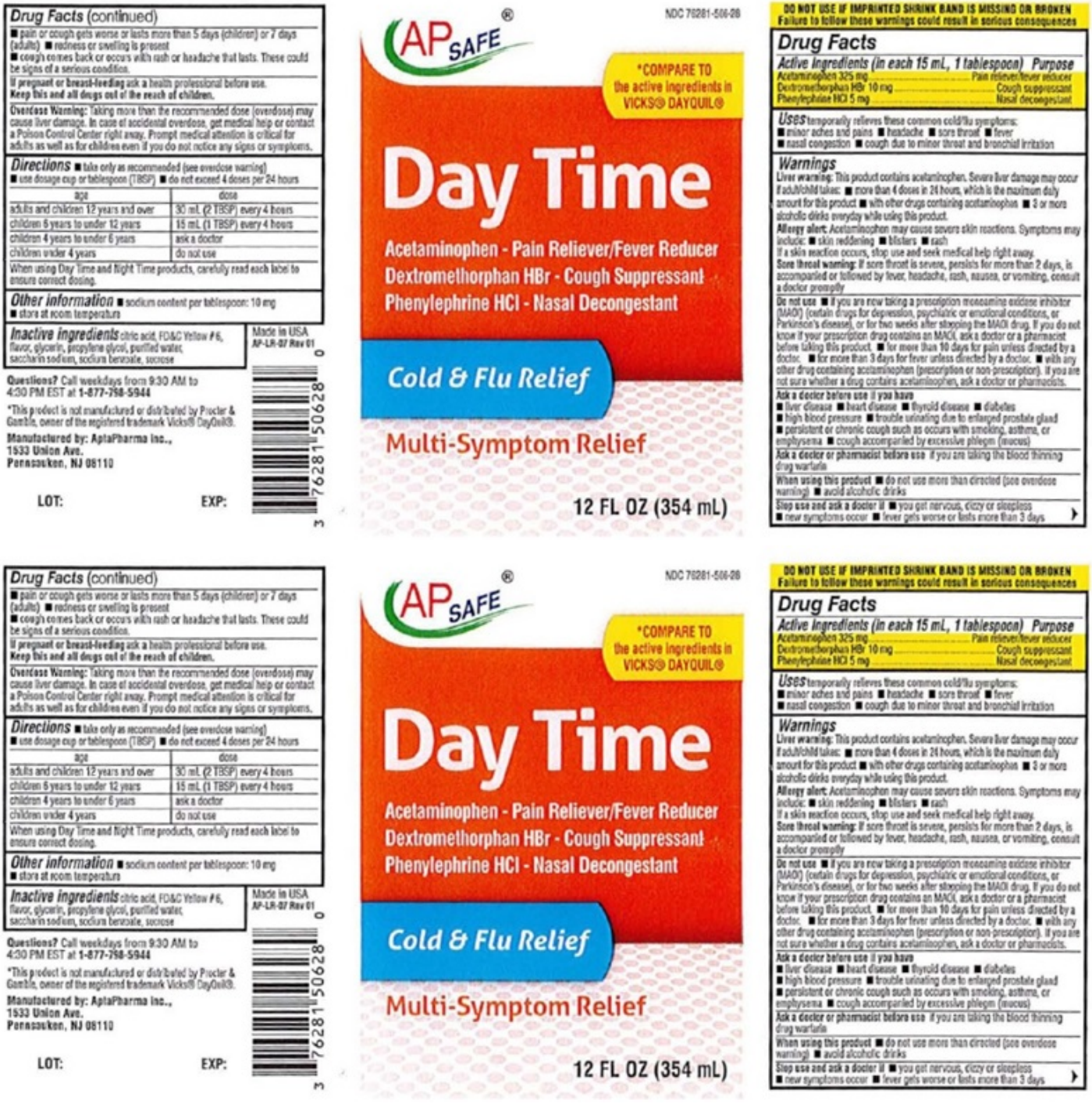
*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® DayQuil®.

Manufactured by: AptaPharma Inc.,

1533 Union Ave.
Pennsauken, NJ 08110

LOT: EXP:

12 OZ



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DAY-TIME COLD/FLU RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76281-506
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	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: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-506-28	354 mL in 1 BOTTLE, PLASTIC; 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(76281-506)