DAYTIME NIGHTTIME COLD/FLU- acetaminophen, dextromethorphan hbr, phenylephrine hcl, diphenhydramine hci
CVS Pharmacy

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 Daytime (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Phenylephrine HCl 10 mg

Active ingredients in Nighttime (in each 30 mL)

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Phenylephrine HCl 10 mg

Purpose for Daytime

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Purpose for Nighttime

Pain reliever/fever reducer

Antihistamine / Cough suppressant

Nasal decongestant

Uses
DAYTIME

- temporarily relieves these symptoms due to a cold
  - minor aches and pains
  - headache
  - nasal and sinus congestion
  - sore throat
  - cough due to minor throat and bronchial irritation

- temporarily reduces fever

NIGHTTIME
- temporarily relieves these symptoms due to a cold
  - minor aches and pains
  - headache
  - sore throat
  - runny nose
  - sneezing
  - itchy, watery eyes due to hay fever
  - nasal and sinus congestion
  - itchy of the nose or throat
  - cough due to minor throat and bronchial irritation
- temporarily reduces fever

Warnings

DAYTIME and NIGHTTIME

Liver warning: These products contain 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

DAYTIME
- 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, ot 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.

NIGHTTIME
- to make a child sleepy
- with any other drug containing acetaminophen (prescription or nonprescription). If

you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on the skin
- 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.

Ask a doctor before use if you have

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

NIGHTTIME
- liver disease
- glaucoma
- high blood pressure
- heart disease
- diabetes
- thyroid disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are

DAYTIME

taking the blood thinning drug warfarin

NIGHTTIME
- the blood thinning drug warfarin
- sedative or tranquilizers

When using this product,

DAYTIME
do not exceed recommended dosage.

NIGHTTIME
- **do not exceed recommended dosage**
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

- marked drowsiness may occur
- excitability may occur, especially in children

Stop use and ask a doctor if

DAYTIME

- nervousness, dizziness or sleeplessness occur
- pain, cough,or nasal congestion 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.

NIGHTTIME

- nervousness, dizziness, or sleeplessness occur
- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- 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.

Keep out of reach of children.

DAYTIME and NIGHTTIME

Overdose warning: Taking more than the recommended dose can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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

DAYTIME and NIGHTTIME

- **do not take more than directed (see Overdose warning)**
- do not take more than 6 doses (180 mL) in any 24-hour peroid
- measure only with dosing cup provided. Do not use any other dosing device.
- mL = milliliter
- keep dosing cup with product
- adults and children 12 years and over:
- children under 12 years: do not use

Other information

DAYTIME

- each 30 mL Contains: sodium 16 mg
- store between 20-25ºC (68-77º). Do not refrigerate

NIGHTTIME

- each 30 mL contains: potassium 10 mg
- each 30 mL contains: sodium 14 mg
- store between 20-25ºC (68-77ºF). Do not refrigerate

Inactive ingredients

DAYTIME

acesulfame potassium, alcohol, citric acid, disodium EDTA, FD&C blue #1, FD&C red #40, flavor, glycerin, maltitol, propylene glycol, purified water, sodium benzoate, sodium citrate

NIGHTTIME

acesulfame potassium, alcohol, citric acid, disodium EDTA, FD&C blue #1, FD&C red #40, flavor, glycerin, maltitol, propylene glycol, purified water, sodium benzoate, sodium citrate

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

DAYTIME & NIGHTTIME

Compare to the active ingredients in Theraflu® ExpressMax® Daytime & Nighttime Severe Cold & Cough*

Daytime

Severe Cold & Cough

ACETAMINOPHEN

Pain reliever; fever reducer

DEXTROMETHORPHAN HBr

Cough suppressant

PHENYLEPHRINE HCl

Nasal decongestant

Relief of:

Nasal congestion; Cough; Fever; Body ache; Sore Throat; Headache

Berry Flavor

Alcohol content 10%

For Ages 12 & Over

Nighttime

Severe Cold & Cough

ACETAMINOPHEN

Pain reliever; Fever reducer

DIPHENHYDRAMINE HCl

Anthihistamine; Cough suppressant

PHENYLEPHRINE HCl

Nasal decongestant

Relief of:

Nasal congestion; Cough; Fever; Body ache; Sore throat; Headache

Dosing Cup Included

Berry Flavor

Alcohol content 10%

for Ages 12 & Over

FL OZ (mL)

*This product is not manufactured or distributed by GSK Comsumer Healthcare, distributor of Theraflu® ExpressMax® Daytime & Nighttime Severe Cold & Cough.

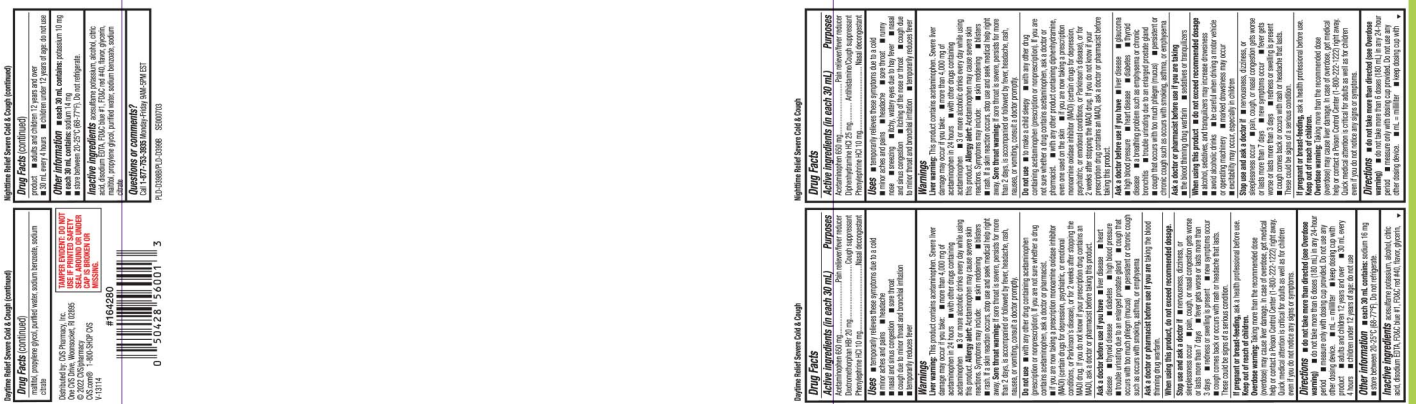
TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND OR UNDER CAP IS BROKEN OR MISSING.

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

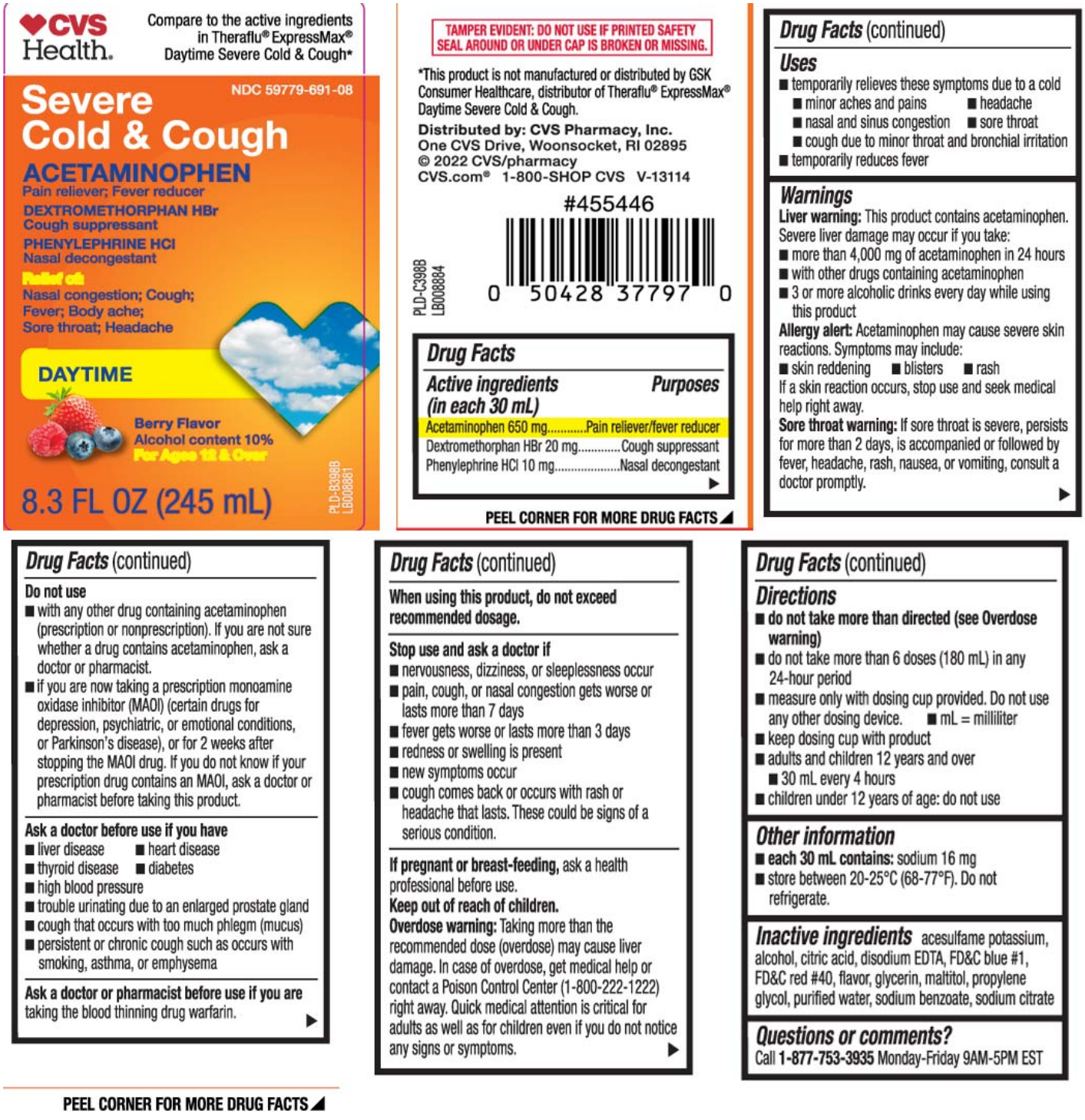
CVS.com® 1-800-SHOP CVS

Product Label



CVS HEALTH Daytime Nighttime Relief Severe Cold & Cough

Product label Daytime



CVS HEALTH Daytime Relief Severe Cold & Cough

Package label Nighttime

CVS HEALTH Nighttime Relief Severe Cold & Cough

DAYTIME NIGHTTIME COLD/FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl, diphenhydramine hci kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59779-686

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:59779-686-16	1 in 1 KIT; Type 0: Not a Combination Product	07/31/2016	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE, PLASTIC	245 mL
Part 2	1 BOTTLE, PLASTIC	245 mL

Part 1 of 2

DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid

Product Information	
Item Code (Source)	NDC:59779-691
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	20 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTITOL (UNII: D65DG142WK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59779-691-08	245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/31/2016	

Part 2 of 2

NIGHTTIME COLD AND FLU

acetaminophen, diphenhydramine hci, phenylephrine hci liquid

Product Information	
Item Code (Source)	NDC:59779-693
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
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

GLYCERIN (UNII: PDC6A3C0OX)	
MALTITOL (UNII: D65DG142WK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-693-08	245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/31/2016	

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/31/2016	

Labeler - CVS Pharmacy (062312574)

Revised: 6/2022 CVS Pharmacy