DAYTIME COLD AND FLU- acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled EQUALINE (SuperValu)

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 softgel)

Acetaminophen 325 mg

Dextromethoprhan HBr 10 mg

Phenlyephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves common cold and flu symptoms:
 - minor aches and pains
 - headache
 - sore throat
 - nasal congestion
 - fever
 - 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 4,000 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

- 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.

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

When using this product,

do not exceed recommended dosage.

Stop use and ask a doctor if

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

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

- do not take more than directed (see Overdose warning)
- do not take more than 4 doses in 24 hours
- adults and children 12 years and over: take 2 softgels with water every 4 hours
- swallow whole; do not crush, chew, or dissolve
- children under 12 years: do not use
- when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

Other information

- store between 15-30°C (59-86°F)
- avoid excessive heat

Inactive ingredients

FD&C yellow#6, FD&C red #40, gelatin, glycerin, lecithin, light mineral oil, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

Questions or comments?

Call toll free 1-855-423-2630

Principal Display Panel

compare to Vicks® DayQuil® Cold & Flu LiquiCaps® active ingredients† non-drowsy, multi-symptom

daytime

cold & flu relief

acetaminophen 325 mg (aches/fever reducer)

dextromethorphan HBr 10 mg (cough suppressant)

phenylephrine HCl 5 mg (nasal decongestant)

relieves:

- aches, fever, sore throat
- nasal Congestion& cough

ALCOHOL & ANTIHISTAMINE FREE

softgels**

(**liquid-filled capsules

†This product is not manufactured or distributed by The Procter & Gamble Company. Vicks®, DayQuil®, and LiquiCaps® are registered trademarks of The Procter Gamble Company.

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

DISTRIBUTED BY UNFI, PROVIDENCE, RI 02908 USA

Package Label

When using this product, do not exceed recommended dosage.

thinning drug warfarin.

Ask a doctor or pharmacist before use if you are taking the blood

- condµ that occurs with too much phiegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, or ■ trouble uninating due to an enlarged prostate gland
- heart disease thyroid disease high blood pressure Ask a doctor before use it you have I liver disease I diabetes

bysrmacist before taking this product. do not know if your prescription drug contains an MAOI, ask a doctor or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you

- (certain drugs for depression, psychiatric, or emotional conditions, or ■ if you are now taking a prescription monoamine oxidase inhibitor (MAOI) acetaminophen, ask a doctor or pharmacist.
 - nonprescription). If you are not sure whether a drug contains with any other drug containing acetaminophen (prescription or osu ton od

nomiting, consult a doctor promptly.

days, is accompanied or followed by fever, headache, rash, nausea, or Sore throat warning: If sore throat is severe, persists for more than 2 If a skin reaction occurs, stop use and seek medical help right away. may include: a skin reddening a blisters areash

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms

- 3 or more alcoholic drinks every day while using this product
 - with other drugs containing acetaminophen
 - more than 4,000 mg of acetaminophen in 24 hours шяй осспиц йол гакв:

Liver warning: This product contains acetaminophen. Severe liver damage Warnings

Drug Facts (continued)

Call toll free 1-855-423-2630 Questions or comments?

glycol, purified water, sorbitan, sorbitol, white ink lecithin, light mineral oil, mannitol, polyethylene glycol, povidone, propylene Inactive ingredients FD&C red #40, FD&C yellow #6, gelatin, glycerin,

> m store between 15-30°C (59-86°F) ■ avoid excessive heat Other information

label to ensure correct dosing

- when using other Daytime or Nighttime products, carefully read each ■ children under 12 years: do not use
 - swallow whole; do not crush, chew, or dissolve
- squits and children 12 years and over: take 2 softgels with water every 4 hours ■ do not take more than 4 doses in 24 hours

DIRECTIONS a do not take more than directed (see Overdose warning)

adults as well as for children even if you do not notice any signs or symptoms. Center (1-800-222-1222) right away. Quick medical attention is critical for damage. In case of overdose, get medical help or contact a Poison Control Overdose warning: Taking more than the recommended dose can cause liver Keep out of reach of children.

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

signs of a serious condition.

- conditioned back or occurs with rash or headache that lasts. These could be
 - redness or swelling is present
 new symptoms occur
 - fever gets worse or lasts more than 3 days
 - uervousness, dizziness, or sleeplessness occur
 - pain, cough, or nasal congestion gets worse or lasts more than 7 days Stop use and ask a doctor if

Drug Facts (continued)

Nasal decongestant Phenylephrine HCl 5 mg. Cough suppressant Dextromethorphan HBr 10 mg. Acetaminophen 325 mg. Pain reliever/fever reducer

Purposes

Active ingredients (in each softgel)

Drug Facts

■ cough due to minor throat and bronchial irritation ■ ussal congestion ■ fever ■ headache ■ sore throat ■ winor aches and pains **NSGS** In temporarily relieves common cold and flu symptoms:

Drug Facts (continued)

NDC 41163-998-24

compare to Vicks® DayQuil® Cold & Flu LiquiCaps® active ingredients[†]

EQUALINE®

non-drowsy, multi-symptom

daytime cold & flu relief

acetaminophen 325 mg (aches/fever reducer)

dextromethorphan HBr 10 mg (cough suppressant) phenylephrine HCl 5 mg (nasal decongestant)

relieves:

- aches, fever & sore throat
- nasal congestion & cough

ALCOHOL & ANTIHISTAMINE FREE



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



DISTRIBUTED BY UNFI, PROVIDENCE, RI 02908 USA



[†]This product is not manufactured or distributed by The Procter & Gamble Company. Vicks®, DayQuil®, and LiquiCaps® are registered trademarks of The Procter & Gamble Company.





EQUALINE Multi-Symptom Daytime Cold & Flu relief

DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information

HUMAN OTC DRUG NDC:41163-998 **Product Type** Item Code (Source)

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients	
Ingredient Name	Strength
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ 989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6092ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
MANNITOL (UNII: 30WL53L36A)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Product Characteristics			
Color	orange	Score	no score
Shape	CAPSULE	Size	20mm

Flavor	Imprint	Code	PC9
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-998- 24	24 in 1 CARTON	07/30/2021	
1		1 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 final	part341	07/30/2021	

Labeler - EQUALINE (SuperValu) (006961411)

Revised: 11/2022 EQUALINE (SuperValu)