NIGHTTIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate 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.

Safeway Nighttime Cold & Flu

Active Ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine Succinate 6.25 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistimine

Purpose

Pain reliever / fever reducer

Cough suppressant

Antihistamine

Uses

- temporarily relieves common cold and flu symptoms:
 - sore throat
 - headache
 - minor aches and pains
 - 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 4,000 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 of pharmacist before taking this product.

Ask a doctor before use if you have

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

Ask a doctor of pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

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.

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 (1888-222-1222) 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 6 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

D&C yellow #10, FD&C blue #1, 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® NyQuil® Cold & Flu LiquiCaps® active ingredients†

multi-symptom

nighttime

cold & flu relief

acetaminophen 325 mg (aches / fever reducer

dextromethorphan HBr 15 mg (cough suppressant)

doxylamine succinate 6.25 mg (antihistamine)

relieves:

- Aches, Fever, SoreThroat
- Cough, sneezing & runny nose

softgels

(**liquid-filled capsules)

†This product is not manufactured or distributed by The Procter & Gamble Company. Vicks®, NyQuil®, 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

- be careful when driving a motor vehicle or operating machinery
 - alcohol, sedatives, and tranquilizers may increase drowsiness
 - msuked drowsiness may occur ■ SVOID SICOPOLIC DYNKS

■ excitability may occur, especially in children When using this product and one exceed recommended dosage

- - taking sedatives or tranquilizers
- taking the blood thinning drug warfarin
- Ask a doctor or pharmacist before use if you are
- condp that occurs with too much phiegm (mucus)
- smoking, asthma, chronic bronchitis or emphysema
- a breathing problem or chronic cough that lasts such as occurs with
 - trouble unnating due to an enlarged prostate gland

■ disncoma Ask a doctor before use if you have I liver disease

pharmacist 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

consult a doctor promptly. is accompanied or followed by fever, headache, rash, nausea, or vomiting, Sore throat warning: If sore throat is severe, persists for more than 2 days, If a skin reaction occurs, stop use and seek medical help right away. Symptoms may include: skin reddening blisters Allergy alert. Acetaminophen may cause severe skin reactions.

Drug Facts (continued)

Drug Facts

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

purified water, sorbitan, sorbitol, white ink lecithin, light mineral oil, mannitol, polyethylene glycol, povidone, propylene glycol, Inactive ingredients D&C yellow #10, FD&C blue #1, gelatin, glycerin,

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

to ensure correct dosing

when using other Daytime or Nighttime products, carefully read each label

■ children under 12 years: do not use swsjjow whoje; do not crush, chew, or dissolve

■ adults and children 12 years and over: take 2 softgels with water every 6 hours ■ do not take more than 4 doses in 24 hours

Directions a do not take more than directed (see Overdose warming)

as for children even if you do not notice any signs or symptoms. (1-800-222-1222) right away. Quick medical attention is critical for adults as well damage. In case of overdose, get medical help or contact a Poison Control Center 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.

These could be signs of a serious condition. cond) comes pack or occurs with rash or headache that lasts. redness or swelling is present
 new symptoms occur

■ fever gets worse or lasts more than 3 days ■ bein or cough gets worse or lasts more than 7 days Stop use and ask a doctor if

Drug Facts (continued)

3 or more alcoholic drinks every day while using this product ■ with other drugs containing acetaminophen

Doxylamine succinate 6.25 mg.

Acetaminophen 325 mg.

Pain reliever/fever reducer səsod.in_d

Warnings

■ runny nose and sneezing ■ cough due to minor throat and bronchial irritation

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

occur if you take: ■ more than 4,000 mg of acetaminophen in 24 hours

■ SOLG ILLOSI ■ UGSQSCUG ■ WILLOOK SCUGS SUG DSIUS ■ 16AGL **NSES** • temporarily relieves common cold and flu symptoms:

Dextromethorphan HBr 15 mg. Condh suppressant

Active ingredients (in each softgel)

Orug Facts (continued)

compare to Vicks® NDC 41163-899-24 NyQuil® Cold & Flu LiquiCaps® active

ingredients[†]

EQUALINE®

multi-symptom

nighttime cold & flu relief

acetaminophen 325 mg (aches/fever reducer) dextromethorphan HBr 15 mg (cough suppressant) doxylamine succinate 6.25 mg (antihistamine)

relieves:

- aches, fever & sore throat
- cough, sneezing & runny nose



24 softgels** (**liquid-filled capsules)

actual size

Date

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



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





EQUALINE Nighttime Cold & Flu Relief

NIGHTTIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-899
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	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: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6092ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
MANNITOL (UNII: 30WL53L36A)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Product Characteristics			
Color	green	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	PC10
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-899- 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)