# DAYTIME COLD AND FLU NON DROWSY- acetaminohpen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled MEIJER, INC.

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.

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# **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
  - o 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 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 at between 15°-30°C (59°-86°F)
- avoid excessive heat

## **Inactive ingredients**

butylated hydroxyanisole\*, butylated hydroxytoluene\*, carminic acid\*, edible white ink, D&C yellow #10\*, FD&C red #40, FD&C yellow#6, gelatin, glycerin, polyethylene glycol\*, povidone, propylene glycol, purified water, sodium metabisulfite\*, sorbitan\*, sorbitol

#### Questions or comments?

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

#### **Principal Display Panel**

Compare to Vicks® DayQuil® LiquiCaps® active ingredients†

Non-Drowsy

**Daytime Cold/Flu Relief** 

**Acetaminophen 325 mg** / Pain reliever / fever reducer

Dextromethorphan 10 mg / HBr-Cough suppressant

Phenylephrine HCl 5 mg / Nasal decongestant

Multi-Symptom Relief

Relief of: aches, fever & sore throat nasal congestion & cough

Alcohol 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 SHOWING ANY SIGNS OF TAMPERING

#### KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

DIST. BY MEIJER DISTRIBUTION, INC.

GRAND RAPIDS, MI 49544

www.meijer.com

### **Package Label**

<sup>\*</sup>contains one or more of these ingredients

Questions or comments?

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nund vacts (continued)

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**Drug Facts** (continued)

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NDC 41250-568-24



Compare to Vicks® DayQuil® LiquiCaps® active ingredients<sup>†</sup>

**Non-Drowsy** 

# eCold&

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

# **Multi-Symptom Relief**

Relief of: aches, fever & sore throat nasal congestion & cough

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PLD-A40P FC003481



#### Meijer DayTime Cold & Flu Softgels

# DAYTIME COLD AND FLU NON DROWSY

acetaminohpen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Dro	duct	Info	rmation	
PIU	CILICI	HIIIO	Tilla UVI	ı

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41250-568

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients	
Ingredient Name	Strength
BUTYLATED HYDRO XYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
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)	
PO VIDO NE (UNII: FZ989 GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6 O9 2 ICV9 RU)	
SORBITOL (UNII: 506T60A25R)	
CARMINIC ACID (UNII: CID8 Z8 N9 5N)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	

Prod	nct	Charact	teristics

Color ORANGE Score no score

Shape	CAPSULE	Size	20 mm
Flavor		Imprint Code	P19;95A;512;P119
Contains			

Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:41250-568-24	24 in 1 CARTON	03/31/2016		
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	03/31/2016	

# **Labeler - MEIJER, INC.** (006959555)

Revised: 12/2019 MEIJER, INC.