

COLD AND FLU RELIEF DAYTIME- acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled
Major Pharmaceuticals

Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

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

Inactive ingredients

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

Questions or comments?

Call **1-800-616-2471**

Principal Display Panel

Compare to the active ingredients in Vick® DayQuil® Cold & Flu LiquiCaps®†

Antihistamine

Non-Drowsy

Alcohol-Free

Cold & Flu Relief

DAYTIME RELIEF

Softgels

Acetaminophen 325 mg - Pain reliever/Fever reducer

Dextromethorphan HBr 10 mg Cough suppressant

Phenylephrine HCL 5 mg - Nasal decongestant

Relieves:

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Nasal Congestion
- Cough

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.

Distributed by:

MAJOR® PHARMACEUTICALS

17177 N laurel Park Drive, Suite 233

Livonia, MI 48152

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

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

Ask a doctor before use if you have ■ liver disease ■ diabetes

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.

■ If you are not sure whether a drug contains

nonprescription), if you are not sure whether a drug contains

■ with any other drug containing acetaminophen (prescription or

Do not use

vomiting, consult a doctor promptly.

Sore throat warning: If sore throat is severe, persists for more than 2

days, is accompanied or followed by fever, headache, rash, nausea, or

If a skin reaction occurs, stop use and seek medical help right away.

may include: ■ skin reddening ■ blisters ■ rash

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

may occur if you take:

Liver warning: This product contains acetaminophen. Severe liver damage

Warnings

Drug Facts (continued)

Directions ■ do not take more than directed (see Overdose warning)

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- 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 ensure 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, glycol, purified water, sorbitan, sorbitol, white ink

Questions or comments? Call 1-800-616-2471

Drug Facts (continued)

Keep out of reach of children. 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.

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

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These could be signs of a serious condition.

- cough comes back 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
- nervousness, dizziness, or sleepiness occur
- pain, cough, or nasal congestion gets worse or lasts more than 7 days

Stop use and ask a doctor if

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■ fever gets worse or lasts more than 3 days

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Drug Facts (continued)

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Uses ■ temporarily relieves common cold and flu symptoms:

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- nasal congestion
- cough due to minor throat and bronchial irritation

Drug Facts (continued)

Drug Facts

Active ingredients (in each softgel)

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

Purposes

Antihistamine-Free
Non-Drowsy
Alcohol-Free

MAJOR[®]

NDC 0904-6995-44
Compare to the active ingredients in
Vicks[®] DayQuil[®] Cold & Flu LiquiCaps[®]

Cold & Flu

DAYTIME RELIEF

Softgels

Acetaminophen 325 mg, Pain Reliever/Fever Reducer
Dextromethorphan HBr 10 mg, Cough Suppressant
Phenylephrine HCl 5 mg, Nasal Decongestant

Relieves:

- ✓ Headache, Fever, Sore Throat, Minor Aches & Pains
- ✓ Nasal Congestion

16 Softgels^{**}



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.

No.:
Date:

Actual Size

✓ Cough

**Liquid-Filled Capsules

Lot
Exp

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Distributed by:
MAJOR® PHARMACEUTICALS
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152

Rev. 07/19 M-58 Re-order No. 701184



PLD-B584A FC006039



MAJOR Cold & Flu Relief

COLD AND FLU RELIEF DAYTIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6995
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
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: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	20mm

Flavor		Imprint Code	PC9	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6995-44	16 in 1 CARTON	07/31/2019	
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 Drug	M012	07/31/2019		

Labeler - Major Pharmaceuticals (191427277)

Revised: 4/2024

Major Pharmaceuticals