**COLD AND FLU SEVERE- acetaminophen,dextromethorphan hbr,guaifenesin,phenylephrine hcl tablet, film coated**
**Wal-Mart Stores 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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**Equate 44-503A-FLU**

### *Active ingredients (in each caplet)*

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

### *Purpose*

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

### *Uses*

- temporarily relieves these common cold and flu symptoms:
  - sore throat
  - cough
  - nasal congestion
  - headache
  - minor aches and pains
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

### *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.
- if you have ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if you have**

- heart disease
- liver disease
- diabetes
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- thyroid disease
- cough that occurs with too much phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- high blood pressure

**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**

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

In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt 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**
- adults and children 12 years and over
  - take 2 caplets every 4 hours
  - swallow whole - do not crush, chew, or dissolve
  - do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

***Other information***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

***Inactive ingredients***

corn starch, crospovidone, D&C yellow #10 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

***Questions or comments?***

**1-888-287-1915**

***Principal display panel***

***equate™***

NDC 49035-053-08

**Compare
to Tylenol®
COLD + FLU
SEVERE Active
Ingredients***

Severe
**Cold & Flu**

**Acetaminophen,**
Dextromethorphan HBr,
Guaifenesin, Phenylephrine HCl

Pain Reliever/Fever Reducer,
Cough Suppressant, Expectorant,
Nasal Decongestant,

- Headache, fever, sore throat
- Nasal congestion
- Cough
- Mucus
- Chest congestion

**24**
CAPLETS

Actual Size

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

Satisfaction guaranteed - Or we'll replace it or give you your money back. For questions or comments or to report an undesired reaction or side effect, please call **1-888-287-1915**.

**DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716**

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® COLD + FLU SEVERE.
50844 REV0718B50308

NDC 49035-053-08

equate™

Compare to Tylenol® COLD + FLU SEVERE Active Ingredients*

Severe

B-2203-503A-08-FLU
REV0718B50308

## Drug Facts

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

### Active ingredients (in each caplet)

| | Purpose |
|---|---|
| Acetaminophen 325 mg | Pain reliever/fever reducer |
| Dextromethorphan HBr 10 mg | Cough suppressant |
| Guaifenesin 200 mg | Expectorant |
| Phenylephrine HCl 5 mg | Nasal decongestant |

### Uses

- temporarily relieves these common cold and flu symptoms:
  - sore throat
  - cough
  - nasal congestion
  - headache
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- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

## Drug Facts (continued)

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- thyroid disease
- cough that occurs with too much phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- high blood pressure

**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**

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- pain, nasal congestion, or cough gets worse or lasts more than 7 days
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## Drug Facts (continued)

### Other information

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- see end flap for expiration date and lot number

## Drug Facts (continued)

### Inactive ingredients

corn starch, crospovidone, D&C yellow #10 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

## Drug Facts (continued)

### Questions or comments? 1-888-287-1915

**PARENTS:** Learn about teen medicine abuse www.StopMedicineAbuse.org

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50844 REV0718B50308

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

Lot/Exp area at minimum size 1.25 x .5"

729665

6 81131 18718 3


**Equate 44-503A**

# COLD AND FLU SEVERE

acetaminophen,dextromethorphan hbr,guaifenesin,phenylephrine hcl tablet, film coated

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:49035-053 |
| **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 |
| **GUAIFENESIN** (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 200 mg |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **CROSPOVIDONE** (UNII: 2S7830E561) | |
| **D&C YELLOW NO. 10 ALUMINUM LAKE** (UNII: CQ3XH3DET6) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POLYVINYL ALCOHOL, UNSPECIFIED** (UNII: 532B59J990) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |

| | |
|---|---|
| **SUCRALOSE** (UNII: 96K6UQ3ZD4) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | yellow | **Score** | no score |
| **Shape** | OVAL | **Size** | 19mm |
| **Flavor** | MENTHOL | **Imprint Code** | 44;503 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:49035-053-08 | 2 in 1 CARTON | 08/04/2005 | |
| **1** | | 12 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **2** | NDC:49035-053-42 | 12 in 1 BLISTER PACK; Type 0: Not a Combination Product | 08/04/2005 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 08/04/2005 | |

## Labeler - Wal-Mart Stores Inc (051957769)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867837 | pack(49035-053) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867894 | manufacture(49035-053) |

Revised: 6/2022 Wal-Mart Stores Inc