

**FLU HBP- acetaminophen, dextromethorphan hbr, chlorpheniramine maleate tablet, film coated  
Walgreen Company**

*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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**Walgreens 44-461**

***Active ingredients (in each tablet)***

Acetaminophen 500 mg  
Chlorpheniramine maleate 2 mg  
Dextromethorphan HBr 15 mg

***Purpose***

Pain reliever/fever reducer  
Antihistamine  
Cough suppressant

***Uses***

- temporarily relieves these common cold and flu symptoms:
  - minor aches and pains
  - sore throat
  - sneezing
  - runny nose
  - cough
  - headache
- temporarily reduces fever

***Warnings***

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

- blisters
- rash
- skin reddening

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**

- difficulty in urination due to enlargement of the prostate gland
- liver disease
- cough that occurs with too much phlegm (mucus)
- glaucoma
- a breathing problem or persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema

**Ask a doctor or pharmacist before use if you are**

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

**When using this product**

- avoid alcoholic beverages
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- excitability may occur, especially in children
- use caution 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
- 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 (1-800-222-1222) 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: 2 tablets every 6 hours while symptoms persist. Do not take more than 6 tablets 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
- protect from excessive moisture

***Inactive ingredients***

corn starch, crospovidone, D&C yellow #10 aluminum lake, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

***Questions or comments?***

**1-800-426-9391**

**Principal Display Panel**

***Walgreens***

NDC 0363-0461-09

MAXIMUM STRENGTH

**FLU HBP**

**ACETAMINOPHEN /**

**PAIN RELIEVER / FEVER REDUCER**

**CHLORPHENIRAMINE MALEATE / ANTIHISTAMINE**

**DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT**

**DECONGESTANT FREE**

- Relieves body aches, pains, headaches, runny nose, fever, cough, sore throat & sneezing
- Flu relief for people with high blood pressure

**20**

**TABLETS**

**ACTUAL SIZE**

**DISTRIBUTED BY: WALGREEN CO.**

**200 WILMOT RD., DEERFIELD, IL 60015**

***Walgreens***

**100% SATISFACTION GUARANTEED**

walgreens.com ©2017 Walgreen Co.

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

Walgreens Pharmacist Recommended

Walgreens Pharmacist Survey

50844 REV0219A46109

Walgreens.com © 2017 Walgreen Co.  
**100% SATISFACTION**  
*Guarantee*  
 DISTRIBUTED BY: WALGREEN CO.  
 200 WILMOT RD., DEERFIELD, IL 60015

Walgreens Pharmacist Survey  
 WALGREENS DO NOT USE IF PACKAGE IS  
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**Drug Facts (continued)**

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**Ask a doctor before use if you have**  
 ■ difficulty in urination due to enlargement of the prostate gland  
 ■ liver disease ■ glaucoma  
 ■ cough that occurs with too much phlegm (mucus)  
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**Drug Facts (continued)**

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**Other information**  
 ■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN

**Drug Facts (continued)**

FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

**Questions or comments?** 1-800-426-9891

NDC 0363-0461-09

## MAXIMUM STRENGTH Flu HBP

ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER  
 CHLORPHENIRAMINE MALEATE / ANTIHISTAMINE  
 DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT

**DECONGESTANT FREE**

- Relieves body aches, pains, headaches, runny nose, fever, cough, sore throat & sneezing
- Flu relief for people with high blood pressure

**20 TABLETS**

ACTUAL SIZE

**Drug Facts**

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**Drug Facts (continued)**

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**Inactive ingredients** com starch, croscopolone, D&C yellow #10 aluminum lake, FD&C red #40 aluminum lake.

**Questions or comments?** 1-800-426-9891

ORG0917-F REV0419

50844 REV0219A46109

ITEM 501546 W00000-0000-0

3 11917 07635 5

No Print or Varnish  
 Lot and Exp. Date ONLY

B-2201-461-09-H  
 REV0219A46109

Walgreens 44-461

## FLU HBP

acetaminophen, dextromethorphan hbr, chlorpheniramine maleate tablet, film coated

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0363-0461 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength             | Strength |
|---|-------------------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)                    | ACETAMINOPHEN                 | 500 mg   |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 15 mg    |
| CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)      | CHLORPHENIRAMINE MALEATE      | 2 mg     |

### Inactive Ingredients

| Ingredient Name                      | Strength |
|--------------------------------------|----------|
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) |          |

|  |
|--|
| MAGNESIUM STEARATE (UNII: 70097M6I30)                    |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)           |
| POVIDONE (UNII: FZ989GH94E)                              |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                       |
| STEARIC ACID (UNII: 4ELV7Z65AP)                          |
| TALC (UNII: 7SEV7J4R1U)                                  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                      |
| STARCH, CORN (UNII: O8232NY3SJ)                          |
| CROSPVIDONE (UNII: 2S7830E561)                           |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)                     |
| FD&C RED NO. 40 (UNII: WZB9127XOA)                       |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)      |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)        |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) |

### Product Characteristics

|          |      |              |          |
|----------|------|--------------|----------|
| Color    | RED  | Score        | no score |
| Shape    | OVAL | Size         | 18mm     |
| Flavor   |      | Imprint Code | 44;461   |
| Contains |      |              |          |

### Packaging

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0363-0461-09 | 2 in 1 CARTON   | 06/01/2005           |                    |
| 1 |                  | 10 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                                  | 06/01/2005           |                    |

### Labeler - Walgreen Company (008965063)

### Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 832867894 | MANUFACTURE(0363-0461) |

### Establishment

| Name                    | Address | ID/FEI    | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. |         | 832867837 | PACK(0363-0461)     |