FLU HBP MAXIMUM STRENGTH- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr 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.

Walgreens 44-738

Active ingredients (in each caplet)

Acetaminophen 325 mg Chlorpheniramine maleate 2 mg Dextromethorphan HBr 10 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
 - headache
 - runny nose
 - cough
- 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:

- 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 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 while symptoms persist. 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
- protect from excessive moisture

Inactive ingredients

corn starch, crospovidone, FD&C red #40 aluminum lake, lecithin, 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 0363-7380-09

Compare to Coricidin® HBP Maximum Strength Flu active ingredients††

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
- For People with High Blood Pressure

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CAPLETS

ACTUAL SIZE

TAMPER EVIDENT: D0 NOT USE IF PACKAGE IS OPENED OR IF BLISTER IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

Walgreens Pharmacist Recommended Walgreens Pharmacist Survey

††This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Coricidin® HBP Maximum Strength Flu.

50844 ORG101973809



FLU HBP MAXIMUM STRENGTH

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-7380	
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			
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg			
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg			

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	

CROSPO VIDO NE (UNII: 2S7830E561)

FD&C RED NO. 40 (UNII: WZB9127XOA)

LECITHIN, SO YBEAN (UNII: 1DI56QDM62)

MAGNESIUM STEARATE (UNII: 70097M6I30)

MICRO CRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)

PO VIDO NE (UNII: FZ989GH94E)

SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)

STEARIC ACID (UNII: 4ELV7Z65AP)

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

Product Characteristics				
Color	RED	Score	no score	
Shape	OVAL	Size	16 mm	
Flavor		Imprint Code	44;738	
Contains				

]	Packaging					
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0363-7380- 09	2 in 1 CARTON	03/19/2020			
1	ı	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	03/19/2020			

Labeler - Walgreen Company (008965063)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	MANUFACTURE(0363-7380), PACK(0363-7380)

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		832867894	MANUFACTURE(0363-7380)		

Revised: 2/2020 Walgreen Company