

MAXIMUM STRENGTH FLU- acetaminophen, dextromethorphan hbr, chlorpheniramine maleate tablet, film coated

Rite Aid

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.

Rite Aid 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:
- minor aches and pains
- headache
- cough
- sneezing
- runny nose
- temporarily reduces fever

Warnings

Liver warning:

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 8 tablets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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

- trouble urinating due to an enlarged 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

- excitability may occur, especially in children
- drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful 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.

Overdose warning: Taking more than the recommended dose (overdose) may 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)**
- adults and children 12 years and over: 2 tablets every 6 hours while symptoms persist. Do not take more than 8 tablets in 24 hours
- children under 12 years: do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other information

- store at controlled room temperature 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

PRODUCT PACKAGING

The product packaging shown below represents a sample of that currently in use. Additional packaging may also be available.

RITE

AID®

PHARMACY

Compare to the Active Ingredients in
Coricidin® HBP Maximum Strength Flu*

See New Warnings Information

Pain Reliever,
Fever Reducer,
Antihistamine,
Cough Suppressant

MAXIMUM STRENGTH

FLU

Decongestant-free

Acetaminophen

Chlorpheniramine maleate

Dextromethorphan HBr

Relieves

- Body aches, pains & headache
- Fever
- Cough
- Runny Nose

Specially formulated for people with high blood pressure

20 TABLETS

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

50844 REV0310D46109

DISTRIBUTED BY:

Rite Aid Corporation

30 Hunter Lane, Camp Hill, PA 17011



Product Packaging

MAXIMUM STRENGTH FLU

acetaminophen, dextromethorphan hbr, chlorpheniramine maleate tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0461
Route of Administration	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)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (UNII: 68401960MK)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	RED	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	44;461
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0461-9	1 in 1 CARTON		
1		20 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	06/01/2005	

Labeler - Rite Aid (014578892)