

HYBRID CF - apap 500 mg phenylephrine hcl 5 mg chlorpheniramine maleate 2 mg tablet, film coated

Hybrid-Rx LLC

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.

Drug Facts

Active Ingredients (in each caplet)

Acetaminophen 500 mg

Chlorpheniramine maleate 2 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever/Fever Reducer

Antihistamine

Nasal Decongestant

Directions

Adults: Take 1 to 2 caplets with water every 6 hours as needed; do not take more than 8 caplets in 24 hours or as directed by a doctor.

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Questions? 1-904-367-8437, Monday-Friday, 9am-5pm EST

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 8 caplets in 24 hours

with other drugs containing acetaminophen

3 or more alcoholic drinks every day while using this product

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

Do Not Use

- 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
- with any other product containing any of the above active ingredients.
- with any other drug containing acetaminophen (prescription or nonprescription).
- Ask a doctor or pharmacist before using with other drugs if you are not sure.

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if

you are taking sedatives or tranquilizers.

When using this product

- do not use more than directed
- excitability may occur, especially in children
- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase the drowsiness
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- redness or swelling is present
- new symptoms occur
- symptoms get worse or last for more than 7 days
- fever gets worse or lasts more than 3 days

If pregnant or breast feeding

ask a health professional before use.

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Hybrid CF

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HYBRID CF

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49804-101(NDC:62959-116)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE	2 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

HYPROMELLOSE 2910 (15 CPS) (UNII: 36SFW2JZ0W)				
TRIACETIN (UNII: XHX3C3X673)				
POVIDONE (UNII: FZ989GH94E)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
Product Characteristics				
Color	yellow	Score	no score	
Shape	CAPSULE	Size	17mm	
Flavor		Imprint Code	PAC	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49804-101-24	1 in 1 CARTON		
1		12 in 1 BLISTER PACK		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part341		02/03/2010	

Labeler - Hybrid-Rx LLC (794846191)