CONTAC COLD AND FLU DAY- acetaminophen and phenylephrine hydrochloride tablet Mylan Consumer Healthcare, 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.

Drug Facts

Active ingredients for Day Formula (in each caplet)

Acetaminophen 500 mg

Phenylephrine hydrochloride 5 mg

Purpose

Pain reliever/fever reducer

Nasal decongestant

Uses

- temporarily relieves common cold/flu symptoms:
 - o nasal congestion
 - o headache
 - o minor aches and pains
 - o stuffy nose
 - o sore throat
 - o sinus congestion and pressure

Warnings

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

- more than 4000 mg 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.

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 persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, ask 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.

Ask a doctor before use if you have

- liver disease
- heart disease
- diabetes
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- thyroid disease

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

- you get nervous, dizzy, or sleepless
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms appear

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: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 of age and over: take 2 caplets every 6 hours as needed.
- do not take more than 8 caplets in 24 hours.
- children under 12 years of age: ask a doctor

Other information

• store at 20°-25°C (68°-77°F)

Inactive ingredients

corn starch, microcrystalline cellulose, polyethylene glycol, polysorbate 80, polyvinyl alcohol, potassium sorbate, povidone, sodium lauryl sulfate, stearic acid, talc.

.

Questions or comments? call toll-free 1-855-874-0970 (English/Spanish) weekdays

Display Panel CONTAC Cold + Flu Day Caplets: 24 count Package

DAY CONTAC® COLD+FLU

Phenylephrine HCl, **Acetaminophen** Nasal Decongestant/Pain Reliever-Fever Reducer

Maximum Strength Multi-Symptom

Nasal Congestion • Sinus Pressure •Sore Throat Head & Body Aches • Fever

24 CAPLETS

TAMPER-EVIDENT PACKAGING FEATURE: This product is protected in a sealed blister. Do not use if blister or printed foil is broken.

Distributed by:

Mylan Consumer Healthcare, Inc.

Morgantown, WV 26505 Made in Canada

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Drug Facts (continued)



Get Well Soon!



Non-Drowsy Relief



See new

warning



Phenylephrine HCl, Acetaminophen Nasal Decongestant/Pain Reliever-Fever Reducer

> Maximum Strength Multi-Symptom

Nasal Congestion • Sinus Pressure • Sore Throat Head & Body Aches • Fever

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Mylan Coresimer Healthcare, Inc.,
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Mogantown, WV 26505 Made in Canada
CONTACO is a registered trademark of
Media AB, a Mylan Company
C201 9 Mylan, Inc.

CONTAC COLD AND FLU DAY

acetaminophen and phenylephrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46017-024
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	500 mg	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients		
Ingredient Name	Strength	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POTASSIUM SORBATE (UNII: 1VPU26 JZZ4)		
PO VIDONE, UNSPECIFIED (UNII: FZ989GH94E)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
STARCH, CORN (UNII: O8232NY3SJ)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TALC (UNII: 7SEV7J4R1U)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		

Product Characteristics			
Color	WHITE	Score	no score
Shape	CAPSULE	Size	21mm
Flavor		Imprint Code	MS
Contains			

]	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:46017-024-08	1 in 1 CARTON	07/01/2011		
	NDC:46017-024-99	8 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:46017-024-24	3 in 1 CARTON	07/01/2011		
2	NDC:46017-024-99	8 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information				
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final part341 07/01/2011

Labeler - Mylan Consumer Healthcare, Inc. (831410522)

Revised: 1/2020 Mylan Consumer Healthcare, Inc.