

**PANADOL COLD AND FLU NONDROWSY- acetaminophen and phenylephrine
hcl tablet, film coated
Haleon US Holdings LLC**

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 325 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever/Fever reducer

Nasal decongestant

Uses

- temporarily relieves these symptoms due to the common cold or flu:
 - nasal congestion
 - stuffy nose
 - sore throat
 - headache
 - sinus congestion and pressure
 - minor aches and pains
- 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, 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 is severe, 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.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

When using this product do not exceed recommend 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
- any 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:

Taking more than the recommended dose can cause serious health problems. 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 of age and over: take 2 caplets every 4 hours, while symptoms persist or as directed by a doctor
- do not take more than 12 caplets in 24 hours, unless directed by a doctor
- children under 12 years of age: ask a doctor
- swallow whole - do not crush, chew or dissolve

Other information

- store below 25°C (77°F)

Inactive ingredients

crospovidone, D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, FD&C red no. 40 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Principal Display Panel

NDC 0135-7031-01

Panadol

COLD+FLU

NON-DROWSY

ACETAMINOPHEN

Pain Reliever/Fever Reducer

PHENYLEPHRINE HCl

Nasal Decongestant

50 PACKETS

2 CAPLETS PER PACKET

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

READ AND KEEP CARTON FOR COMPLETE INFORMATION

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Warren, NJ 07059

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PANADOL COLD AND FLU NONDROWSY

acetaminophen and phenyleprine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-7031
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPROVIDONE (120 .MU.M) (UNII: 68401960MK)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	CAPSULE	Size	6mm
Flavor		Imprint Code	PAN;CF
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-7031-01	50 in 1 CARTON	12/20/2022	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0135-7031-02	24 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/20/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	12/20/2022	

Labeler - Haleon US Holdings LLC (079944263)