

**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

acesulfame potassium, carnauba wax, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, flavor, lecithin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Principal Display Panel**NDC 0135-0607-02****Panadol[®]****COLD+FLU*****NON-DROWSY*****ACETAMINOPHEN****Pain Reliever/Fever Reducer****PHENYLEPHRINE HCl****Nasal Decongestant****NEW FORMULA AND DIRECTIONS****24 CAPLETS****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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NEW FORMULA AND DIRECTIONS
NDC 0135-0607-02
gsk

COLD+FLU
NON-DROWSY

Panadol®

ACETAMINOPHEN
Pain Reliever/
Fever Reducer
PHENYLEPHRINE HCl
Nasal Decongestant

Non-Drowsy

24 CAPLETS

PANADOL COLD AND FLU NONDROWSY

acetaminophen and phenyleprine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0607
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

CROSPVIDONE (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)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
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)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL (caplet)	Size	16mm
Flavor	VANILLA	Imprint Code	CF
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0607-03	50 in 1 CARTON	06/01/2017	
1	NDC:0135-0607-01	2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0135-0607-02	3 in 1 CARTON	06/01/2017	
2		8 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 Drug	M013	06/01/2017	

Labeler - Haleon US Holdings LLC (079944263)