THERAFLU POWERPODS NIGHTTIME SEVERE COLD- acetaminophen, diphenhydramine hcl, phenylephrine hcl powder, for solution Haleon US Holdings LLC

Drug Facts

Active ingredients (in each pod)

Acetaminophen 650 mg Diphenhydramine HCl 25 mg Phenylephrine HCl 10 mg

Purposes

Pain reliever/Fever reducer Antihistamine/cough suppressant Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:
 - minor aches and pains
 - minor sore throat pain
 - headache
 - nasal and sinus congestion
 - runny nose
 - sneezing
 - itchy nose or throat
 - itchy, watery eyes due to hay fever
 - cough due to minor throat and bronchial irritation
- 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
- 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 consult a doctor promptly.

Do not use

- in a child under 12 years of age
- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or a pharmacist.
- with any other product containing diphenhydramine, even one used on the skin
- 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 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
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma or emphysema

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- do not exceed recommended dosage
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- 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 care professional before use.

Keep out of reach of children.

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

Directions

- do not use more than directed
- take every 4 hours, while symptoms persist. Do not take more than 5 pods in 24 hours unless directed by a doctor.

Age	Dose
adults and children 12 years of age and over	one pod
children under 12 years of age	do not use

- do not remove the foil seal as the pod will not work properly and could result in hot water burns
- place pod in compatible brewer
- use a minimum of 8 oz. of water
- when finished, the pod will be hot and may drip. Tilt the pod during removal to avoid dripping.
- remove used pod and flush brewer after each use with a minimum of 8 oz. of water
- sip while hot. Consume entire drink within 10-15 minutes.

Other information

- each pod contains: potassium 10 mg, sodium 23 mg
- phenylketonurics: contains phenylalanine 13 mg per pod
- do not open pouch until time of use
- store at controlled room temperature 20°-25°C (68°-77°F). Protect product from heat and moisture.

Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, flavors, maltodextrin, silicon dioxide, sodium citrate, sucrose, tribasic calcium phosphate

Questions or comments?

call **1-855-328-5259**

Principal Display

NDC 0067-6095-01

NEW

THERAFLU

POWERPODS

NIGHTTIME

SEVERE COLD

ACETAMINOPHEN - PAIN RELIEVER/FEVER REDUCER

DIPHENHYDRAMINE HCI - ANTIHISTAMINE/COUGH SUPPRESSANT

PHENYLEPHRINE HCI - NASAL DECONGESTANT

- Nasal Congestion
- Sore Throat Pain
- Cough
- Headache
- Body Ache
- Fever
- Runny Nose
- Sneezing

HONEY LEMONINFUSED WITH CHAMOMILE & WHITE TEA FLAVORS

8 PODS

FOR USE ONLY WITH COMPATIBLE SINGLE SERVE BREWING MACHINES INCLUDING KEURIG AND MR. COFFEE*

*This product is not affiliated with Keurig Incorporated or Mr. Coffee.

READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE.

KEEP CARTON FOR REFERENCE. DO NOT DISCARD.

TAMPER EVIDENT POUCH. PRODUCT IS PACKAGED IN INDIVIDUAL SEALED POUCHES. DO NOT USE IF POUCH IS TORN OR BROKEN. DO NOT OPEN POUCH UNTIL TIME OF USE.

POWERFUL RELIEF FOR COLD SYMPTOMS

PRESS

Press the 8 oz. setting on your machine to brew.

SIP

Sip while hot. Consume entire drink within 10-15 minutes. Remove used pod and flush brewer after use with a minimum of 8 oz. of water.

CAUTION: PRODUCT LIQUID AND POD WILL BE HOT.

RELIEF

Prepare to experience powerful cold & flu multi-symptom relief.

1-855-328-5259

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POWERPODS NIGHTTIME SEVERE COLD

THERAFLU

ACETAMINOPHEN – PAIN RELIEVER/FEVER REDUCER DIPHENHYDRAMINE HCI – ANTIHISTAMINE/COUGH SUPPRESSANT PHENYLEPHRINE HCI – NASAL DECONGESTANT



FOR USE ONLY WITH COMPATIBLE SINGLE SERVE BREWING MACHINES INCLUDING KEURIG AND MR. COFFEE* * This product is not affiliated with Keurig

affiliated with Keurig Incorporated or Mr. Coffee. ^E Nasal Congestion Sore Throat Pain • Cough Headache • Body Ache • Fever Runny Nose • Sneezing

8 PODS

🕽 🕻 NIGHT

HONEY LEMON INFUSED WITH CHAMOMILE & WHITE TEA FLAVORS

THERAFLU POWERPODS NIGHTTIME SEVERE COLD

acetaminophen, diphenhydramine hcl, phenylephrine hcl powder, for solution

Product Infor	mation					
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:006	7-6095
Route of Admini	stration	ORAL				
Active Ingredi	ent/Active	e Moiety				
	Ingr	edient Name		Basis of Stre		Strengt
ACETAMINOPHEN	(UNII: 362091 ⁻	209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN			Ν	650 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)				DIPHENHYDRAMINE HYDROCHLORIDE		25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - PHENYLEPHRINE JNII:1WS 297W6MV) HYDROCHLORIDE			-	10 mg		
Inactive Ingre	dients					
		Ingredient Name			S	trength
ACESULFAME POT						
ANHYDROUS CITR						
ASPARTAME (UNII: Z0H242BBR1)						
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)						
FD&C BLUE NO. 1						
FD&C RED NO. 40		·				
MALTODEXTRIN (U						
SILICON DIOXIDE						
SODIUM CITRATE,	UNSPECIFIE	D FORM (UNII: 1Q73Q2JULR)				
SUCROSE (UNII: C1						
TRIBASIC CALCIUN	M PHOSPHAT	E (UNII: 91D9GV0Z28)				
Product Chara	acteristics	5				
Color			Score			
Shape			Size			
Flavor	HOI	NEY, LEMON	Imprint	t Code		
Contains						
Packaging						
# Item Code	Pa	ackage Description		eting Start Date		ting End ate
1 NDC:0067-6095- 01	8 in 1 CARTO	DN	07/28/203	18		
1 NDC:0067-6095- 02	95- 1 in 1 POUCH; Type 0: Not a Combination Product					
2 NDC:0067-6095- 03	1 in 1 CARTO		01/20/201	19		
2	1 in 1 POUC Product	H; Type 0: Not a Combination	1			

Marketing Information							
MarketingApplication Number or MonographCategoryCitation		Marketing Start Date	Marketing End Date				
OTC Monograph Drug	M012	07/28/2018					

Labeler - Haleon US Holdings LLC (079944263)

Revised: 1/2024

Haleon US Holdings LLC