THERAFLU POWERPODS DAYTIME SEVERE COLD- acetaminophen, dextromethorphan, phenylephrine powder, for solution
Haleon US Holdings LLC

Drug Facts

Active ingredients (in each pod)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/Fever reducer

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
  - 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 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 doctor before use if you have

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

When using this product

- **do not exceed recommended dosage**

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 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 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 20 mg
- **phenylketonurics:**contains phenylalanine 14 mg per pod
- do not open pouch until time of use
- store at controlled room temperature 20 º-25 ºC (68 º-77 ºF). Protect product from heat and moisture.

Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, 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 0067-6094-01

NEW

THERAFLU

POWERPODS

DAYTIME

SEVERE COLD

ACETAMINOPHEN – PAIN RELIEVER/FEVER REDUCER

DEXTROMETHORPHAN HBr – COUGH SUPPRESSANT

PHENYLEPHRINE HCl – NASAL DECONGESTANT

- **Nasal Congestion**
- **Sore Throat Pain**
- **Cough**
- **Headache**
- **Body Ache**
- **Fever**

BERRY INFUSED WITH MENTHOL & GREEN 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.

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

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

Distributed by:

GSK Consumer Healthcare, Warren, NJ 07059

13019

THERAFLU POWERPODS DAYTIME SEVERE COLD

acetaminophen, dextromethorphan, phenylephrine powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-6094
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-6094-01	8 in 1 CARTON	07/28/2018	
1	NDC:0067-6094-02	1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0067-6094-03	1 in 1 CARTON	01/20/2019	
2		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/28/2018	

Labeler - Haleon US Holdings LLC (079944263)