**THERAFLU SEVERE COLD RELIEF NIGHTTIME WITH HONEY ELDERBERRY FLAVOR- acetaminophen, diphenhydramine hcl, phenylephrine hcl powder, for solution**
**Haleon US Holdings LLC**

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## *Drug Facts*

### *Active ingredients (in each packet)*

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 packets in 24 hours unless directed by a doctor.

| Age | Dose |
|---|---|
| adults and children 12 years of age and over | one packet |
| children under 12 years of age | do not use |

- dissolve contents of one packet into 8 oz. hot water; sip while hot. Consume entire drink within 10-15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water; stir briskly before and after heating. Do not overheat.

***Other information***

- **each packet contains:**potassium 5 mg, sodium 21 mg
- **phenylketonurics:**contains phenylalanine 12.9 mg per packet
- store at controlled room temperature 20 -25 ºC (68-77 ºF). Protect product from heat and moisture.

***Inactive ingredients***

acesulfame potassium, acetic acid, aspartame, citric acid, elderberry juice concentrate, FD&C blue no. 1, FD&C red no. 40, honey solids, isomalt, maltodextrin, natural flavors, silicon dioxide, sodium citrate, soy lecithin, sucrose, sunflower lecithin, triacetin, tribasic

calcium phosphate

***Questions or comments?***

**1-855-328-5259**

**Additional Information**

**READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE.**

**KEEP CARTON FOR REFERENCE. DO NOT DISCARD.**

**TAMPER EVIDENT INNER UNIT**

**DO NOT USE IF SEALED THERAFLU PACKET IS TORN OR BROKEN**

**1-855-328-5259**

Distributed by: GSK Consumer Healthcare

Warren, NJ 07059

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**Principal Display Panel**

**THERAFLU**

**NEW FLAVOR**

MULTI - SYMPTOM COLD RELIEF

**SEVERECOLD RELIEF**

**NIGHTTIME**

**HELPS YOU REST**

**Acetaminophen**
Pain Reliever/Fever Reducer

Diphenhydramine HCl
Antihistamine/Cough Suppressant

Phenylephrine HCl
Nasal Decongestant

**Hot liquid therapy**
that relieves:

/ Nasal and sinus congestion
/ Cough
/ Sore throat pain
/ Headache
/ Runny nose

/ Fever

**Honey Elderberry**

**6 PACKETS**

PA 62000000200565 – Carton Front


| **THERAFLU SEVERE COLD RELIEF NIGHTTIME WITH HONEY ELDERBERRY FLAVOR** |
| --- |
| acetaminophen, diphenhydramine hcl, phenylephrine hcl powder, for solution |

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0067-8212 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 650 mg |
| **DIPHENHYDRAMINE HYDROCHLORIDE** (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 25 mg |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ACESULFAME POTASSIUM** (UNII: 23OV73Q5G9) | |
| **ACETIC ACID** (UNII: Q40Q9N063P) | |
| **ASPARTAME** (UNII: Z0H242BBR1) | |
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **EUROPEAN ELDERBERRY JUICE** (UNII: Z4IFJ0AK1E) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **HONEY** (UNII: Y9H1V576FH) | |
| **ISOMALT** (UNII: S870P55O2W) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM CITRATE, UNSPECIFIED FORM** (UNII: 1Q73Q2JULR) | |
| **LECITHIN, SOYBEAN** (UNII: 1DI56QDM62) | |
| **SUCROSE** (UNII: C151H8M554) | |
| **LECITHIN, SUNFLOWER** (UNII: 834K0WOS5G) | |
| **TRIACETIN** (UNII: XHX3C3X673) | |
| **TRIBASIC CALCIUM PHOSPHATE** (UNII: 91D9GV0Z28) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white (off-white, beige, brown) | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | HONEY (Elderberry) | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0067-8212-01 | 6 in 1 CARTON | 05/01/2023 | |
| **1** | | 1 in 1 PACKET; 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 | 05/01/2023 | |

## Labeler - Haleon US Holdings LLC (079944263)

Revised: 3/2024 Haleon US Holdings LLC