

**THERAFLU SEVERE COLD RELIEF DAYTIME BERRY BURST- acetaminophen,  
dextromethorphan hbr, phenylephrine hydrochloride powder  
Haleon US Holdings LLC**

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***Drug Facts***

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

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:
  - o minor aches and pains
  - o minor sore throat pain
  - o headache
  - o nasal and sinus congestion
  - o 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 a 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 last 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 packets in 24 hours unless directed by a doctor.

| Age   | Dose       |
|---|------------|
| adults and children<br>12 years of age and over | one packet |
| children under<br>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 10 mg, sodium 20 mg
- **phenylketonurics:** contains phenylalanine 14 mg per packet
- 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, FD&C blue no. 1, FD&C red no. 40, flavors, maltodextrin, silicon dioxide, sodium citrate, soy lecithin, sucrose, tribasic calcium phosphate

### **Questions or Comments?**

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

### **Additional Information**

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

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

**PARENTS:**

Learn about teen medicine abuse

[www.StopMedicineAbuse.com](http://www.StopMedicineAbuse.com)

**TAMPER EVIDENT INNER UNIT  
DO NOT USE IF SEALED THERAFLU PACKET  
IS TORN OR BROKEN**

**1-855-328-5259**

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Warren, NJ 07059

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***HOT LIQUID THERAPY***

that relieves:

Nasal and sinus congestion

Cough

Sore throat pain

Headache

Fever

CARTON

RECYCLE

**Principal Display Panel**

**HALEON**

**NDC 0067-6800-02**

**MULTI-SYMP TOM COLD RELIEF**

***THERAFLU***

**SEVERE**

***COLD RELIEF***

***DAYTIME FORMULA***

**ACETAMINOPHEN**

Pain Reliever/Fever Reducer

**Dextromethorphan HBr**

Cough Suppressant

**PHENYLEPHRINE HCl**

Nasal Decongestant

**Hot liquid therapy  
that relieves:**

- / Nasal and sinus congestion
- / Cough
- / Sore throat pain
- / Headache
- / Fever

**Berry Burst Flavor**

**6 PACKETS**



**THERAFLU SEVERE COLD RELIEF DAYTIME BERRY BURST**

acetaminophen, dextromethorphan hbr, phenylephrine hydrochloride powder

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0067-6800 |
| <b>Route of Administration</b> | ORAL           |                           |               |

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)             |          |
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)            |          |
| <b>ASPARTAME</b> (UNII: Z0H242BBR1)                        |          |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)              |          |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)              |          |
| <b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)                     |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                  |          |
| <b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR) |          |
| <b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)                |          |
| <b>SUCROSE</b> (UNII: C151H8M554)                          |          |
| <b>TRIBASIC CALCIUM PHOSPHATE</b> (UNII: 91D9GV0Z28)       |          |

## Product Characteristics

|                 |                    |                     |  |
|-----------------|--------------------|---------------------|--|
| <b>Color</b>    | PINK (Pink-purple) | <b>Score</b>        |  |
| <b>Shape</b>    |                    | <b>Size</b>         |  |
| <b>Flavor</b>   | BERRY (Burst)      | <b>Imprint Code</b> |  |
| <b>Contains</b> |                    |                     |  |

## Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0067-6800-02 | 6 in 1 CARTON; Type 0: Not a Combination Product | 01/20/2022           |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012                                     | 01/20/2022           |                    |

**Labeler** - Haleon US Holdings LLC (079944263)