

**THERAFLU SEVERE COLD RELIEF DAYTIME- acetaminophen,  
dextromethorphan hbr powder, for solution  
R J General Corporation**

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**THERAFLU  
SEVERE COLD RELIEF**

**Acetaminophen  
pain Reliever/Fever Reducer**

**Dextromethorphan HBr  
Cough Suppressant**

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

| <b><i>Active ingredients (in each tablet)</i></b> | <b><i>Purpose</i></b>             |
|---|-----------------------------------|
| Acetaminophen 500 mg                              | Pain<br>reliever/Fever<br>reducer |
| Dextromethorphan HBr 20<br>mg                     | Cough<br>Suppressant              |

***Uses***

- temporarily relieves these symptoms due to a cold:
  - minor aches and pains
  - minor sore throat pain
  - headache
  - 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.
- 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
- 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

**Stop use and ask a doctor if**

- 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 6 packets in 24 hours unless directed by a doctor.

| Age  | Dose       |
|--|------------|
| adults and children<br>12 years of age and<br>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 20 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, D&C yellow no.10, FD&C blue no. 1, FD&C red no. 40, maltodextrin, natural and artificial flavors, silicon dioxide, sodium citrate, soy lecithin, sucrose, tribasic calcium phosphate

***Questions or comments?***

**1-855-328-5259**

**PRINCIPAL DISPLAY PANEL**

**THERAFLU SEVERE COLD RELIEF - Acetaminophen, Dextromethorphan HBr -  
NDC 70264-047-01 - 25s Packets Caton Label**



# THERAFLU SEVERE COLD RELIEF DAYTIME

acetaminophen, dextromethorphan hbr powder, for solution

## Product Information

|                                |                |                           |                               |
|--------------------------------|----------------|---------------------------|-------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC: 70264-047(NDC:0067-0100) |
| <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                 | 500 mg   |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 20 mg    |

## Inactive Ingredients

| Ingredient Name                                     | Strength |
|---|----------|
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)             |          |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)            |          |
| ASPARTAME (UNII: Z0H242BBR1)                        |          |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)                |          |
| 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) |          |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62)                |          |
| SUCROSE (UNII: C151H8M554)                          |          |
| TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)       |          |

### Product Characteristics

|          |  |              |  |
|----------|--|--------------|--|
| Color    | white (to off white, yellow and brown) | Score        |  |
| Shape    |  | Size         |  |
| Flavor   | HONEY (Lemon)                          | Imprint Code |  |
| Contains |  |              |  |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70264-047-01 | 25 in 1 CARTON                                   | 11/12/2024           |                    |
| 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                                     | 11/12/2024           |                    |

**Labeler** - R J General Corporation (122542830)

### Establishment

| Name                    | Address | ID/FEI    | Business Operations |
|-------------------------|---------|-----------|---------------------|
| R J General Corporation |         | 122542830 | repack(70264-047)   |

Revised: 11/2025

R J General Corporation