# RELIEF-PE- acetaminophen, phenylephrine, chlorpheniramine tablet, coated HART Health

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#### **Relief-PE**

Active Ingredients (in each tablet):

Acetaminophen 325mg

Phenylephrine HCI 5mg

Chlorpheniramine Maleate 2mg

Purpose:

Pain Reliever/Fever Reducer

**Antihistamine** 

Nasal Decongestant

Temporarily relieves nasal congestion, sinus pressure, and minor aches and pains due to:

- the common cold
- hay fever
- upper respiratory allergies
- headache
- itchy/watery eyes
- runny nose
- muscular aches

Temporarily reduces fever

Liver warning: this product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4000mg of acetaminophen 24 hours
- with other drugs containing acetaminophen
- 3 or more alcohol drinks every day while using this product

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

#### Do not use:

- with any other drug containing acetaminophen (prescription or non-prescription)
- 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, or if you do not know if your prescription drug contains an MAOI

## Ask a doctor or pharmacist before use if

• you are taking sedatives or tranquilizers

- you are taking the blood thinning drug warfarin
- you do not know if other drugs you are taking contain acetaminophen

## Ask a doctor before use if you have

- heart, liver, or thyroid disease
- high blood pressure
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

When using this product to not use more than directed. This product may cause excitability or drowsiness. Alcohol, sedatives and tranquilizers may increase the drowsiness effect. Use caution when driving a motor vehicle or operating machinery.

#### Stop use and ask a doctor if

- an allergic reaction occurs, seek medical help right away
- you get nervous, dizzy or sleepless
- new symptom occur
- fever worsens or lasts for more than 3 days
- pain or nasal congestion gets worse or lasts more than 7 days
- redness or swelling is present

These could be signs of serious condition

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

### **Overdose warning:**

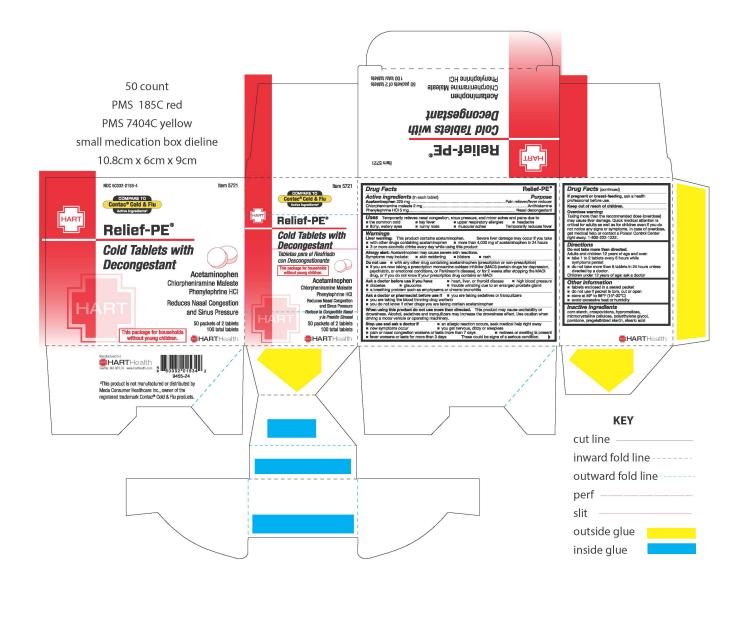
Taking more than the recommended dose (overdose) may cause liver damage. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. In case of overdose, get medical help or contact a Poison Control Center right away. 1-800-222-1222.

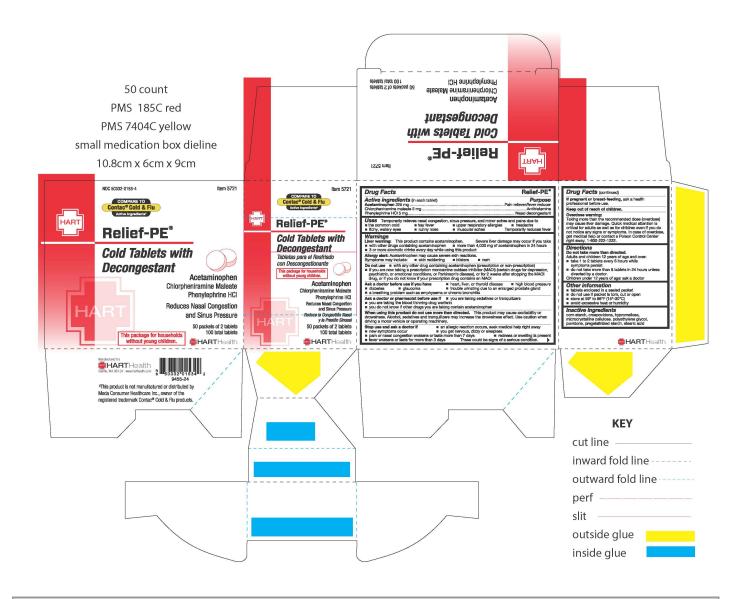
**Directions: Do not take more than directed**. Adults and children 12 years of age an over:

- take 1 to 2 tablets every 6 hours while symptoms persist
- do not take more than 8 tablets in 24 hours unless directed by a doctor

Children under 12 years of age: ask a doctor

corn starch, crospovidone, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelantined starch, stearic acid





#### **RELIEF-PE**

acetaminophen, phenylephrine, chlorpheniramine tablet, coated

| Product Information     |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:50332-0153 |
| Route of Administration | ORAL           |                    |                |

| Active Ingredient/Active Moiety   |                                |          |  |
|---|--------------------------------|----------|--|
| Ingredient Name   | <b>Basis of Strength</b>       | Strength |  |
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)               | ACETAMINOPHEN                  | 325 mg   |  |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV) | PHENYLEPHRINE<br>HYDROCHLORIDE | 5 mg     |  |
| CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - UNII: 3U6I01965U) | CHLORPHENIRAMINE<br>MALEATE    | 2 mg     |  |

| Inactive Ingredients |          |
|----------------------|----------|
| Ingredient Name      | Strength |

STARCH, CORN (UNII: 08232NY3SJ)

STEARIC ACID (UNII: 4ELV7Z65AP)

CROSPOVIDONE (UNII: 2S7830E561)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

HYPROMELLOSES (UNII: 3NXW29V3WO)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

POVIDONE (UNII: FZ989GH94E)

| Product Characteristics |       |              |          |
|-------------------------|-------|--------------|----------|
| Color                   | white | Score        | no score |
| Shape                   | ROUND | Size         | 11mm     |
| Flavor                  |       | Imprint Code | AZ 275   |
| Contains                |       |              |          |

| ı | Packaging            |  |                         |                       |  |
|---|----------------------|--|-------------------------|-----------------------|--|
| 1 | # Item Code          | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |  |
| : | NDC:50332-<br>0153-4 | 100 in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product | 04/16/2012              |                       |  |
| : | NDC:50332-<br>0153-7 | 250 in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product | 04/16/2012              |                       |  |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC Monograph Drug    | M   | 04/16/2012              |                       |
|                       |   |                         |                       |

## Labeler - HART Health (069560969)

# Registrant - HART Health (069560969)

| Establishment    |         |           |                         |  |
|------------------|---------|-----------|-------------------------|--|
| Name             | Address | ID/FEI    | Business Operations     |  |
| Allegiant Health |         | 079501930 | manufacture(50332-0153) |  |

Revised: 2/2024 HART Health