

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

Relief-PE

Active Ingredients (in each tablet):

Acetaminophen 325mg

Phenylephrine HCl 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.

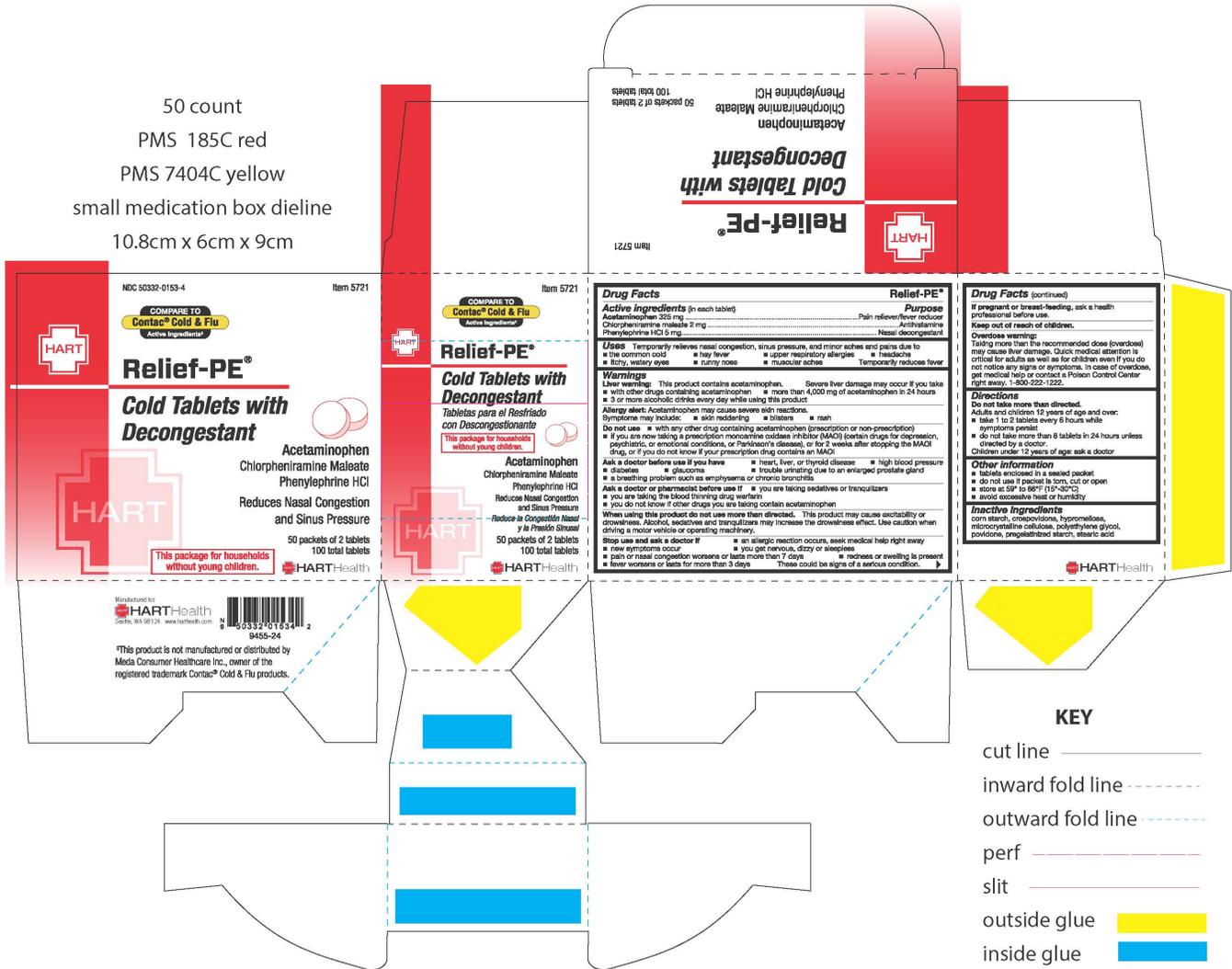
Directions: Do not take more than directed. Adults and children 12 years of age and over:

- 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, pregelatinized starch, stearic acid

50 count
PMS 185C red
PMS 7404C yellow
small medication box dieline
10.8cm x 6cm x 9cm



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	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg

Inactive Ingredients

Ingredient Name

Strength

STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSPROVIDONE (UNII: 2S7830E561)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	AZ275
Contains			

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End 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)